

Ultrasound Transducers. Function and Quality Control in Hospitals

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Studie av Ultraljudsgivare Funktion och Kvalitet i Sjukhusmiljö

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Sammanfattning

Nu för tiden försöker de flesta tillverkare täcka de höga kraven på kvalitet och design som finns på ultraljudsutrustning och givare: lätt att använda, flexibel bildhantering, givare som med flera frekvenser, som möjliggör olika tillämpningar, bra upplösning samt penetration. Denna typ av medicintekniska produkter är extremt känsliga och bör upprätthålla nödvändiga fysiska och funktionella krav genom regelbundna tester (Moore, 2006).

Detta examensarbete har två syften. Främst är det att undersöka den fysiska och funktionella statusen för varje enskild givare i landstinget Gävleborg. Det ger möjlighet att definiera ett eventuellt problem innan det kommer att påverka bild och diagnostik. Det andra är att hitta fördelarna och nackdelarna med användning av ultraljudsutvärderingstest, FirstCall aPerio Testing Accreditation Program, tillverkad av Sonora Medical System i Longmont, USA (www.4sonora.com). Utvärderingstestet utförs i tre steg; testning av ultraljudsgivare, klassificerad datainsamling och analys.

Utvärderingstest använts i denna rapport är ett högt kvalificerat system, för att undvika och minimera diagnostiska risker och på samma gång maximera patientsäkerheten. Det ger möjligheter att urskilja dolda tillverkningsfel samt defekter som uppträder under givarens livslängd.

Under utvärderingstestet kontrollerades 73 givare, som tillhör olika kliniker på fyra sjukhus i landstinget Gävleborg. De testade givarna representerar Siemens, GE Healthcare och Aloka. Totalt 61 av givarna klarade testet och 12 klarade inte testet. Det konstaterades i slutresultatet att de givare som inte klarade utvärderingstest, oftast hade flera döda element i rad eller i mitten av givaren.

Tack vare programvaran FirstCall aPerio, blir resultaten från utvärderingstestet omedelbart synliga i rapporten. Det är användbart vid tidig upptäckt av felkälla i givaren samt minimering av felaktig diagnos. Testsystemet ger en möjlighet att testa givare utan ultraljudsutrustning och för att samla information till en databas.

Nyckelord: ultraljud, FirstCall aPerio Testing Accreditation Program, ultraljudsgivare, utvärderingstest, feldiagnostik.

Abstract

Nowadays, most of the medical technology manufacturers try to meet the high demands of quality and design of ultrasound equipment, including transducers: easy to use, flexible image handling, multi frequencies operation use of various applications, good resolution and penetration. It is known that this kind of medical devices is extremely sensitive and should be maintained in compliance with the necessary physical and functional requirements, via regular tests (Moore, 2006).

This master thesis has two purposes. The major one is to examine the physical and functional status of every single transducer in Gävleborg hospitals. It allows defining a possible problem before it has influenced formation image and diagnosis. The second purpose is to find out the advantages and disadvantages of using the ultrasound evaluation test FirstCall aPerio Testing Accreditation Program, manufactured by Sonora Medical System in Longmont, USA (www.4sonora.com). The scientific method of this evaluation test is based on three steps which are as follows: testing of ultrasound transducers, classified data collection and analysis.

The evaluation test used in this report is a highly qualified system which has been designed to avoid and minimize diagnostic risks, and at the same time, maximize patient's safety. It allows distinguishing any hidden manufacturing defects with new devices or those appearing during the operation period.

For this evaluation test, 73 transducers were controlled, belonging to clinics of four different hospitals within the Gävleborg area. Tested transducers were manufactured by Siemens, GE Healthcare and Aloka. A total of 61 of transducers passed the test and 12 did not pass it.

Finally it was observed, that the reason for not passing the evaluation test was mostly due to dead elements in a row in the centre of the transducers.

Thanks to the software program of FirstCall aPerio, the results of the evaluation test are immediately visible, through the report. It is useful in early discovering the source of error in transducer and minimizing of wrong diagnosis. The testing system gives a possibility to test the transducer without US equipment and to collect the database information.

Keywords: ultrasound, FirstCall aPerio Testing Accreditation Program, ultrasound transducers, evaluation test, wrong diagnosis.

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Abbreviations

ADC	Analogue to digital converter
CW	Continues Wave
DGC	Depth Gain Compensation
DSP	Digital signal processing
EST	Electrical Safety Test
FOV	Field of View
LNA	Low noise amplifier
MHz	Mega Hertz
pF	Pico Farads
PW	Pulsed wave
PZT	Lead Zirconate Titanate
RF	Radio Frequency
TEE	Transesophageal Echocardiography
TGC	Time Gain Compensation
US	UltraSound

1. Introduction to Evaluation Tests and Ultrasound

1.1 Background

Ultrasound is one of the most useful diagnostic imaging systems, mainly due to its characteristics: lack of radiation, real-time data, compact and easy for operation. It gives a possibility to investigate most of the internal human organs without any physical discomfort. The first heart examination took place in the middle of the 20th century by using diagnostic ultrasound. In the beginning, only the so called A-mode, M-mode and B-mode scanning were available. Doppler ultrasound was developed in the mid-1950s. The real-time imaging began to be used in 1975. Nowadays, pulse wave (PW) and continuous wave (CW) Doppler ultrasound is routinely used for the non-invasive assessment of blood flow velocity of cardiac and cardiovascular systems (Walker, 2003).

Transducer is the uniting part between US and human tissue. It converts electrical signals to echo pulses and vice versa. In the diagnostic imaging field, it is recommended to use the transducer in a range from 1 to 15 MHz.

In the context of this project, two main problems have been outlined. The first one revealed the absence of a current overview on the functional status of transducers and ultrasound systems. Because of this, there are probabilities of fault diagnosis and inaccurate treatment. In 2006, Mårtensson and colleagues reported that some patients suffered from congenital heart disease, however, they were not diagnosed in their examination in 2004. The authors suggested that the wrong diagnosis was due to a defective transducer (delaminated) (Mårtensson, Olsson et al. 2009). As it has been mentioned above, the defective transducers of Heart and vascular diseases can be missed if using a defective transducer. That means a very high patient hazard resulting in even probable lethal outcome (Mårtensson, Olsson et al. 2010).

The second problem came out of the first one. Shortly, it can be called financial losses. The main reason for them is the failure to detect some manufacturing defects and this is due to the lack of a suitable test.

It has been observed that there are some manufacturing defects, which can hardly be discovered immediately without any test control. The problem with such kind of failures is that they remain hidden during the operation period, which affects the image quality and the

quality of diagnosis. On the other hand it is also important to check regularly the physical and functional condition of all available US transducers.

This master thesis study has 2 basic goals: the first one is focused on the main control over the functional state of every single element of the acquired new transducers and available probes. It avoids the commissioning of a transducer, which does not cover the needed requirements. In a long period perspective, it is recommended to perform a periodical test of all transducers in each department, approximately on every 6 months. This ensures the high level of quality and security of medical health care. During this process it is possible to keep under control every transducer, which has passed the previous test, but its parameters are close to failure. Such kind of US transducers must be selected for observation. The regular test is very helpful, because it gives a very clear 'picture' of the functional situation of the equipment. Those devices which are still in warranty are to be replaced with new ones, however if the warranty period has passed, then a repair is performed or acquisition of new transducers.

The second aim is to find out the advantages and disadvantages of using FirstCall aPerio evaluation test. It is important to notice the level of reduced risk of error of medical diagnostics and avoidance of patient's hazard. The removal of most common defects in transducers, the reduction of rate of error between different transducer models and, respectively, which hospital departments have faulty transducers are all possible through data collection and analysis.

Nowadays, parallel with FirstCall aPerio there are two other tests, called String Doppler Phantom and Multi Tissue Phantom. The first one evaluates the function of Doppler and the second one checks the intensity, depth of penetration, gray scale, focal zone, lateral and axial resolutions of US apparatus. They play a big role for the evaluation of the US system as well as in the avoidance of the risks of patient hazard.

In a long term perspective, all these tests will continue to enhance the quality of work in US field, in particular, concerning the resolution of US apparatus and Doppler tests. Another goal is to buy as many adapters as possible for the different types of transducers and manufacturers which will allow more transducers to be involved in regular control. The focus is turned towards developing higher and higher patients' safety, thanks to choosing the best equipment at lower price as well as increasing the qualification of medical engineering staff.

1.2 Overview of Ultrasound

Sound is a physical occurrence that transfers energy from one point to another. It can pass only through matter, because it is necessary to return a vibration as a response of the sound. If there is no matter, nothing can vibrate and sound cannot exist. As it is known, the basic measuring unit of frequency is hertz. It can be described as one cycle per second. Ultrasound bandwidth has a very high frequency in diagnostic imaging, between 2MHz and 20MHz, for comparison- an adult human being can distinguish frequencies from 20Hz to 20 kHz (Gibbs, Cole et al. 2009).

US is used as a diagnostic method, because it can pass like a beam through the human being, interacting with the tissue and then return echoing information to the transducer. Piezoelectric crystals are situated within the probe. They are activated by applying of electrical pulses, which produce very high frequency sound waves. These echoes reach the body tissues; receive information and return it back to the transducer. Crystals are activated again and convert the sound waves into electrical pulses; as a result, a reconstruction of images is seen on the US display.

The US image shows the location of reflecting structures or echo sites within the body. The location of a reflecting structure interface in the horizontal direction is determined by the position of the beam. In depth direction, it is determined by the time required for the pulse to travel to the reflecting site and for the echo pulse to return back.

The ultrasound consists of energy, travelling in a beam form. The energy transferred in the time unit defines the power that is measured in watts, due to the small power in (mW). The power of beam cross sectional area per unit represents the average intensity (mW/cm^2). Power and intensity are proportional to the square of the wave amplitude. When power increases the intensity increases but the cross section of the beam decreases. The focused beam and unfocused beam are inversely related. The first one is characterised with high intensity but small cross section, the second one has large cross section but low intensity (Galiuto, Garbi et al. 2011).

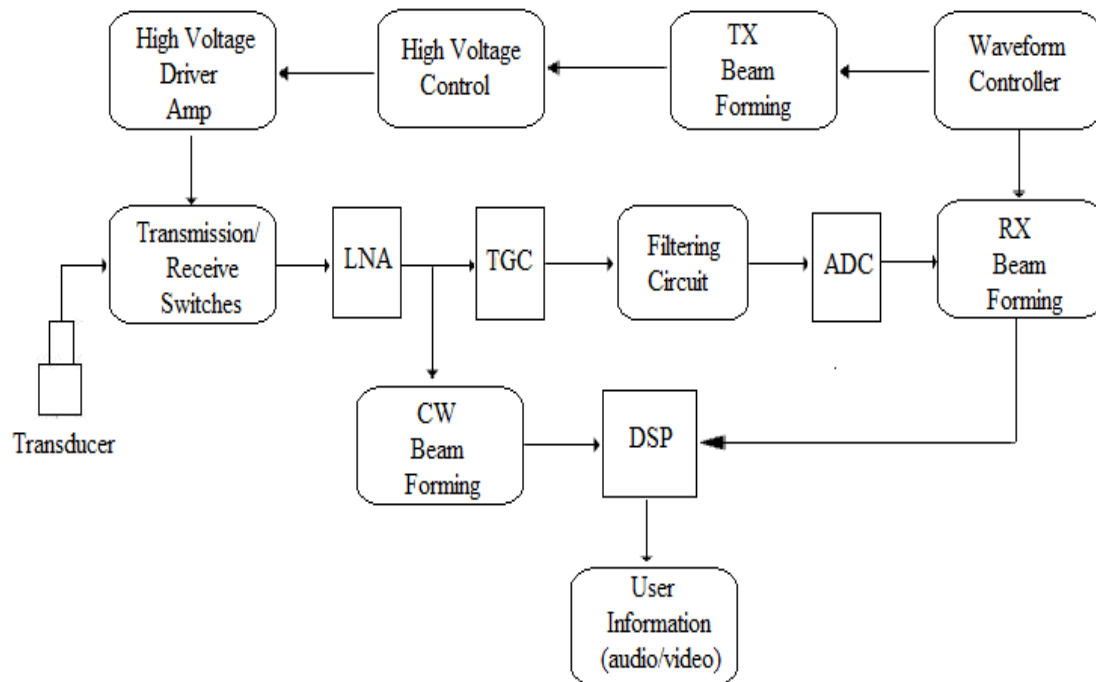


Fig.1 Simplified block diagram highlighting principal components of a US imager, modified from (Chatterjee and Miller, 2009).

1.2.1 What are the advantages vs. disadvantages of US?

1.2.1.1 Advantages

Some of the advantages of US examination are real time imaging with non ionizing radiation. The scanning procedure undergoes with minimal inconvenience for the patient and it is easy to be repeated, if necessary. The US apparatus is compact and mobile which makes it easy for use by the medical staff.

1.2.1.2 Disadvantages

Ultrasound gets poor echo pulses in gas medium. The acoustic mismatch has a big influence over the amount of US reflected pulses. Due to mechanical effect, some side effect may occur, such as “cavitation”. When US beams propagate in the fluid and create bubbles caused by dissolved gases in the fluid, this phenomenon is called cavitation. The ultrasound examination can produce negative effects on the tissues due to temperature parameters. The process of conversion of ultrasound energy excretes heat. The level of damage depends on the acoustical exposure time and the type of used US modes (Maulik, 2005).

Ultrasound imaging is not completely suitable diagnostic tool for a very deep penetration examination. This could lead to losing of detailed image because of bad resolution with low frequency.

1.3 Ultrasound transducer design

The transducer consists of the following parts: acoustic lens, matching layer, piezoelectric acoustic ceramic array or Lead Zirconate Titanate PZT and backing layer (See Fig.2).

The acoustic lens ensures the electrical safety of the patients and it participates in out-of-plan acoustic focus.

The matching layer is built of a material, which matches the acoustic impedance of the transducer to the impedance of the body tissue. It minimizes the loss of the transmitted and reflected echoes.

PZT acoustic ceramic array is designed of a component of ceramic materials and they are cut into a separate column of elements (See Fig.4). Different types of transducers have different sum of elements, for instance 64, 128, 288, etc. Each element, individually, interacts with a short duration electrical pulse of approximately 60 to 120 volts, mechanically vibrates and creates ultrasound echoes that propagate into the body as a sound beam. On the other hand, the reflected echoes come to the piezoelectric acoustic ceramic array and interact with the elements again (See Fig.3). Here, it converts echoed pulses to electrical pulses. The most important function of PE ceramic array is to convert electrical pulses into mechanical and vice versa. The electrical pulses are processed by the ultrasound system resulting in a B-mode image, Doppler signal or colour flow image viewed on the system display.

Every element of the US transducer is connected to the system via a very thin wire and is bundled into shielded cable. The total number of wires into the transducer cable is the same as the number of elements (See Fig.5). This type of construction is used for transducers with up to 128 elements. For the wide array transducers, which have a large number of elements, multiplexers are used to reduce the number of wires by providing a set of wires controlling a larger number of elements (Mårtensson, Olsson et al. 2011).

The backing layer is a material based on heavy metal or damping material, it is directly connected with PE elements on the opposite side of the matching layer and ensures low noise and optimal resolution of the ultrasound system.

The functional and structural status of piezoelectric elements and wires are very important for the evaluation of the transducer. This includes the functional condition of matching layers in front of the elements and the backing material behind the elements, too (Mårtensson, Olsson et al. 2009).

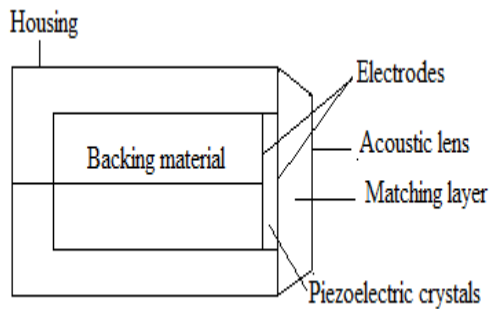


Fig. 2 The construction of US transducer

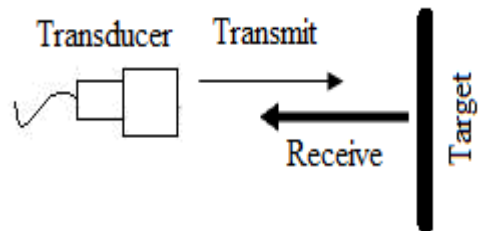


Fig.3 Transmit and receive echoes

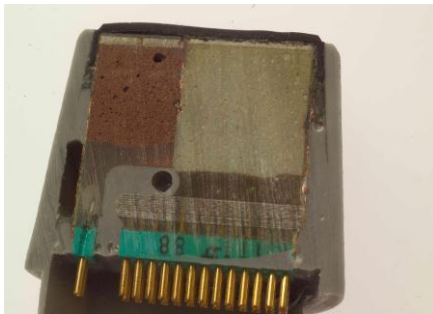


Fig.4 Ceramic layer inside a linear array transducer

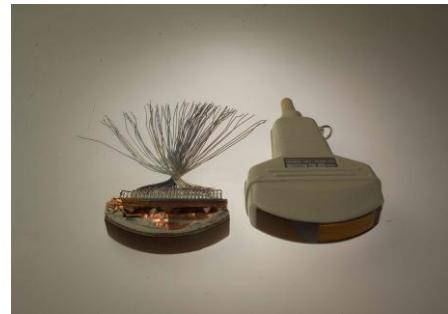


Fig.5 Internal structures of a transducer with connected cables

1.3.1 Advantages of PZT Composite Transducers imaging sonars

- Increased Sensitivity
- Broader Bandwidth
- Better Resolution
- Improved image contrast
- Improved impedance match to water
- Better efficiency (Zagzebski, 1996)

1.3.2 Most important types of transducers

The “linear array” transducer transmits parallel sound pulses and creates a rectangular image. This kind of transducer has a good near field resolution and is mostly used with high frequencies from 5.0 to 10.0 MHz (See Fig. 6a).

The second type of transducer, the so-called “sector” transducer, is characterised by fan-like image which increases width with the depth of penetration. (See Fig.6b) It is more useful in cardiology because of the deeper penetration. The frequency rate is between 2.0 and 3.0MHz. Poor resolution is observed in the near field while, in the far field, the line density decreases.

The third type of transducer is “curved” or “convex array” (See Fig.6c). Its main advantage is that it combines the above two types of transducers. It exhibits a good near field and far field resolution, with depth decreasing resolution. The image is pie-shaped. The transducer is useful in abdominal sonography with frequency from 2.5 to 5.0 MHz (Hofer, 2005).



Fig.6 a) Linear array transducer; b) Sector array and c) Curved array

1.4 Beam properties

According to the design of the transducer, it can produce two different beams: focused or unfocused beams. Focused beam is preferred for use in imaging applications, because it gives better details of the image, which results from the fact that a focused beam produces pulses with a small diameter (See Fig. 7). If we want to find the best details, we can find them, observing structures in the focal zone. The distance between a transducer and a focal zone is called a focal depth.

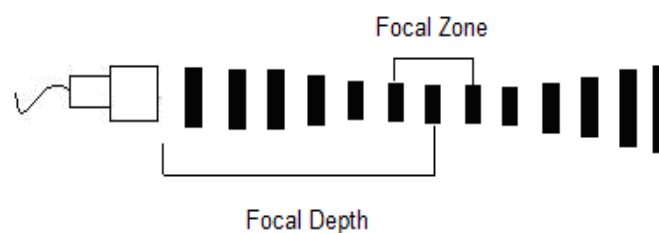


Fig. 7 Focused beam

The second type of beams, the so-called unfocused transducer, creates a beam with two regions. The first one is called “near field” and the other one is “far field” (See Fig.8).

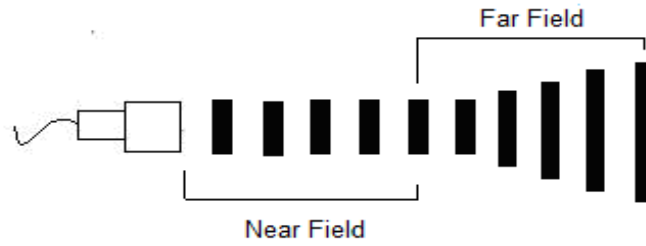


Fig.8 Unfocused beam

The near field is more useful for imaging. It has a beam with a constant diameter, which depends on the diameter of the transducer (See Fig.9). The length of the near field is related to the diameter, **D**, of the transducer and the wavelength, λ , of the ultrasound by:

$$\text{Equation 1} \quad \text{Near field length} = D^2/4\lambda \quad (\text{Asher, 1997})$$

As it has been established, the wavelength depends on the frequency. The length of the near field is inversely related with the wave length (See Equation 1). The higher the frequency, the longer the length of the near field is (Asher, 1997).

The second beam region, the so-called far field (See Fig.9) is characterised with diverges of the beam. The ultrasound pulses become larger in diameter, but we observe less intensity along the central axis. The approximate angle of divergence is related to the diameter of the transducer, **D**, and the wavelength, λ , by:

$$\text{Equation 2} \quad \sin\Theta = 1.2\lambda/d \quad (\text{Zagzebski, 1996})$$

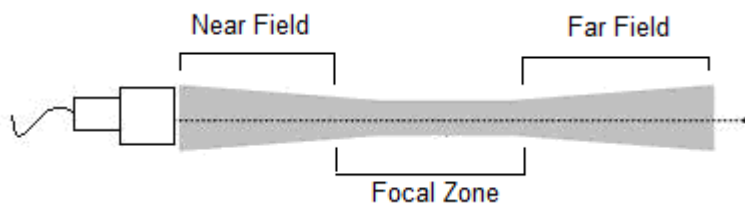


Fig.9 Focal Zone, Near and Far field

As it is obtained from the physical laws (See Equation 2), the connection between wavelength and frequency is inversed; divergence decreases by increasing the frequency. The basic advantage of using higher ultrasound frequencies is that the beam has less divergence and the result is a better resolution (Narouze, Chan et al. 2010).

The ultrasound pulse consists of several wavelengths or vibration cycles. The wavelength is determined by the velocity, v , and frequency, f , in this relationship:

$$\text{Equation 3} \quad \text{Wavelength } (\lambda) = v/f \quad (\text{Asher, 1997})$$

1.5 Beam former

The beam former provides the pulse-delay sequences applied to individual elements to achieve transmission focusing. It also controls the dynamic focusing of received echoes and controls the beam direction of electronically scanned arrays.

Usually, the received focus and the scanning part of a beam former, have two different types of formation. The first one, analogue beam former, makes delays for all echoes and then converts them into digital, the result is a reconstructed image (See Fig.10). When time delays for focusing are applied the echo signal remains in analogous format, and summation of signals from individual channels is done.

The another type is called digital beam former, which immediately converts every single echo to digital and then delays each echo, and finally provides digital format for image storage (See Fig.11). Time delays and summation are made for echo signals after they have been digitized.

Each of the both types of beam former is used in US medical equipments, depending on manufacture system and requirements.

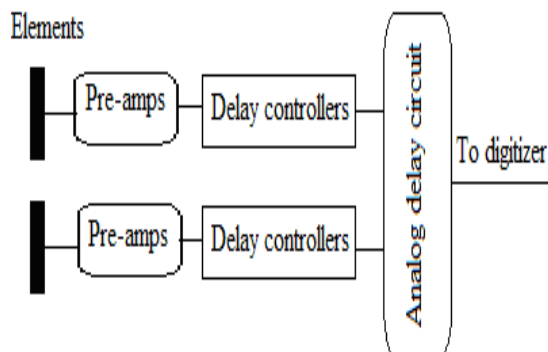


Fig.10 Analogue beam former

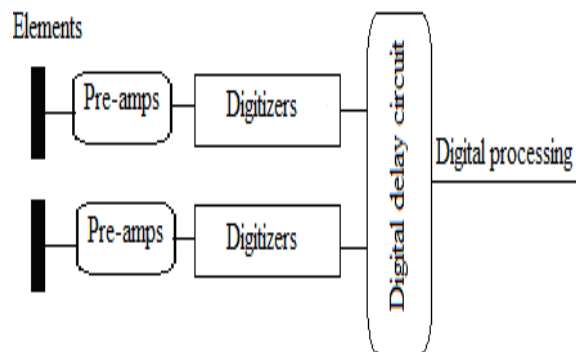


Fig.11 Digital beam former

1.6 Ultrasound Pulse Frequency

Respectively for the aim of investigation, such frequency of ultrasound pulses should be chosen as to ensure a balance between depth of penetration and image details or resolution. High frequency pulses create higher quality images or high resolution but they cannot be use for deep penetration examination, for instance: foetus examination.

One of the parts of diagnostic ultrasound equipment is the transducer. It produces sound waves actually there are crystals inside the transducer which vibrate with the required frequency.

According to the type of transducer, there are 2 different designs: the first one is designed to vibrate with only one frequency, called resonant frequency. The disadvantage of this type is that it can be used only for a certain application.

The second one of transducers has more than one resonant frequency. It can be used for different applications without replacing the transducer, which is a big advantage (Bertolotto, Derchi et al. 2008).

1.6.1 Factors Related to US Pulse Velocity

The velocity of sound is determined by the characteristics of the materials, not by the characteristics of the sound.

$$\text{Equation 4} \quad \text{Velocity} = \sqrt{E/\rho} \quad (\text{Asher, 1997})$$

E is the factor related to the elastic properties or “stiffness” of the material

ρ is the material density

The velocity of sound in air is 330m/s, in fat and water, respectively, it is 1450 and 1480m/s. Soft tissue conducts sound with 1540m/s, blood with 1570m/s, muscle with 1600 m/s and bone with 3500m/s (Goldberger, 2010).

1.6.2 Reflection of ultrasound pulses

When pulses reach the soft tissue interface, only a small part of them is reflected, another part is turned back to the transducer as echo. It produces weak echoes. When pulses reach matter,

such as bone, stones and gas, strong reflections are generated. That's why it can get a very poor or no echo.

The percentage of reflection of ultrasonic energy for normal incidence at various boundaries: Between muscles and fats it is equal to 1%; bone/muscle it is 41%; bone/fat it is 49%; soft tissue/air it is 99.9% and between soft tissue/water it is 0.2% (Ostensen, 2005)

1.7 Resolution

Resolution is the possibility to distinguish two separate objects from each other. It branches into spatial and temporal resolution.

Temporal resolution is characterized with correct localization of structures at a particular time point.

Spatial resolution is an accurate determination of two separate objects, located near to each other. On the other hand, the spatial resolution is also divided into two branches: axial resolution, following along the axis of ultrasound beam, and lateral resolution, which is perpendicular to the beam axis.

Pye and colleagues have reported that, because of the function of depth, the ultrasound resolution imaging of gray scale is limited. (Pye, Ellis et al. 2004).

Frequency MHz	Penetration depth mm	Resolution mm	
		Axial	Lateral
3.5	160	1	2
5	100	0.6	1.2
7.5	50	0.4	0.8

Table 1 Reference values for penetration depth and resolution as a function of frequency

Field of View Shapes

The sector FOV is typically used for abdominal application.

Sector FOV is produced by:

1. Oscillating
2. Rotating

3. Curved arrays

4. Phased arrays

The rectangular FOV is typically used for superficial application

- Linear array (Sanders, Del Prince et al. 2007)

1.8 Ultrasound imaging and its application

Nowadays, ultrasound is very useful in most medical applications, for instance, the development of foetus during pregnancy and bodily function such as urination and movement. Ultrasound is also used for the evaluation of kidneys, liver, heart, blood vessels. Sometimes it is used in biopsy to facilitate the sampling of cells from the body and testing in a lab (Gibson, Feng et al. 2005).

In diagnostic ultrasound, frequency of 2.25 to 3.5 MHz is useful in deep abdominal, general abdominal and renal imaging. Peripheral vascular, cerebrovascular, breast as well as pediatric patient are examined with 5 to 7.5 MHz (Machi, 2005).

2. Materials and methods

FirstCall aPerio Testing Accreditation Program is manufactured by Sonora Medical System in Longmont, USA. This kind of testing tool has been chosen because the medical representative of Sonora Medical System, BBS Medical AB, is well known on the medical US equipment and testing devices market in Sweden. Support and maintenance, as well as the relevant discount for US transducers, are included in the package of service. The FirstCall aPerio testing system has been recommended by GE Health Care, Siemens and Karolinska University Hospital, which have a big experience in this field and their recommendations are highly appreciated. By the time it has been used for the master thesis work purposes, there were no other available evaluation tests similar to the FirstCall aPerio.

The evaluation test was created to detect acoustic or electrical defects. By activating of each crystal within the probe, the test system can measure the sensitivity of each element, and analyse the acoustic condition of the returning echo.

Sonora FirstCall aPerio toolbar program allows entering of information about particular transducer. It begins with the type of transducer, serial number, date of investigation, operator and the name of the department to which the transducer belongs. Other options, as report, also can be chosen (See Fig.12).

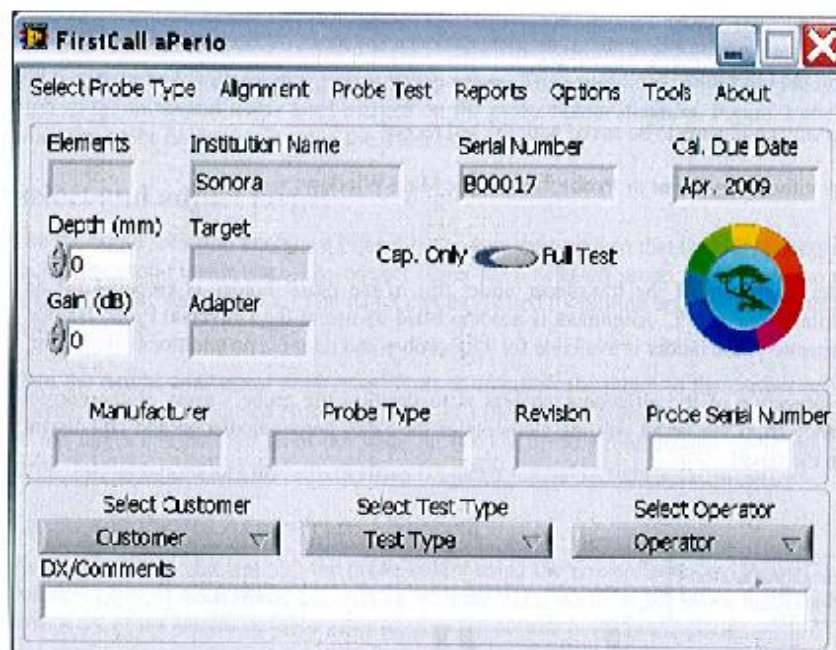


Fig.12 Main window of FirstCall aPerio application

Alignment

The proper alignment of the tested transducer in the probe holder is essential for obtaining of acceptable test result. Alignment is accomplished using the Universal Probe Holder. For Transesophageal Echocardiography (TEE) probes, as separate probe holder is available and it requires no additional alignment.

Instruction and functioning of Sonora FirstCall aPerio :

The tank should be filled with water near a room temperature, to the level marked on the probe holder (See Fig.13). The target should be selected by pulling and turning the target selection knob, according to the type of transducer (See Fig.13). By turning the height adjustment knob (See Fig.13), the target will be set up to the correct depth, which is indicated on the main window (See Fig.12). By using the scale on the universal probe holder the depth of the target can be determined. For flat targets the top arrow is used. For curved or tightly-curved targets, the bottom arrow should be used.

Linear and phased array probe Alignment: Using the probe clamp (See Fig.14) the probe should be placed into the probe holder. It is important to keep the centre of the probe's lens up with the white arrow on the probe holder. The lens of the probe should be at the same level as the bottom of the probe clamp. The same rule must be kept for curved or vaginal array (See Fig.15, 16).

The universal probe holder should be placed into the water tank by using the universal probe holder handles. If there are bubbles, they should be removed, because they can influence negatively the evaluation test. Select 'Alignment' from the tool bar on the Main Window (See Fig.12).

The depth bars should be centred at approximately zero. If the scale is above or below zero, it means that the probe is too far or too close to the target. The scale of amplitude should be close to maximum, otherwise the probe knobs must be adjusted for optimal results (See (Fig.17).



Fig.13 Probe holder

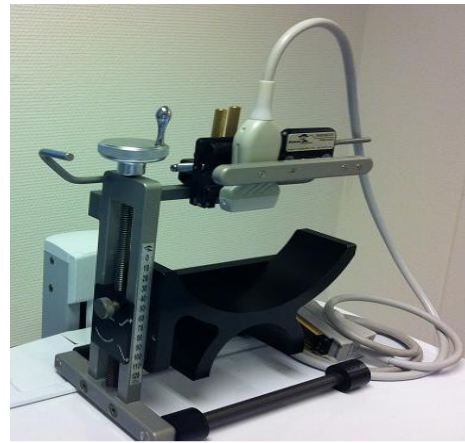


Fig.14 Linear and phased probe alignment

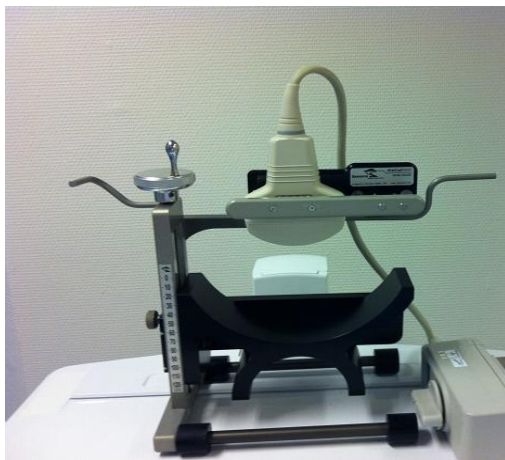


Fig.15 Curved probe alignment

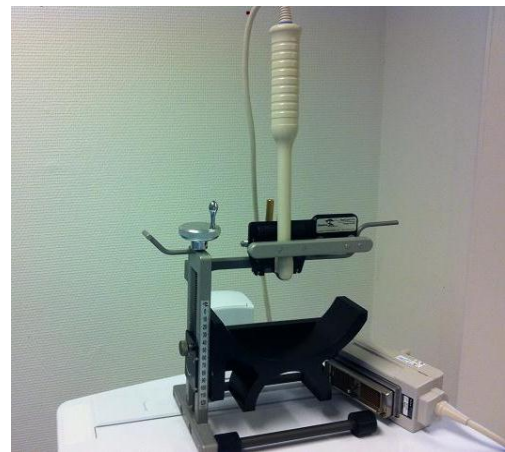


Fig.16 Vaginal probe alignment

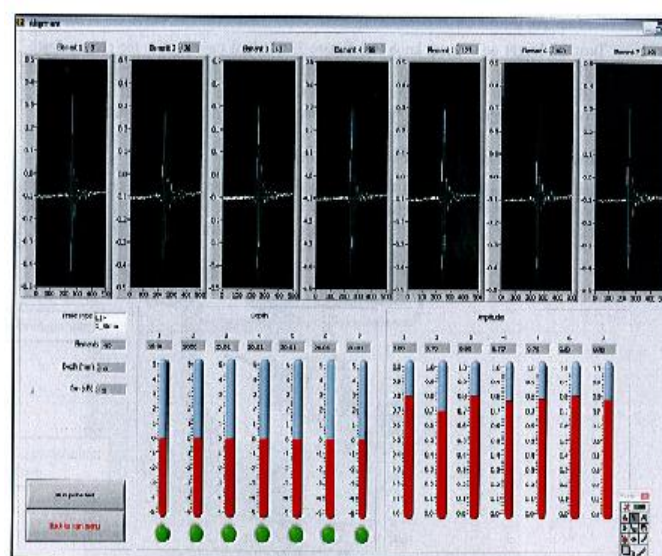


Fig.17 Control of alignment transducer for optimal result

The FirstCall aPerio also consists of a main device, connected directly via USB-cable to the PC where the Sonora FirstCall aPerio and manufacturer's software have been installed. It can be used for all types of connected with the software manufactured transducers. In the main device we place manufacturer's adapter, definite for every single manufacturer, such as Siemens, GE and Aloka, etc. It will be a disadvantage if we do not have a matching adapter (See Fig.18).

The manufacturer's adapter is connected with the transducer and is directly turned to the target. The FirstCall aPerio main device, via manufacturer's adapter, has the possibility to apply electrical signals for activating all elements in the transducer. In this step of the process, the already activated elements send echoed pulses to the target and the reflected information echoes return back to the crystals. The crystals activate again and convert mechanical vibrations into electrical pulses. The FirstCall aPerio main device measures the sensitivity value of the PZ elements in V-pp and capacitance value of the crystals and cable in pF. The received measurements are analyzed with the FirstCall aPerio program and the operator can immediately observe the status of every single crystal. When the scanning is finished, the evaluation test ends with a final report.

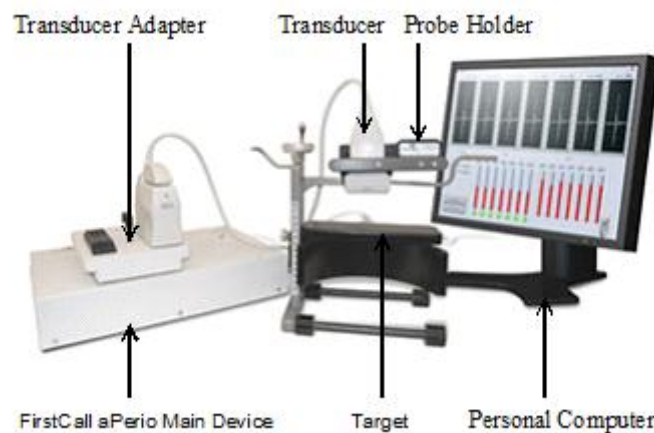


Fig.18 The whole procedure of Sonora FirstCall aPerio

The FirstCall aPerio evaluation test is useful for:

- Testing the condition of the piezoelectric elements.
- Testing the wires within the transducer.
- Testing the function of matching layers in front of the elements.

- Testing the backing material behind the elements.

2.1 Acceptance criteria according to FirstCall aPerio Operator's Manual

Number of contiguous or non-contiguous weak or dead elements not allowed:

- More than 4 non-contiguous weak elements.
- Equal to 2 contiguous weak elements.
- More than 1 dead element (Moore, 2006).

Accepted criteria by FirstCall aPerio concern all tested probes and it does not matter if the transducer is in warranty or not. During the project work one of the established criteria was modified: no more than 2 non-contiguous elements classified as "weak elements" instead of no more than 4 non-contiguous weak elements. This new criterion is only in regard to probes in warranty. From an economical point of view, the purpose was to limit, as much as possible, the number of fault elements and avoid the use of defective transducers influencing both the image and diagnosis quality. During operation, probably, these weak elements will become dead, the probe should be replaced with a new one, which leads to financial losses for the hospital.

2.2 How to determine if a probe is allowed to be repaired, according to the recommendations by FirstCall aPerio operator's manual

Any array with no more than 4 consecutive weak elements and no more than 2 non-consecutive dead elements, otherwise these elements are evaluated in the context of a lens delamination; i.e. if the lens is delaminated elements may look as weak or dead while in fact they are not (Moore, 2006).

2.2.1 Effects of long cables in Ultrasonic

- Cable attenuation: The resistance in long cables provides a disadvantage, causing loss of signal, which increases with the length of the cable.
- Cable noise pickup: it can catch RF noise from the environment and this affects the quality of many applications.
- Cable reflection: the excitation pulse transmits from the ultrasound system to the transducer move speed of light. When the pulse arrives to the transducer, a big part of

electrical energy converts into sound waves. Part of this energy is reflected back to the ultrasound system, and part of it is reflected back to the transducer.

- Cable delay: the wires of the transducer cable are a part of total distance and thickness measurement. When they are too long the pulses times become longer, which activates the elements. It affects the examination processes.

2.3 FirstCall aPerio evaluation report

The most important parts of the evaluation report are to observe the sensitivity and capacitance. They are observed by the operator or medical engineer.

2.3.1 Sensitivity

Sensitivity measures the functional status of every single PE crystal within the transducer array. There should be only minor variations among the amplitudes of the signals for the individual crystals in an array. The sensitivity is shown as a graph: the X-axis shows the numbers of the PZ elements. The Y-axis shows the sensitivity as response of the PZ elements within the probe, which measures peak to peak amplitude (the change between highest amplitude value and lowest amplitude value) of the reflected pulses in voltage (V) (See Fig.19 and 20).

The 3 differently coloured thresholds (red, yellow and green) determine the functional state of crystals in a transducer. In contrast with the 3 differently coloured columns (red, yellow and green), which represent the three different zones of probe, they determine the criteria of the transducer evaluated test. The red zone is the most important because it covers the central part of a transducer, respectively the image, and then follows the two yellow zones that border both sides of the red. The two-side parts of the transducer are occupied by two green zones, they are less important than the others; because green zones cover the peripheral parts of an image (See Fig.19 and 20).

According to its functional status, every element can be good, weak or dead. In order to be defined as good, the sensitivity of the element should be equal to or over 75% of the mean value of all separate elements. On the bar graph this level is shown in green colour threshold that defines the initial border of acceptable functional status of the elements.

As weak elements are classified those ones, whose sensitivities vary within the range of 10% - 75% of the mean values of all separate crystals: all elements which are situated between red and green colour threshold are evaluated as week. Sensitivity level equal to or less than 10% of the mean value of all separate elements is an indicator for a dead element, short circuit, break in cable, opening in the pin connector or lens delamination, which is determined later by capacitance value bar graph. On the sensitivity graph, the level which limits the non-functional elements from the other is shown in red colour threshold (Moore, 2006).

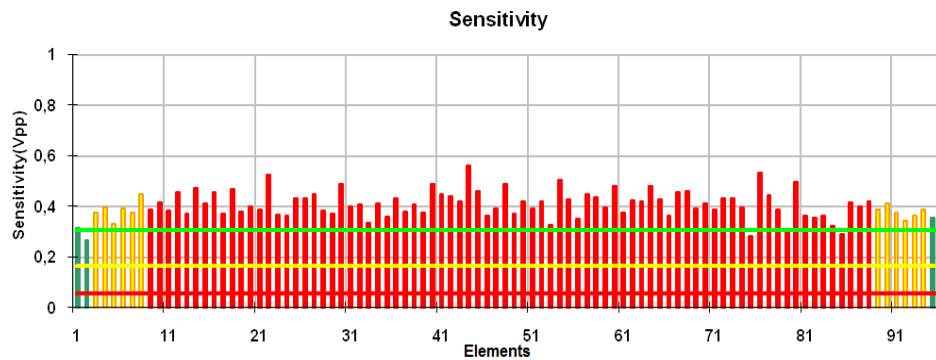


Fig.19 Sensitivity of PE elements within the transducer phased array 10 MHz. It was determined as a good working transducer because there were 3 non-consecutive week elements (2 in the red zone and one in the green zone), and no dead elements that respond to the FirstCall operator's manual references.

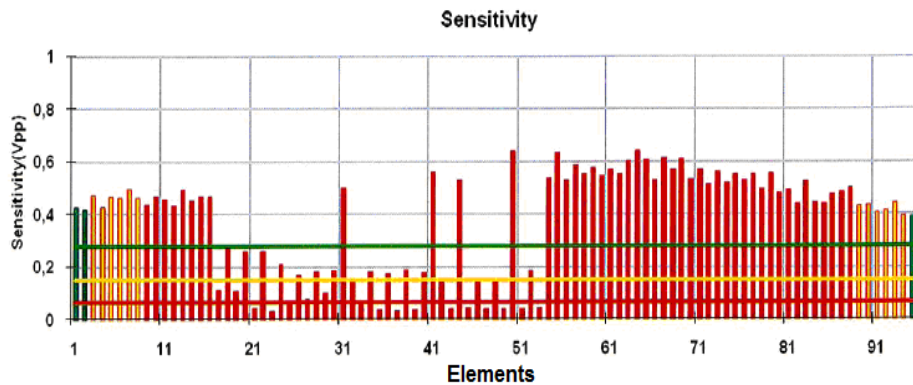


Fig.20 Sensitivity of PE elements within the transducer phased array 10MHz. This probe was classified as defective because there were much more than the accepted weak and dead elements and they were evaluated as lens delamination, according to the FirstCall operator's manual references.

2.3.2 Capacitance

Capacitance is the measure of the electrical performance of each individual element circuit. The acoustic array naturally works as a capacitor. For instance: Linear array of high frequency, such as 7.5 MHz and above are usually smaller arrays and have a lower capacitance nearly 50 pF. Lower frequency transducer as curved array 3.5 MHz has larger elements and higher capacitance nearly 350 pF. The cable itself also has capacitance.

The new ultrasound apparatus probe cables have been designed to have low capacitance, approximately equal to 85pF. But the old probe cables have higher capacitance, equal to 120pF.

The capacitance is shown as a bar graph, which translates the received information from sensitivity graph. It exactly determines the type of defect in the elements. The numbers of PZ crystals are situated on the X-axis, and the Y-axis shows the capacitance measured in pF. Foremost the mean value of capacitance in pF should be defined, for all elements, and then the maximum and minimum capacitance thresholds (shown in the bar graph with blue colour) should be determined. The maximum threshold was assigned +10% of mean value capacitance. The minimum threshold was defined -10% of mean value capacitance (See Fig.21 and Fig.22). The capacitance values of good working elements appeared on and within the maximum and minimum capacitance thresholds. If the capacitance test of an element appears under the minimum threshold and approximately to the mid-point of the mean value capacitance scale, the element is dead. When the capacitance is close or equal to zero a wire could be opened in the connector or there might be a break in the cable. If the capacitance is higher than maximum threshold and mean capacitance value of the other elements, it indicates a short somewhere in the circuit (Moore, 2006).

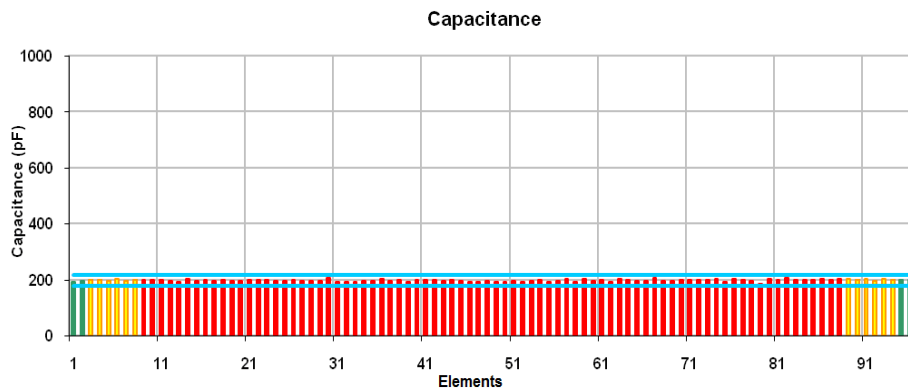


Fig.21 Capacitance of PE elements within the transducer phased array 10MHz. It was determined as a good working transducer because the capacitance values of all elements appeared on and within the maximum and minimum capacitance thresholds that respond to the FirstCall operator's manual references.

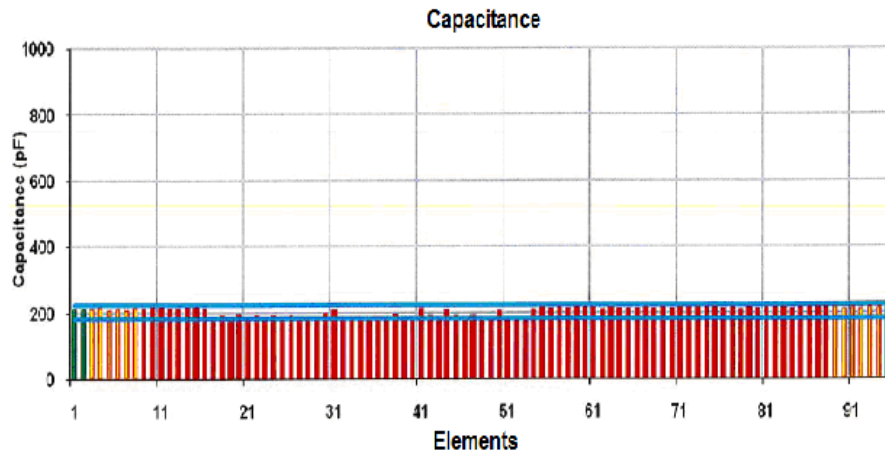


Fig.22 Capacitance of PE elements within the transducer phased array 10MHz. This probe was classified as defective with dead elements, because the capacitance values of many elements appeared under the minimum capacitance threshold, according to the FirstCall operator's manual references.

It is visible in the FirstCall aPerio operator's manual that the Y-axis scale on sensitivity and capacitance bar graphs has variable values, depending on the mean value of all separate elements in a certain probe, i.e. the mean value varies depending on the number of elements and their certain sensitivity (V-pp) or capacitance (pF) values.

Mårtensson suggested that the returning pulse could be measured by pulse width, pulse waveform, bandwidth, peak-to-peak amplitude and centre frequency. To avoid breaks in the cable and short circuits, it is necessary to control the capacitance of every single element and the wires within the transducer cable. The transmitting and receiving of US pulses can be measured with peak to peak amplitude sensitivity (Mårtensson, 2011).

3. Results

3.1 Review of the results after the evaluation test

For the thesis project, a total of 73 transducers were tested produced by 3 different manufactures: Siemens, GE healthcare and Aloka.

After the evaluation test using FirstCall aPerio Testing Accreditation Program and manufacturers recommendations, 61 transducers have passed and 12 have failed; 6 of 12 had dead elements as a common reason for not passing. The following defects were also observed: from 73 transducers, 33 elements were dead, 38 had breaks in the cables, 6 had short circuits and 26 elements were weak in the red zone. In the green zone, 12 crystals were dead, 1 had a break in the cables, no short circuits were found and 4 elements were weak. The yellow zone was represented by 19 dead elements, a break in cable, no short circuit crystals were found and there were 3 weak elements.

Delamination appeared in two probes, one of them had the dead elements of the 3 different zones and the other one had the dead elements of the red zone.

The analysis showed that most of the defective crystals were situated in the red zone. This zone is the middle part of the transducer and, due to that, any failure there has much bigger influence over the quality of the image than the problems in the other two zones (See Table 2).

Manufacturer	No: of probes	Red zone elements				Green zone elements				Yellow zone elements			
		Dead	Broken	Short	Weak	Dead	Broken	Short	Weak	Dead	Broken	Short	Weak
I	32	14	3	6	14	12	0	0	4	19	1	0	2
II	9	14	0	0	9	0	0	0	0	0	0	0	1
III	32	5	35	0	3	0	1	0	0	0	0	0	0
Total	73	33	38	6	26	12	1	0	4	19	1	0	3

Table 2 Red, green and yellow zone error distribution for FirstCall aPerio

Classified by manufacturer, I had 32 transducers from the whole quantity of 73. Their equipment, however, had some common defects. In linear array, there was 1 broken transducer. In curved array, there were 3, and in phased array 6 non-functioning transducers. Manufacturer II had 9 transducers and only one phased array transducer showed a defect.

Manufacturer III had 32 transducers; one curved array did not pass the evaluation test (See Table 3).

Manufacturer	Total Trans.	Number of Failed Linear Array	Number of Failed Curved Array	Number of Failed Phased Array	Total error % Linear Array	Total error % Curved Array	Total error % Phased Array
I	32	1	3	6	2,77	8,33	16,66
II	9	0	0	1	0	0	6,25
III	32	0	1	0	0	2,94	0
Total	73	1	4	7	1,16	4,65	8,13

Table 3 Transducer Evaluation Test Result for linear, curved and phased array

The higher level of error in transducers appeared in Radiology Department. The reason for the highest quantity of fault transducer can be the aging of US equipment, intensive exploitation or a staff working incorrectly with the system (See Table 4).

Manufacturer	Total Trans.	Radiology	Physiology	Gynaecology	Childbirth	Cardiology
I	32	8	0	0	0	2
II	9	0	0	0	1	0
III	32	0	0	0	0	1
Total	73	8	0	0	1	3

Table 4 Transducer Evaluation Test Result (bad working probes for different departments)

Manufacturer	Total Trans.	Pass	Fail	Manufacturer Error (%)	Total Error (%)
I	32	22	10	31,25	13,69
II	9	8	1	11,11	1,36
II	32	31	1	3,125	1,16
Total	73	61	12	16,44	16,44

Table 5 Transducer Evaluation Test Result

The regular evaluation test using FirstCall aPerio of all newly acquired and available transducers gives an actual and precise review of the functional status of US equipment. In this way, the quality of diagnosis and patient's safety is increased, which is the main focus of this thesis. Out of the financial part, it has become clear that nearly half of the defect US transducers were in warranty and were replaced with new ones. Thus, the newly acquired transducers which have shown defects were immediately replaced.

3.2 Images from probes that passed and did not pass the evaluation test

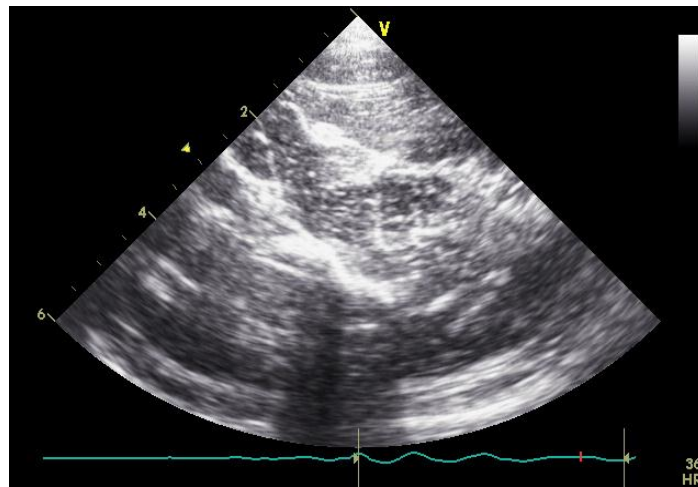


Fig.23a The image was taken by transducer phased array 10 MHz. The received image is clear, which indicates a good quality of the probe.

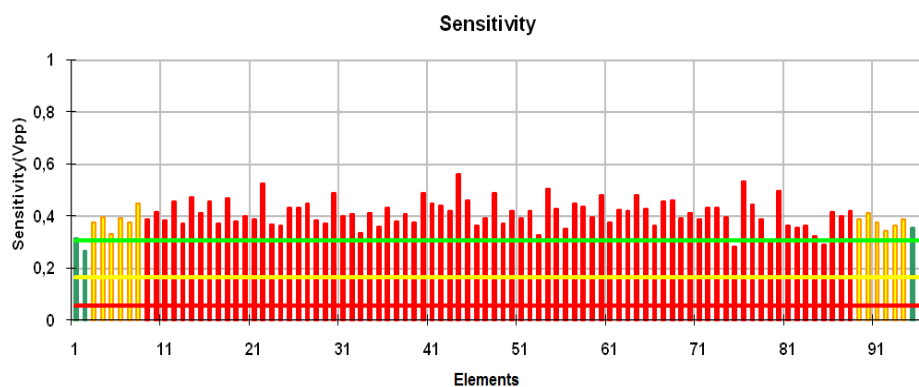


Fig.23b Sensitivity of PE elements within the transducer phased array 10 MHz. It was determined as a good working transducer because there were 3 non-consecutive weak elements (2 in the red zone and one in the green zone), and no dead elements that respond to the FirstCall operator's manual references.

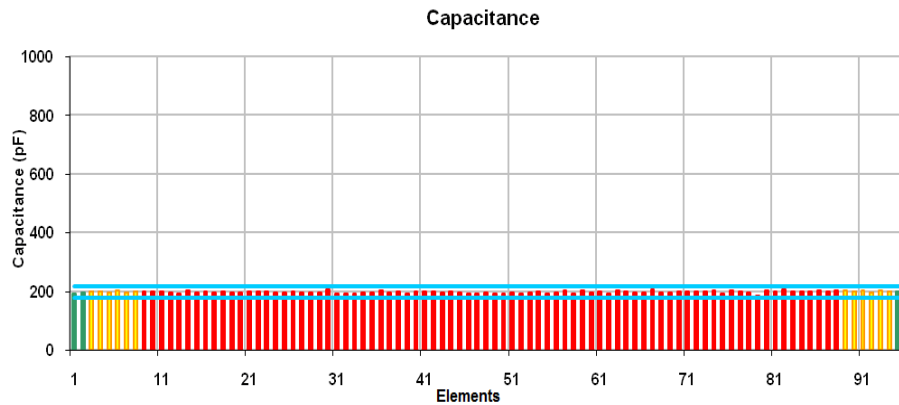


Fig.23c Capacitance of PE elements within the transducer phased array 10MHz. It was determined as a good working transducer because the capacitance values of all elements appeared on and within the maximum and minimum capacitance thresholds, that respond to the FirstCall operator's manual references.

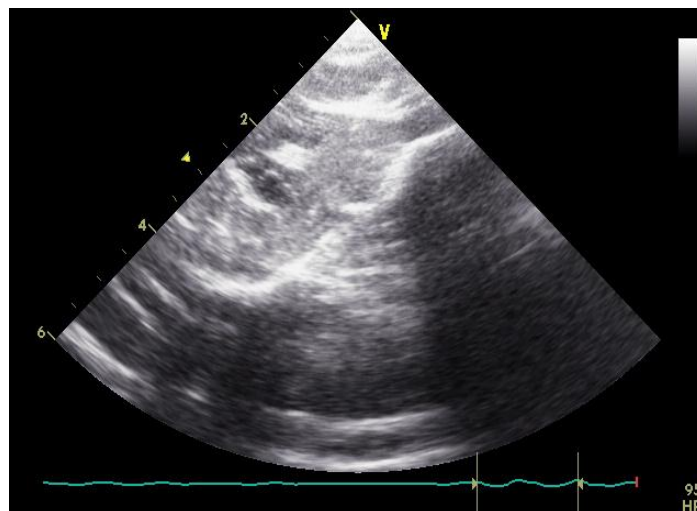


Fig.24a The image was taken by transducer phased array 10 MHz. The received image exhibited some black areas, resulting from the defective probe.

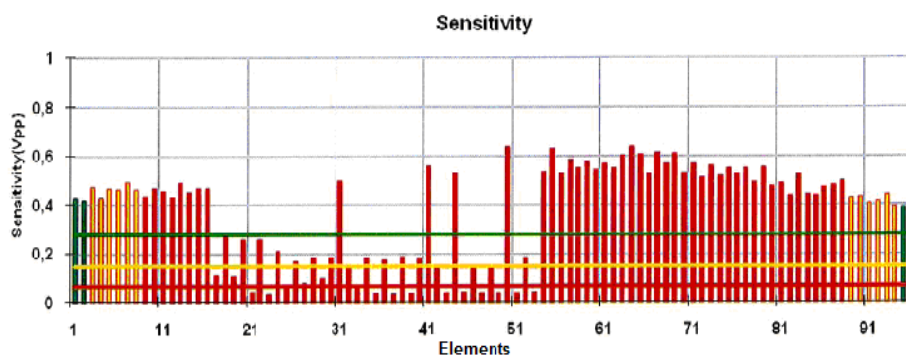


Fig.24b Sensitivity of PE elements within the transducer phased array 10MHz. This probe was classified as defective because there were much more than the accepted weak and dead elements and they were evaluated as lens delamination, according to the FirstCall operator's manual references.

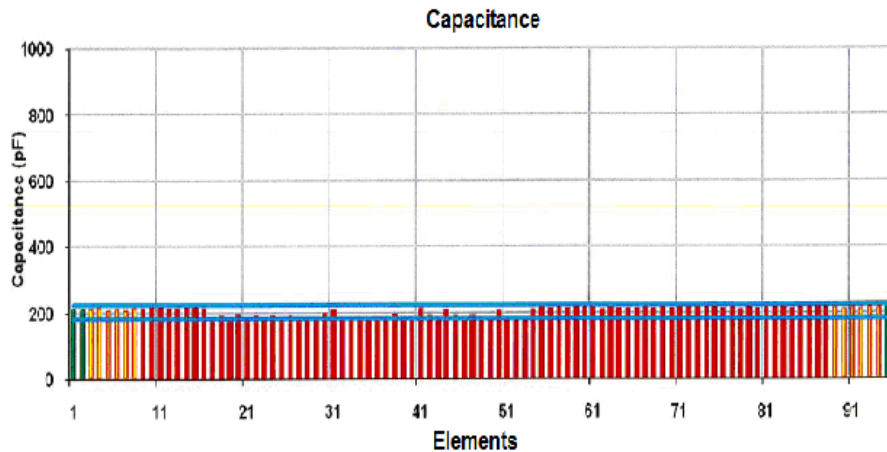


Fig.24c Capacitance of PE elements within the transducer phased array 10MHz. This probe was classified as defective with dead elements, because the capacitance values of many elements appeared under the minimum capacitance threshold, according to the FirstCall operator's manual references.

3.3 Common US probe failures discovered during the project

- During the inspection, the transducer probes showed the following common failures:
 - Cracks on the handle.
 - Destroyed lens material.
 - Swelling of the lens material.
 - Damaged pins in the probe connector.
 - Using a 'pin-less' connector, for example Siemens/Acuson sequoia probes, ensures that the surface of the connector is clean.

Lens problems:

- Dislocation of the lens from housing.
- Hole in lens (See Fig.26).
- Swollen lens.
- Scratches on the lens

Various structural defects:

- Destroyed structure of the pins in the connector.
- Bad contact, dirty pin-less connector.
- Broken lens cap.

Cable problems:

- Scratches in the cables (See Fig.28).

- Cable which is run over by the wheels of the US equipment (See Fig. 27).

TEE Re-coat and Re-Label:

The most common problem of TEE probe is to re-coat and re-label the depth markers. They can disappear during sterilization procedure.

What can damage a transducer?

- Perfume gels or other molecular changing substances.
- Discharging of electric signals on or around the lens of the transducer or on the probe connectors.
- Dropping the transducer, or some other force damage (See Fig.25)
- Incorrect handling during cleaning and sterilization process.
- Bad storage environment.
- Not ensuring that the image has frozen before connecting to or removing the transducers out of the system.



Fig.25 Broken case of probe



Fig.26 Holes in the lens



Fig.27 Cable runs over



Fig.28 Scratches in the cable

4. Discussion

4.1 Overview of master thesis goals and results considerations

The master thesis project started with two basic purposes. The first one was to test all of the available and newly acquired transducers in four hospitals in Gävleborg area. According to this aim, there were 73 transducers were tested by the FirstCall aPerio system 61 of them passed the evaluation test, and 12 did not pass. The probes were produced by 3 manufacturers: GE Health Care, Siemens and Aloka. Unfortunately during the performance a limitation was met because of the absence of suitable adapters for all of different manufactures and models of probes. Some probes have missed the evaluation test. It is a long period perspective to provide as many as possible adapters for the different types of probes and manufactures.

The second aim of the master study was to find out the advantages and disadvantages of FirstCall aPerio evaluation test. The most important of them are presented below as follow:

Advantages

- It is easy and flexible for testing.
- During the evaluation test, it is immediately visible, through the report, in which element the defect is.
- It can precisely distinguish the source of error: weak, dead element, short circuit and break or open connector in the wire.
- It helps to early discover the error, and repair the transducer.
- By reducing the transducer faults, the risk of wrong diagnosis is also minimized.
- Database collections save all measurements data.
- It is possible to test the transducer without US equipment.

Disadvantages

- No acceptance criteria for transducer's evaluation test, according to zone distribution of the defective elements and according to the different types of probes.
- Not enough adapters for all types of transducers.
- Bubbles sometimes affect the evaluation test of the transducer.

- Environmental factors and noise can badly affect the diagnostic test.
- Some of the units of the FirstCall aPerio are made of metal and when regularly in connect with water they can get rust which changes the chemical structure of the water and can, respectively, influence the final test result.
- Sometimes, in controlling the alignment transducer application window, it is difficult to reach the absolute zero level of depth to get the optimal distance between the transducer and a target.

From the presented above advantages and disadvantages, it can be concluded that FirstCall aPerio evaluation test is a suitable testing system, which allows controlling the functional status of a transducer and can distinguish the source of error. According to the accepted criteria, the operator can determine if the probe can be repaired on time, thus avoiding its influence on the quality of image. Parallel with the advantages of the testing device, there were outlined some disadvantages were outlined as described above. At the time of the project preparing, on the medical market of Sweden, there was no other evaluation testing system for transducers, so the used testing device of FirstCall aPerio gave possibility for a basic overview on the functional status of US probes. Nowadays, some of the new generation US equipment has a self-control function for testing of the transducer. Together with a suitable evaluation test, it is a big advantage to compare and consolidate the test results.

Usage of defective transducers appears as a common reason for misdiagnosis. Such cases are described by Mårtensson in his Ph.D study *High incidence of defective US transducers in use in routine clinical practice*, 2011. Some of the reports concern missed congenital heart disease and incorrect diagnosis of miscarriages.

The process of evaluation test consists of two main parts. Generally, the first one is the functional control of the elements within the probe. This part is a basis for the further process of evaluation because it clarifies what is the condition of the crystals. When there is a clear view of the number of weak and dead elements or if there are any other defects, the operator should decide whether the probe has passed the test, can be repaired or it should be replaced, in compliance with the second part of the evaluation test. Nowadays, one of the fundamental problems is that there are no constant and well built acceptance criteria for evaluation of transducers. These ones established by FirstCall aPerio, concern all tested probes, however, they do not distinguish the different types of transducers and cannot make clear if the probe is still in warranty or not. As Mårtensson has observed during his project work, which was also

noticed during the time of master thesis performance, according to the activation pathway, every of the three types of transducers had a different predisposition to various defects. Just one dead element in linear array can influence the image quality but more than one dead element in the phased array could hardly be distinguished only from the received image.

During the project work, the acceptance criteria of the FirstCall aPerio evaluation test for transducers turned to be important. One of the established criteria was modified: no more than 2 non-contiguous elements classified as "weak elements" instead of no more than 4 non-contiguous weak elements. This new criterion covered all types of probes in warranty. From an economical point of view, the purpose was to limit, as much as possible, the number of fault elements and avoid use of transducers which might influence both the image and diagnosis quality. During operation, probably, these weak elements will become dead, the probe should be replaced with a new one, which leads to financial losses for the hospital. It was already marked that the accepted criteria of FirstCall aPerio operator's manual were similar for every type of transducers. As it is known, however, the number and situation (red, yellow and green zone) of defect crystals have different influence on the image, for the various types of probes. The fault elements in the probe red zone have higher influence over the image quality than the elements defects in the other two zones. If the situation of the eligible weak and dead elements, when the acceptance criteria were created, was specified, it would be much better. In this case, the final assessment would depend on the operator and on the individual transducer, leading to many variations from operator to operator and from hospital to hospital. During the project work, the minimizing of defect elements in the red zone of all types of probes was a priority. Sometimes, more weak elements are permitted than the determined ones in the operator's manual acceptance criteria, if the fault elements are situated in the green zone (in the peripheral parts of an image), however, only if it is not a risk for misdiagnosis. The functional status of such transducers should be observed more often than usual.

As a future plan, it was established to more precisely observe the connection between every single type of probe and the number and situation of errors influencing the image quality. According to this purpose, additional changes of the acceptance criteria of transducer's evaluation should be expected.

The observations on common US transducers defects, drawn under the period of thesis work were: as it was mentioned above, 12 transducers were determined as defective, the dead

elements among the tested probes had the highest error rate, of course, according to the types of transducers, the highest defect level was observed in the phased arrays. The most defective probes were found in the radiology department. Delamination appeared in two of the tested probes, during the master project work, as one of them had the dead elements within the 3 different zones, and the other one had the dead elements within the red zone, one probe showed electrical fault as high leakage current. According to the influence of different types of defects over patient's safety, short circuit and break in cable, causing high leakage current or voltage, appear as higher risk agents than the elements classified as non-operating items. Electrical fault as high voltage or/and high leakage current, however, affects not only the quality of an image but can have a lethal impact. Basically, dead elements and especially delamination affect the quality of the image and increase the possibility of false diagnosis and treatment.

Some speculations could be emphasized in regard to the reason of fault, number of defective transducers and the departments they belong to. Basically, the reasons can be categorized as follow: aging of US equipment, intensive exploitation (longer period of using of the US transducers decrease the functional lifetime of probes), a staff working incorrectly with the system or incorrect transportation and storage of the US equipment (scratching the cables and transducer's lenses, break in the cable and hitting the probe) or handling system. One of the observations made under the period of probe testing was that in some departments, for instance, radiology department, the transducers were constantly connected and disconnected from the US equipment. Probably, it could be the common reason for the highest rate of defective probes in the mentioned department. Also, it should be mentioned that the transducer's functional status was tested for the first time, which means that some of the fault probes could be repaired on time, before the appearance of delamination or would be replaced.

The exact reason for appearing of defect is still unclear: sometimes, it can be a complex of more than one reason. US equipment is a sensitive and expensive medical device. It is extremely important to determine in which cases the defective probe should be replaced and when it can be marked to be followed but still in operation. Foremost, the patient's safety should be guaranteed.

4.2 Patient Safety

Patient's safety is a very important part of the health care system. It can be achieved by avoiding the incorrect diagnosis and treatment and minimizing the recovery time.

According to the influence of different types of defects over patient's safety, short circuit and break in cable, causing high leakage current or voltage, appear as higher risk agents than elements classified as non-operating items. Basically dead elements affect the quality of image. Electrical fault as high voltage or/and high leakage current, however, it affects not only the quality of an image but can have a lethal impact.

4.2.1 Patient's safety problems caused by unsafe medical care

- Medical drug treatment and device errors.
- Errors during surgery and respectively anesthesia.
- Infections.
- Blood products, which are not under control.
- Incomplete health care for children, pregnant women, newborns and elderly people.
- Misdiagnosis, error in diagnosis and errors in interpreting test results for instance: images.
- Non-qualified staff.
- Communication errors, for instance: language problem and lack of discussion with the patient about future plans and variants of treatment.
- Technical problems, including old or broken apparatus.
- Leakage of the current test.

4.3 Requirements regarding design and manufacture

1. The properties of chemical, physical and biological characteristics.
2. Infection and microbial pollution.
3. Environmental characteristics of manufacturing.
4. Precise measuring of the devices functioning.
5. Protection against radiation.
6. Information and technical report supplied by the manufacturer.

4.4 Reducing of risk factors

It can be provide by:

1. The risk level can be reduced by optimization of the design, protection measure and by providing the users with information.
2. Performance verification procedure: approximately on every 6 months.
3. Following the safety instruction during operation.
4. Correct storage and transport.
5. Correct usage of US equipment or transducer.
6. Avoiding of design or manufacturing defects, for instance: sometimes, the evaluation test of a new transducer encounters a process of delamination which means defect in the lens material.
7. High qualification of the staff.
8. Limitation of deficiencies in maintenance.

The following can be included in risk analysis: Transducer, different components, equipment, operation systems and projects. In risk analysis, it is important to use questions, such as:

- What can go wrong?
- How likely is it?
- What are the consequences?
- Is it acceptable?

Acceptable risks: these are risks in determining parameters, which do not influence the quality of the image and diagnosis. The most important thing is to ensure that the negative side effect must never overweigh the positive. This is an obligatory requirement of the directives and allows marking the product by CE sign.

Nowadays, the medical market in Sweden offers only one transducer test device, FirstCall aPerio, which limits the possibility to compare the received results of the evaluation test with another probe test device. Fortunately, some of the medical manufacturers introduced a new US system which includes self-control for the functional status of the transducers. It provides a big advantage because in combination with the evaluation test device it will confirm the test measurements.

5. Conclusions

This study has two aims: The first one has orientated into early discovering of defect in acquired new transducers and available probes. It is often observed that there are some manufacturing defects, which can hardly be discovered immediately without any test control. The problem with such kind of failures is that they remain hidden during operation, which reflects over the image quality and the quality of diagnosis. During the project there was detected such probe thanks to the evaluation test and they were replaced immediately.

Unfortunately, some difficulties appeared in the initial phase of the project, because of the absence of adapters to some models of US probes. Because of that, those transducers are still in operation, skipping the evaluation test. This may cause some risk for inaccurate medical diagnosis.

Future perspective is based on periodical observation of physical and functional status of existing US transducers at the mentioned above hospitals. The basic purpose is to increase the quality of health care.

Second aim is to find out the advantages and disadvantages of The FirstCall aPerio evaluation test. The test was developed to reduce the risk level of wrong diagnosis and to ensure optimal results by regular test of physical properties of the US transducer. With this device it is easy to classify and document the key indicators of potential areas of transducer problems, for instance: weak or dead elements, short circuit or break in the cables. It gives a possibility to compare the final result of the images and a received report, which are based on well working or bad working probes.

Collecting of statistical data and analysis are the next points of interest, corresponding to the second goal of this study. It is extremely important to have a clear technical overview on the status of available US equipment and transducers; to keep under control every probe marked for observation; to see the common defects in the probes. For the leading hospitals, it is necessary to invest time and money to improve the professional level of medical staff. The basic purpose of the medical health care is to keep high level of patient's safety and to minimize the possibility of errors. This could be ensured not only by the equipment but also by the staff's skills to work with it. For this reason, lots of trainings were organized about the correct use of US systems. According to the received results, this basic purpose can be classified as fulfilled.

Based on the study made, the following conclusions were drawn: a functional test of the elements of US transducer gives a clear clinical picture and at any time, it is known in what condition the available probes are. Those ones which did not pass the test (amongst the acquired new probes and transducers in warranty) were immediately replaced with new devices. The financial advantages for the hospital were significant.

During the test period, the functions of transducers were observed. Devices have been belonging to different departments of 4 hospitals in Gävleborg area. The total number of tested transducers was 73. They were produced by 3 different manufactures: Siemens, GE health care and Aloka. 12 of them did not pass the evaluation test. Only 1 transducer showed a high leakage current fault under the evaluation test. To avoid a future wrong diagnosis, all of the transducers which were detected with some errors, were immediately replaced with new ones.

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