Cape Peninsula
University of Technology

2D & 3D ULTRASOUND SYSTEMS IN DEVELOPMENT OF MEDICAL IMAGING TECHNOLOGY.

by

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DECLARATION

I, **Abdalla Agila Eljaaidi**, declare that the contents of this dissertation/thesis represent my own unaided work, and that the dissertation/thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

Signed **Date**

ABSTRACT

Ultrasound is widely used in most medical clinics, especially obstetrical clinics. It is a way of imaging methods that has important diagnostic value. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. The use of two-dimensional ultrasound (2DUS) in obstetrics has been established. However, there are many disadvantages of 2DUS imaging. Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three- and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound, has boomed, particularly in the United States. However, long-term epidemiological studies have failed to show the adverse effects of ultrasound in human tissues. Until now, there is no proof that diagnostic ultrasound causes harm in a human body or the developing foetus when used correctly. While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses (bio-effects). The two most important mechanisms for effects are thermal and non-thermal. These two mechanisms are indicated on the screen of ultrasound devices by two indices: The thermal index (TI) and the mechanical index (MI). These are the purposes of this thesis:

- evaluate end-users' knowledge regarding the safety of ultrasound;
- evaluate and make a comparison between acoustic output indices (AOI) in B-mode (2D) and three-dimensional (3D) ultrasound – those measured by thermal (TI) and mechanical (MI) indices;
- assess the acoustic output indices (AOI) to benchmark current practice with a survey conducted by the British Medical Ultrasound Society (BMUS); and
- review how to design 2D and 3D arrays for medical ultrasound imaging.

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Lastly I would like to thank whole my family (my mother, my wife, my brothers, my sisters and my kids) for their support and encouragement, especially my unborn child (foetus) who is a part of this study.

DEDICATION

To whole my family, may they see in this work the fruit of their love and support.

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GLOSSARY

TERM	EXPLANATION
US	Ultrasound
1D	One-dimensional
2D	Two-dimensional
3D	Three-dimensional
4D	Four-dimensional
WHO	World Health Organization
TI	Thermal Index
MI	Mechanical Index
BMUS	British Medical Ultrasound Society
AOI	Acoustic Output Indices
NCRP	National Council on Radiation Protection
HFSW	High Frequency Sound Waves
SPL	Sound Pressure Levels
PZT	Piezo-Transducer
λ	Wavelength
f	Frequency
$\vee$	Speed of propagation
T	Time required for one wavelength to pass a certain point
P_{signal}	Pressure of the signal in Pa.
P_{ref}	Reference sign at 20 μPa.
A	Amplitude (the maximum value of the wave function)
C	Speed of sound
W	The angular velocity of the oscillation
n	The number of samples in one cycle
ΔT	The time between adjacent samples
P0	The mean density
B	The adiabatic bulk modulus
K	Adiabatic compressibility
r	the distance of propagation of wave in the medium
Z	The acoustic resistance
A	The attenuation
TP	Transducer probe
CPU	Central processing unit
TPC	Transducer pulse controls
DS	Display screen
DSD	Disk storage device
BMUS	British Medical Ultrasound Society Safety
TUIS	Transmission ultrasound imaging system
Z1	The resistance of the medium
Z2	The resistance of the body part
Θ_1	The incident angle
Θ_2	The refraction angle
Θ_3	The reflection angle
4DIT	Four-dimensional imaging technology
FDA	The Food and Drug Administration
AIUM	The American Institute of Ultrasound in Medicine
AOL	Acoustic output levels
I_{SPTA}	Spatial peak temporal average intensity
ALARA	As low as reasonably achievable

ODS	**Output display standard**
DUS	**Diagnostic ultrasound**
AOI	**acoustic output indices**
TIS	**the soft tissue thermal index**
TIB	**the bone thermal index**
TIC	**the cranial bone thermal index**
W	**acoustic power output from the transducer**
W_{deg}	**the power required to cause a maximum tissue temperature**
P-0.3	**the maximum value of peak negative pressure**
NEMA	**the National Electrical Manufacturers Association**
R_r	**the linear resonant radius**
SPPA	**the spatial peak pulse average**
KAUH	**king Abdul-Aziz University Hospital**
NT	**Nuchal translucency**
NO	**nitric oxide**
SMPD2	**sphingomyelin phosphodiesterase 2**
UGT8	**UDP glycosyltransferase 8**
COX6B1	**cytochrome C oxidase**
MAP2K1	**mitogen activated protein kinase 1**
CPA	**conventional phased array**
CSA	**classical synthetic aperture**
SNR	**signal-to-noise ratio**
$C(n_x, n_y)$	**the 2-D transmit array**
$A_T(n_x, n_y)$	**receive array**
$A_R(n_x, n_y)$	**co-array functions**
d	**the inter-element distance**
θ_x	**the angles in azimuth**
θ_y	**the angle of elevation direction**
CW	**continuous wave**
PSF	**point spread function**
XT-FR	**X-shaped transmitter and full receiver**
XT-PR	**X-shaped transmitter and plus-shaped receiver**
XT-BR	**X-shaped transmitter and boundary receiver**
BRT-BCR	**boundary-rows transmitter and boundary-columns receiver**

RESEARCH OUTPUTS

A) Journal papers

1) Acoustic Output as Measured by Thermal and Mechanical Indices and its Bio-effect During Ultrasound Scanning in Obstetrics. The paper was published in Journal of Energy Technologies and Policy (IISTE) Vol.4, No.9, pp., 58-64, 2014.

2) The Knowledge of Users Regarding Safety of Ultrasound During Pregnancy. The paper was published in the European Journal of Biotechnology and Genetic Engineering (EJBGE) Vol. 2, No. 1, pp., 25-31, 2015).

3) User Defined Parameters for Ultrasound Safety. **Submitted** November 2015, Journal of Engineering Design (**DHET Credited Journal**).

CHAPTER ONE

INTRODUCTION

1.0 Introduction

1.1 A historical perspective of ultrasound

Ultrasound (US) research can be traced back to 1794 when Lazzaro Spallanzani, a physiologist, concluded that bats use ultrasound to transfer echolocation. In 1877 Lord Raleigh developed the Theory of Sound. This was based on previous research on the speed of sound by a Swiss physicist named Daniel Colladon. Colladon carried out experiments to calculate the speed of sound through water, using an under-water church bell (see Figure 1.1).

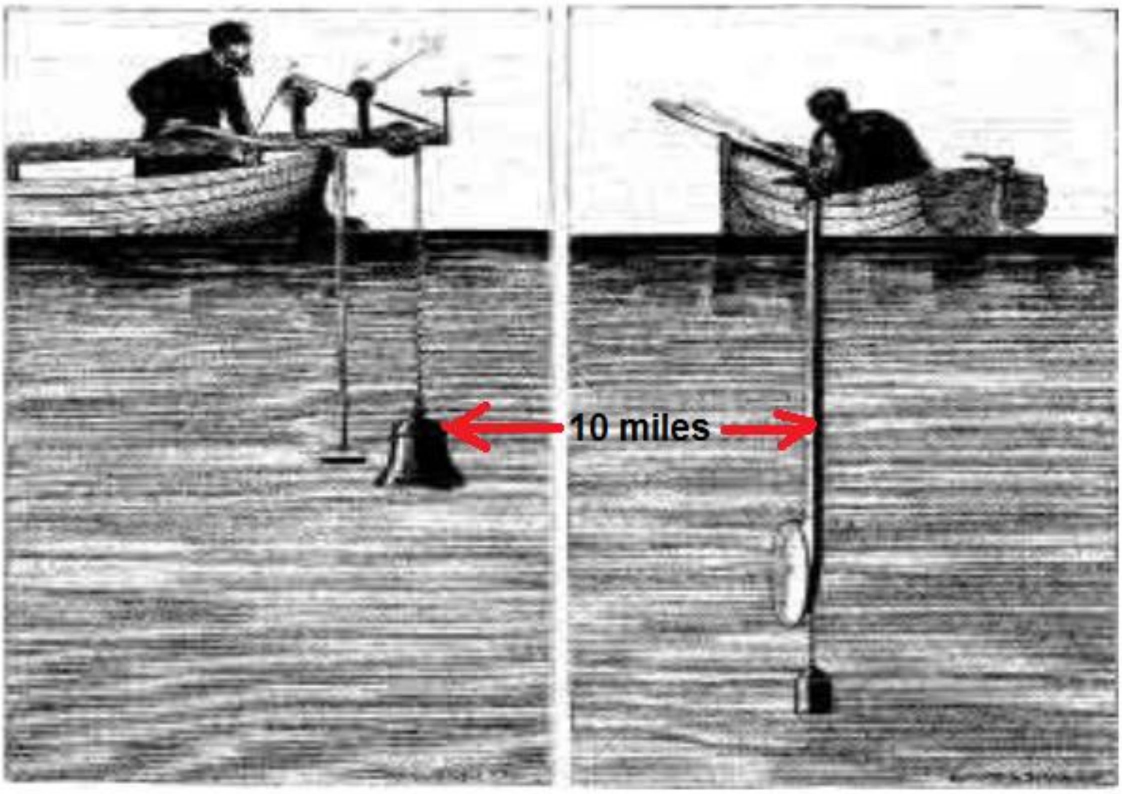


Figure 1.1: Daniel Colladon's research on the speed of sound through water (Tsung, 2011)

The reception of ultrasound became possible for the first time in 1880 when Pierre Currie discovered the piezoelectric effect. In 1915, shortly after the sinking of the Titanic (1912), Paul Longevin invented the hydrophone, which was the first transducer. It was made to detect submarines and icebergs under water from two miles away. Dr Karl Dussik was the first to use ultrasound for medical purposes. He used it for the diagnosis of brain tumours (Figure 1.2). According to Spekowius and Wendler (2006), the history of ultrasound progressed from the early days of A-line or one-dimensional imaging (1-D), to B-mode presentation of multiple A-lines as a two-dimensional (2-D) imaging technique, to a three-dimensional imaging technique of multiple B-modes as a volume.

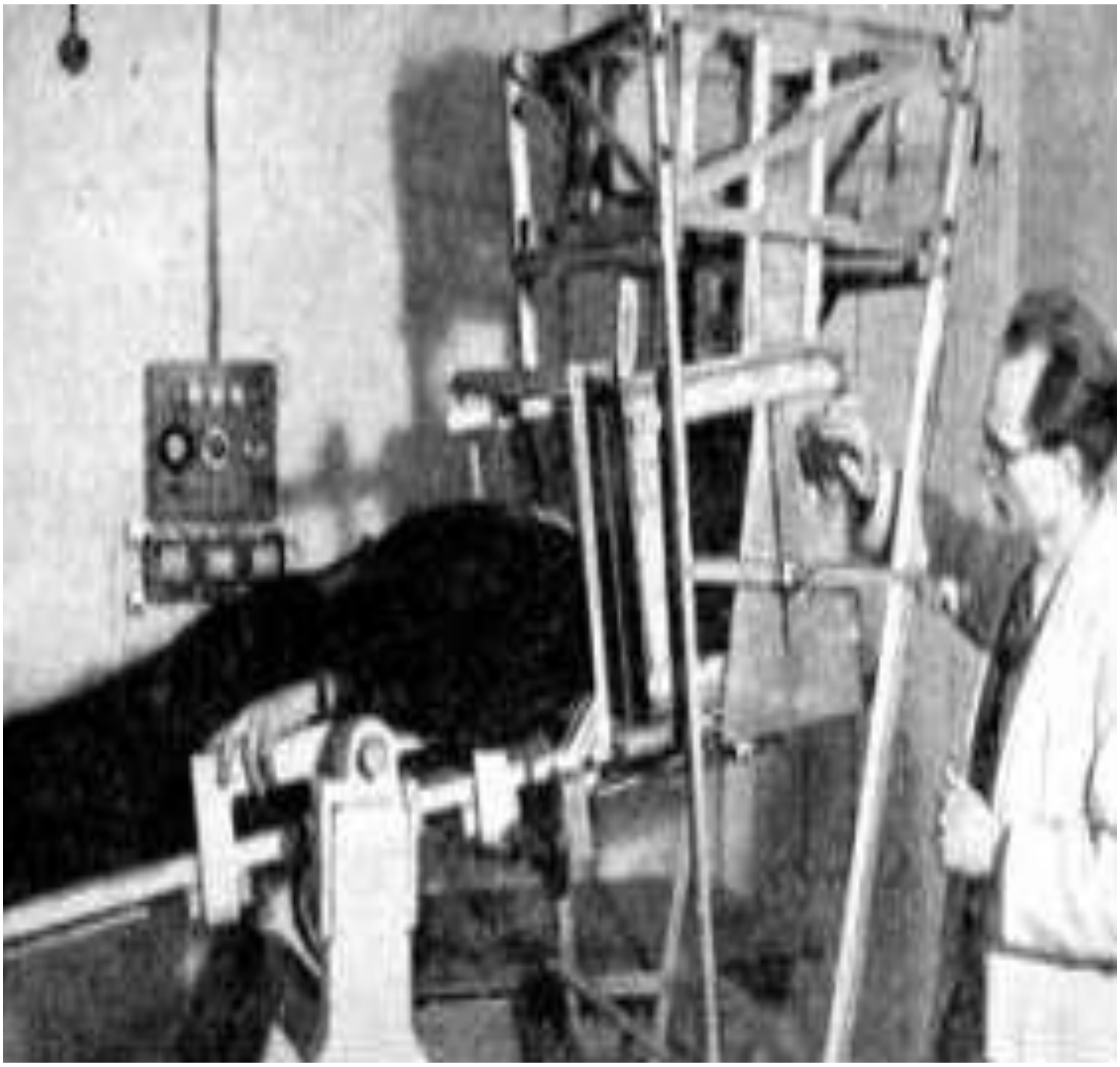


Figure 1.2: Dussik and his ultrasonic apparatus in 1946 (Tsung, 2011)

The evolution in the field of ultrasound use for medical purposes sprang up in the 1950s. The first development of 2D was presented by Howry and his engineers (Layyous, 2013; Goldberg et al., 1992). However, the equipment was large in size and patients had to be fully or partially immersed in it for a long time, making it impractical and impossible to use in clinics (Figure 1.3).

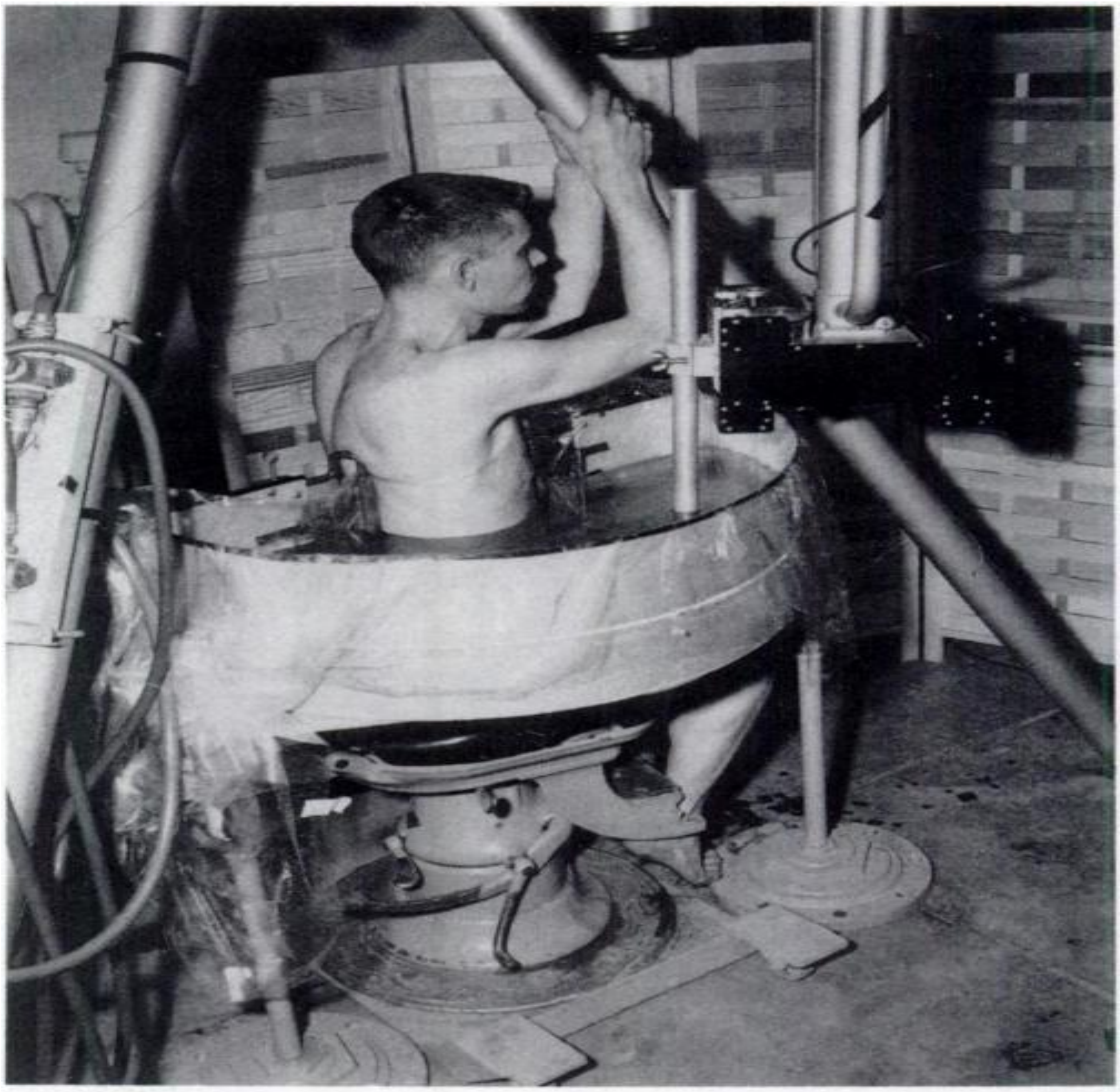


Figure 1.3: Howry team's 'pan scanner', developed about 1957-1958 (Goldberg et al., 1992)

Focus then moved towards developing ultrasound machines that were smaller in size, easier to use and more sensitive. The devices used in the beginning (A-mode and B-mode) produced only static or non-movement images. Using this technique, it was possible to image the abdomen and pelvis, including evaluating the foetus during pregnancy (Figure1.4) (Layyous, 2013; Troxclair et al., 2011). Developments in countries such as the United States of America (USA), Japan, Australia and the United Kingdom opened the doors for ultrasound devices to be used in Obstetrics and Gynaecology. In the 1980s there was a great revolution in ultrasound machines. A live imaging (2D) became a reality. A device was developed which could capture a foetus's movement, heart pulse and breathing.

Figure 1.4: Articulated arm bistable scanner in 1978 (Troxclair et al., 2011)

The dimensions of the vicinity of a foetus's head became the accredited method to study growth of the foetus. After a few years, it was possible to study pregnancy (Layyous, 2013). In 1986 and 1996 the 3D and 4D ultrasound devices were developed respectively.

Ultrasound (US) has become an important diagnostic tool used for obtaining information about function or structure in human beings (Minister of Public Works and Government Services, Canada, 2001). It is widely used in health care institutions, especially obstetrical clinics. The World Health Organization manual of diagnostic ultrasound (WHO, 2013) states that during the last decades, the use of ultrasonography increased in health care practice globally, and the benefits have been widely reported. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. Malhotra, Shah, Kumar, Acharya, Panchal and Malhotra (2014) state that the use of two-dimensional ultrasound (2DUS) in obstetrics is well established. But there are many disadvantages of 2D-US imaging. Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound has boomed, particularly in the United States, even though long-term epidemiological studies have never succeeded in showing the adverse effects of ultrasound on human bodies (Hershkovitz et al., 2002; Newnham et al., 2004). Until now, there is no proof that diagnostic ultrasound causes harm in humans or the developing foetus when used correctly (Chan & Perlas, 2011). While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses. From the early days of ultrasound, researchers have been aware of the potential bio-effects of ultrasound. After World War I, Chilowsky and Langevin took advantage of the enabling technology of piezoelectricity for transducers and vacuum tube amplifiers to realise the practical echo range in water (Szabo, 2004). They used high-powered echo-ranging systems to detect submarines and, during transmissions, they observed schools of dead fish floating at the water surface (Szabo, 2004).

The two most important mechanisms for effects are thermal and non-thermal. These two mechanisms are indicated on screens of ultrasound devices by two indices: the thermal index (TI) and the mechanical index (MI).

Ultrasonic imaging has been used for more than five decades and its use as a means of diagnosis is becoming more popular (Hangiandreou, 2003:1019-1033). Epidemiological studies have failed in the past to identify the adverse effects of ultrasound on human bodies (Lyons et al., 1988:687-690; Newnham et al., 2004:2038-2044), which is considered a form of energy that causes bio-effects. The two mechanisms of ultrasound are heating and cavitation (AIUM, 2000:69-72).

1.2 Problem statement

The majority of physicians depend on ultrasound diagnoses in their clinics. However, there are no studies concerning safe ultrasound. Also, long-term epidemiological studies have failed to show harmful effects of ultrasound in humans which, as a form of energy, might cause bio-effects. Most sonographers are not aware of the significance of those indices, which might cause risks to patients. In this thesis we will evaluate end-users' knowledge regarding the safety of ultrasound, evaluate and make a comparison between acoustic output indices (AOI) in B-mode (2D) and three-dimensional (3D) ultrasound – those measured by thermal (TI) and mechanical (MI) indices and assess the acoustic output indices (AOI) to benchmark current practice with a survey conducted by the British Medical Ultrasound Society (BMUS).

1.3 Scope of the study

The scope of this study of 2D and 3D ultrasound systems in the development of medical imaging technology, focuses on technical aspects of ultrasound diagnostics during examination, using acoustic output indices. An evaluation end-users' knowledge regarding the safety of ultrasound are considered. Evaluate and make a comparison between (AOI) in (2D) and (3D) ultrasound. Finally, these indices are also compared to those of the British Medical Ultrasound Society (BMUS).

1.4 Motivation

1.4.1 Significance of the research

The research can explain if the acoustic outputs are low or high; that is one of the elements threatening the safety of the patient. The research also investigates if there are differences between ultrasound devices in acoustic outputs.

1.5 Main objective

The main objective of this study is to:

1.5.1 Evaluate end users' knowledge regarding the safety of ultrasound

1.5.2 Investigate and evaluate acoustic output as measured by Thermal (TI) and Mechanical (MI) indices from different studies during ultrasound scanning

1.5.3 Compare the values of Acoustic Output Indices (AOI) in 2D and 3D

1.5.4 Compare these values to those from the British Medical Ultrasound Society (BMUS).

1.6 .Organisation of the thesis

The thesis is organised into eight chapters:

Chapter One gives a brief introduction on the historical perspective of the use of ultrasound, the background, problem statement, scope of the study, motivation of the study and the objectives.

Chapter Two consists of background. It provides a depth of knowledge relevant to the physics of ultrasound.

Chapter Three consists of the literature review. It gives information about previous studies relevant to this study.

Chapter Four presents the methodology that was applied to answer the research question. Various sections are included such as the methodology and research design, setting, population, sample size and sampling, instrumentation and data collection, and analysis and ethical considerations.

Chapter Five presents how to design 2D and 3D arrays for medical ultrasound imaging.

Chapter Six presents the knowledge of users regarding safety of ultrasound during pregnancy in Cape Town's hospitals. The results are presented in tables and figures.

Chapter Seven consists of data analysis of the results of the thesis. The data are shown in tables and figures.

Chapter Eight presents the discussion of the results that have been done.

CHAPTER TWO

Physics of ultrasound

Chapter Two presents the background of this study. This chapter provides a review of literature on ultrasound. The literature is relevant to the topic and was found in various databases including Medline, ultrasound, IEEE, Science Direct and Google Scholar.

2.1 Introduction

Ultrasonic waves have become an important tool to use in medicine. As a tool of diagnostics, it shows no risks if it is used well (but for some bio-effects to the health of patient) (Weiss, 2008). Ultrasound is known simply as medical imaging but it has many uses in medicine, such as:

A. Cleaning teeth
B. Physical therapy
C. Lithotripsy
D. Flow rate measurement.

Ultrasonic imaging is considered the most important and widely known application of ultrasound and will be presented in this chapter.

According to Ahmadian (2001) the primary advantages of medical ultrasound imaging are:

- It is regarded by medical experts to be safe with no risk to the health of patient.
- There are portable ultrasonic systems available, so it is easy to move it from one place to another.
- Its price is lower than other imaging devices.
- It can be used to measure movement inside the body, such as the movement of blood in the heart and arteries.
- It is able to construct imaging of soft tissue.

2.2 Definition of ultrasound

Infrasound, sound and ultrasound refer to the frequency bands in a spectrum of waves. They have been divided into three sections according to their sensitivity thresholds to the human ear. Ultrasound is an oscillating sound pressure wave with a frequency greater than the upper limit of the range of human hearing (Huntsville, 2003). Ultrasound is similar to sound that can be heard, but with very high frequency (NCRP, 2002:1-8). Ultrasound waves travel in media such as air, water and solids in the form of longitudinal vibrations away from the source of the sound. Ultrasound has a high frequency of 20 kHz to 200 MHz, which is higher than sound waves and can be heard, as shown in Figure 2.1 and Figure 2.2. Ultrasound can be described as mechanical force waves that have frequencies above 20,000 Hz (over the range which is audible).

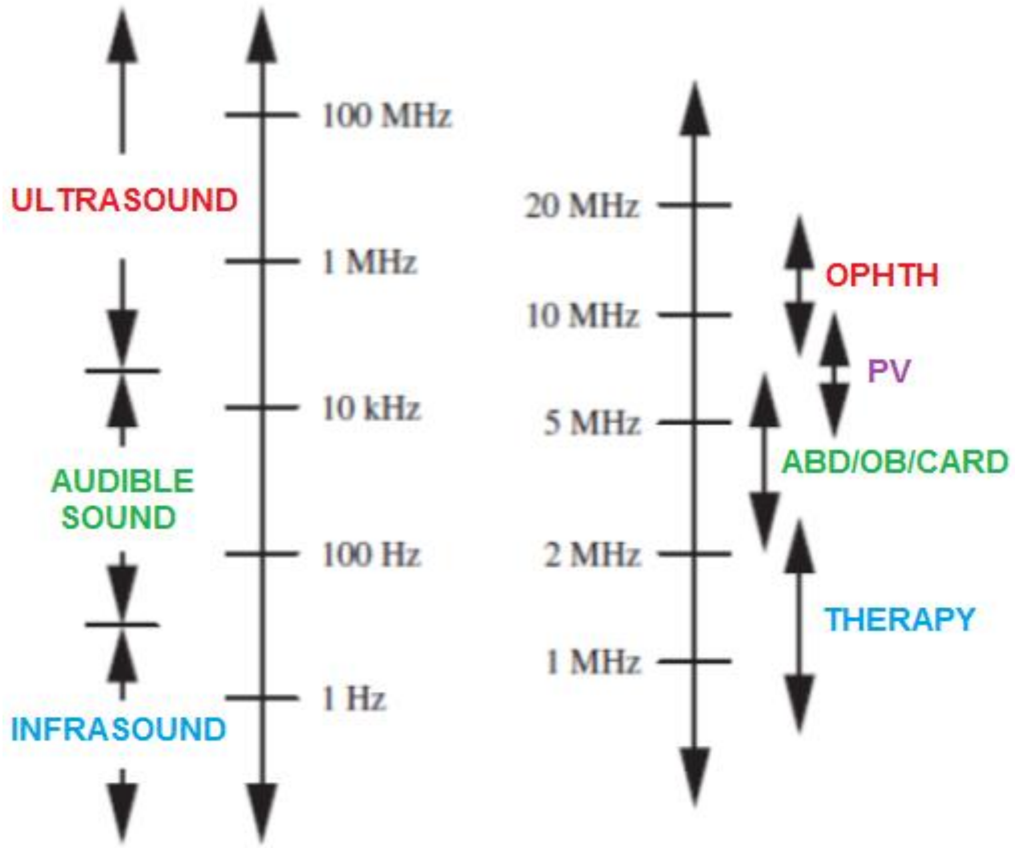


Figure 2.1: The spectrum of sound. Ultrasound is defined as above audible sound (~>20 kHz) (left). The spectrum of medical ultrasound (right) (Zieske, 2011)

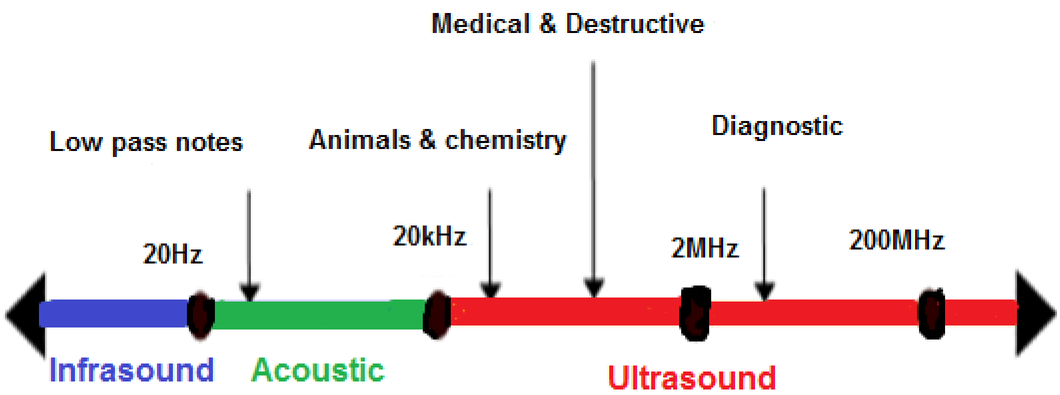


Figure 2.2: Approximate frequency ranges corresponding to ultrasound

2.3 Basic characteristics of ultrasounds

2.3.1 Ultrasound waves

Ultrasound refers to high frequency sound waves (HFSW) above the hearing range of humans (Gibbs, Cole & Sassanno, 2009). Diagnostic ultrasound consists of minute mechanical vibrations, which are pulses of ultrasound, transmitted into the body (Gibbs et al., 2009). According to Miller (2008), during vibrations, particles compress and spread apart in a process called compression and rarefaction (Figure 2.3 and Figure 2.4). The sequence of compression and rarefaction is described using sine waves and is characterised in terms of wavelength, frequency, amplitude and propagation velocity. A wavelength is described as the distance between two peaks of the sine wave.

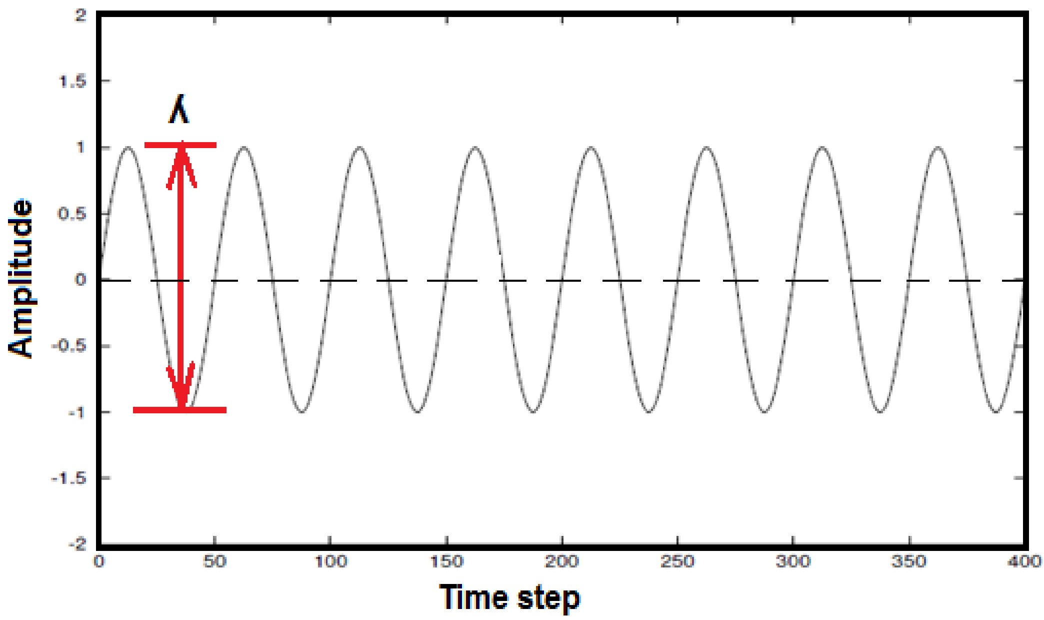
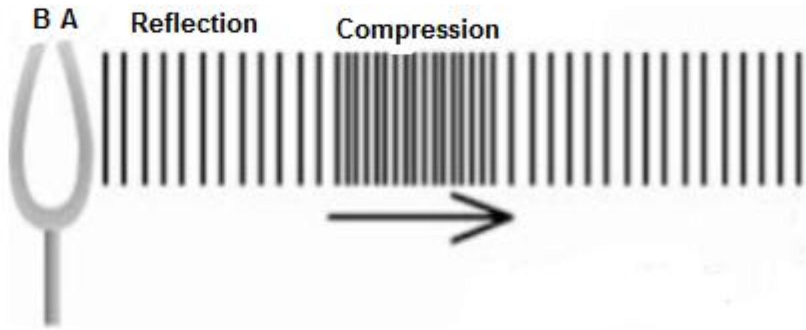


Figure 2.3 Graph of a simple harmonic oscillation

(A)

(B)



(C)

(D)

Figure 2.4: Propagation of sound waves (A, B, C and D).

2.3.2 The spectrum of ultrasound

Sound waves with frequencies above those used by humans are called ultrasound. The human ear can hear sounds with a range from above zero to near 20 kHz. The good scope of ultrasound pressure waves is from 20 KHz to nearly (10 MHz). The medical imaging is probably the one the general public are most aware of (The Xtal Set Society, 2008)**.** Experiments were conducted on the part of the ultrasound spectrum used by several insects, rodents, bats, and fish for feeding, communication and navigation. Some of these creatures use both audio and ultrasound. Ultrasound is not found above about 160 kHz for biological use, except for medical and structural testing, because of the close total absorption of the wave over short distances through the air. Table 2.1 notes a brief listing (The Xtal Set Society, 2008).

Table 2.1: Ultrasound users (The Xtal Set Society, 2008)

Band	Frequency range (KHz)	Users
Audio	0 – 20	Human, animals, insects, fish, sonar
Ultrasound	20 – 30	Rodents
Ultrasound	20 – 75	Insects
Ultrasound	20 – 160	Bats, dolphins
Ultrasound	100 – 2000	Structures testing
Ultrasound	1 k – 10 k	Medical applications
Radio	30 – up	Low frequency radio to mm-wave applications

Sound pressure levels (SPL) transmitted across mediums are registered to be at 35cm to be about 70 to 110 dB. Signals emitted are different and range from simple sine waves to complex wavelengths with bandwidths and centre frequencies as high as 120 kHz. With the dividing and shifting of frequency (direction conversion) receivers, the most activity will be heard as a pattern of clicks (The Xtal Set Society, 2008).
SPL is defined as follows:

$$L_P = 201\text{og}\left(\frac{\mathcal{P}_{signal}l}{\mathcal{P}_{ref}}\right) \text{dB} \qquad (2.1)$$

where
P_{signal} is the pressure of the signal in Pa [n/sq-m].
P_{ref} is the reference sign at 20 μPa – the threshold of hearing.
1 Pa is equal to (perhaps the more familiar) 10^{-5} bar.
Rearranging, 1 Pa is equal to 10 μbar.
According to The Xtal Set Society (2008), the absorption of the signal by the air has been measured at 40 kHz to be about 0.0065 dB/cm, which is not so bad. Thus a quite strong signal at 110dB where the SPL Sound pressure levels) would constitute a pressure at the source of:

$$P_{signal} = P_{ref}\,(10^{SPL/20}) = (20e\text{-}6)\,(10^{110/20}) = 6.3 \text{ Pa}. \qquad (2.2)$$

Several of the equations are used? for radio projects to apply to acoustic projects. For example, the speed of a wave in a medium is equal to the produce of its frequency and wavelength (The Xtal Set Society, 2008). Subsequently:

$$\vee = f\lambda \qquad (2.3)$$

where,

f *is* the frequency in Hz.

λ is the wavelength in meters.

$\vee$ is the speed of propagation.

Table 2.2 shows the wavelength (**λ**) of many ultrasound signals at dissimilar frequencies (**λ**) by using the formula that is shown in (2.3). Be aware that that wavelength (**λ**) in the general 40 kHz empirical frequency is just 1.5 cm. Due to that fact, 30.5 cm parabolic dish can be used effectively to increase weak signals along with a piezo-transducer (PZT) receiver.

Table 2.2: Ultrasound parameters (The Xtal Set Society, 2008)

Band	Frequency KHz	Speed m/sec	Wavelength meters	Wavelength feet
Audio	1	330	0.3300	1.0827
Ultrasound	20	330	0.0165	0.0541
Ultrasound	40	330	0.0083	0.0271
Ultrasound	120	330	0.0028	0.0090
Ultrasound	1000	330	0.0003	0.0011
Radio	7000	3.00E+08	42.8571	140.6071

2.3.3 Parameters of sound *waves*

The main parameters and equations of sound waves are as follows:

- The wavelength ʎ (m) is the horizontal length of one cycle of the wave.
- The period T (sec) is the time required for one wavelength to pass a certain point.
- The amplitude A (m) is the maximum value of the wave function.
- The frequency f (Hz) is related to the period.

The frequency f of the oscillation can be calculated by using the following formula:

$$f = \frac{w}{2\pi} \tag{2.4}$$

where w is the angular velocity of the oscillation.

The definition of frequency (f) of the oscillation is the number of oscillations per second (n/sec). If we assume that the time for one oscillation is T, then the frequency can be calculated as follows:

$$f = \frac{1}{T} \tag{2.5}$$

In a discrete system when the time is discrete too, the frequency can be as follows:

$$f = \frac{1}{n\Delta T} \tag{2.6}$$

Where (ΔT) is the time between adjacent samples and (n) is the number of samples in one cycle.

- The speed of sound c (m/s) is independent of the above parameters of the sound wave.

$$\lambda = c/f \tag{2.7}$$

The acoustic parameters of the medium are its density (ρ) and adiabatic compressibility (κ). It is the local changes in those two parameters that allow sound to propagate. The propagation speed of the disturbance is a property of the medium and is given by:

$$C = \sqrt{\frac{1}{\rho_0 k}} = \sqrt{\frac{B}{\rho_0}} \tag{2.8}$$

where (p_0) is the mean density and (*B)* is the adiabatic bulk modulus, assuming there is no net transfer of energy from the wave to the medium.

The speed of sound and the density of various tissues in the human body are given in Table 2.3.

Table 2.3: Approximate densities and sound speeds in human tissues (Aristides, 2010).

Medium	Density (kg/m^3)	Speed of sound (m/s)
Air	1.2	333
Lung	0.40×10^3	650
Distilled water	1.00×10^3	1480
Blood	1.06×10^3	1566
Fat	0.92×10^3	1446
Kidney	1.04×10^3	1567
Liver , spleen	1.06×10^3	1566
Muscle	1.07×10^3	1542-1626
Bone	$1.38\text{-}1.81 \times 10^3$	2070-5350
Brain	1.03×10^3	1505-1612

●The acoustic resistance Z (Kg/ [m2.s]).

The electricity analogue has been used here, where pressure is equivalent to voltage and particle speed to current; the definition of the acoustic resistance is known as the proportion of the pressure at a specific point to the particle speed at the same point, which has units of Kg/ [m^2.s], occasionally called Ray1 (1 Ray1= 1 Kg/ [m^2.s]). The acoustic is a property of the medium and of the kind of wave that is propagated. Getting a wave with equal pressure at any normal surface to the propagation direction (plane normal), the acoustic resistance is:

$$Z = p_0\,c \qquad (2.9)$$

Where an ultrasound hits a tissue interface between two mediums and with different acoustic resistance Z1 and Z2, just some of the wave energy passes through. So the reflection coefficient to an incident wave normal to the boundary can be defined by using transmission line theory as shown below:

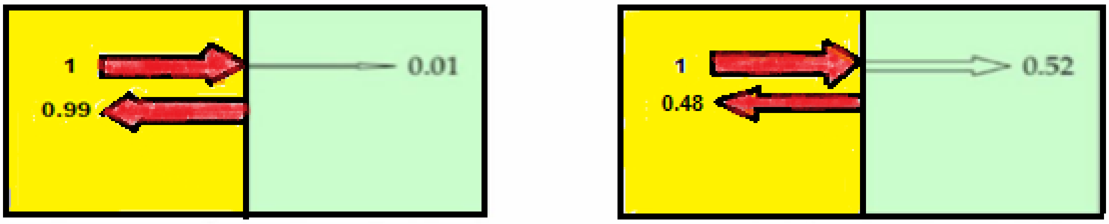
$$R_a = \frac{Z_2 - Z_1}{Z_2 + Z_1} \qquad (2.10)$$

And,

$$T_a = 1 - R_a \qquad (2.11)$$

If we look at the previous formula we note that the reflection coefficient is quite clear. As we can see in Figure 2.5, two of the most important interfaces inside the human body which transmit and reflect ultrasound are shown.

FAT/AIR INTERFACE MUSCLE/BONE INTERFACE



$Z_{fat} = 1.33\times10^6$ $Z_{air} = 0.4\times10^3$ $Z_{muscle} = 1.7\times10^6$ $Z_{bone} = 6\times10^6$

Figure 2.5: Reflection coefficient between two mediums, adapted from Aristides, 2010

Table 2.4 shows the values of density, propagation speed and acoustic resistance of some of the most important tissues in the human body.

Table 2.4: Values of density, propagation speed and acoustic resistance of human tissues (Aristides, 2010)

Medium	**Density (Kg/m^2)**	**Sound speed (m/s)**	**Acoustic Resistance**
Air	1.200E+00	3.330E+02	3.996E+02
Lung	4.000E+02	6.500E+02	6.500E+05
Distilled water	1.000E+03	1.480E+03	1.480E+06
Blood	1.060E+03	1.566E+03	1.660E+06
Fat	9.200E+02	1.446E+03	1.330E+06
Kidney	1.040E+03	1.567E+03	1.630E+06
Liver	1.060E+03	1.566E+03	1.660E+06
Spleen	1.060E+03	1.566E+03	1.660E+06
Muscle	1.070E+03	1.630E+03	1.744E+06
Bone	1.600E+03	3.050E+02	4.880E+06
Brain	1.030E+03	1.550E+03	1.597E+06

The first case is the fat/air interface, where 99% of the sound wave is backscattered, which makes it very difficult to imagine the heart that is placed behind the ribs. Because of these limitations, the medical effects of ultrasound were limited to soft tissue imaging, where the reflection coefficient is -10% to 10% (Aristides, 2010) (Panagiota, 2011).

● The attenuation A (dB / [MHz · cm]).

Attenuation is the second important property of the medium which strongly affects the medical implications of ultrasound. When the sound wave propagates inside any medium it will lose a part of its energy, and that phenomenon is called attenuation. Attenuation includes energy that is lost from both scattering of the sound wave and absorption. Absorption is a physical phenomenon where the energy of the sound wave is absorbed by the tissue and turned into heat, and it accounts for 75% of the total energy loss. The attenuation is dependent both on the medium and on the frequency of the propagating wave, and it increases linearly as the depth increases (Aristides, 2010; Panagiota, 2011).

The attenuation is given by:

$$A(f,r) = e^{-2\pi\beta f r}\left[\frac{dB}{MHz \cdot cm}\right] \qquad (2.12)$$

where (f) is the frequency of the wave and (r) is the distance of propagation of the wave in the medium. The attenuation has two units, which are N_p / (MHz · cm) or dB / (MHz · cm) where 1 dB / (MHz · cm) = 8,6859 N_p / (MHz · cm). The ultrasound attenuation values for human tissues are shown in Table 2.5.

Table 2.5: Approximate ultrasound attenuation values for human tissues (Aristides, 2010)

Tissue	Attenuation dB / (MHz · cm)
Liver	0.6 – 0.9
Kidney	0.8 – 1.0
Spleen	0.5 – 1.0
Fat	1.0 – 2.0
Blood	0.17 – 0.24
Plasma	0.01
Bone	16.0 – 23.0

2.3.4 The parts of an ultrasound machine

Ultrasonic systems are used to construct images of the human body because of the relation between the tissues of the body and ultrasound oscillation (Ahmadian, 2001). It is useful for imaging several parts of the body such as foetus, vascular system, heart, kidneys and liver. Figure 2.6 shows a typical medical ultrasound system.

Figure 2.6 A typical medical ultrasound system (Ahmadian, 2001)

A basic ultrasound machine has the following parts:

2.3.4.1 Transducer probe (TP)

The Transducer probe is a device that both sends and receives ultrasound waves. Inside the transducer unit, a scanner receives the reflected sound waves as they bounce off structures in the body. The active part of an ultrasound machine‘s transducer probe is the transducer. This device has the ability to convert energy from one form to another (Gill, 2012). Transducers are bidirectional as they convert electrical pulses into ultrasound and convert ultrasound echoes back into electrical signals. According to Haschek, Rousseaux and Wallig (2013), sounds are generated in the transducer by piezoelectric crystals that vibrate when exposed to electric currents.

Figure 2.7 Different typical transducers that are usually used in medical imaging

Figure 2.8 Different types of transducers (Freudenrich, 1998)

A transducer has 128 transducer elements to transmit and receive at any one time. Sound waves are focused into a beam and transmitted into the tissue as the transducer is held in contact with the surface of the subject's body. Transducers can be hand held or fixed on a grid system (Haschek et al., 2013). Large transducer bandwidth is necessary for images with high resolution (Gill, 2012). Figures 2.7 and 2.8 above show different typical transducers that are usually used in medical imaging.

2.3.4.2 Central processing unit (CPU)

The CPU is computer-like equipment containing the microprocessor, memory, amplifiers and power supplies for the microprocessor and transducer probe. It produces an image on the monitor after making calculations.

2.3.4.3 Transducer pulse controls (TPC)

The transducer pulse controls are used to produce and send ultrasound waves and detect backscattered ultrasound waves duration and changing frequency of ultrasound pulses. So that transducer is piezoelectric crystals which were designed to vibrate at particular frequencies. These frequencies are called the natural frequencies of the transducer. In medical applications, these frequencies are commonly 1 MHz to 30 MHz (Freudenrich, 1998).

By applying a short duration voltage pulse to the transducer, the ultrasound will be produced. Figure 2.9 shows a typical medical ultrasound imaging system.

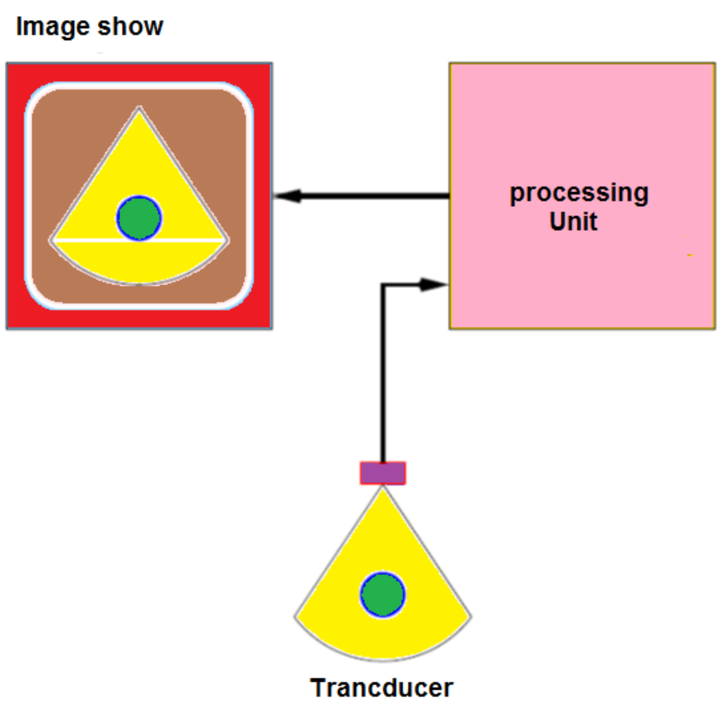


Figure 2.9: Scheme of a typical medical ultrasound imaging system

2.3.4.4 Display screen (DS)

The display screen converts information from the CPU into an image. Some models have coloured images while others have black and white.

2.3.4.5 Keyboard/cursor

Like computers, ultrasound machines have keyboards and cursors. These allow the user to add notes and make measurements of images.

2.3.4.6 Disk storage device (DSD)

Devices for storage of data in ultrasound machines include floppy disks, hard disks, compact disks and digital versatile disks. These store data from the machine.

2.3.4.7 Printer

Printers of ultrasound machines are used to print out images. Several ultrasound systems have printers which are usually thermal printers that can be used to capture a hard copy of the images from the display unit (see Figure 2.10).

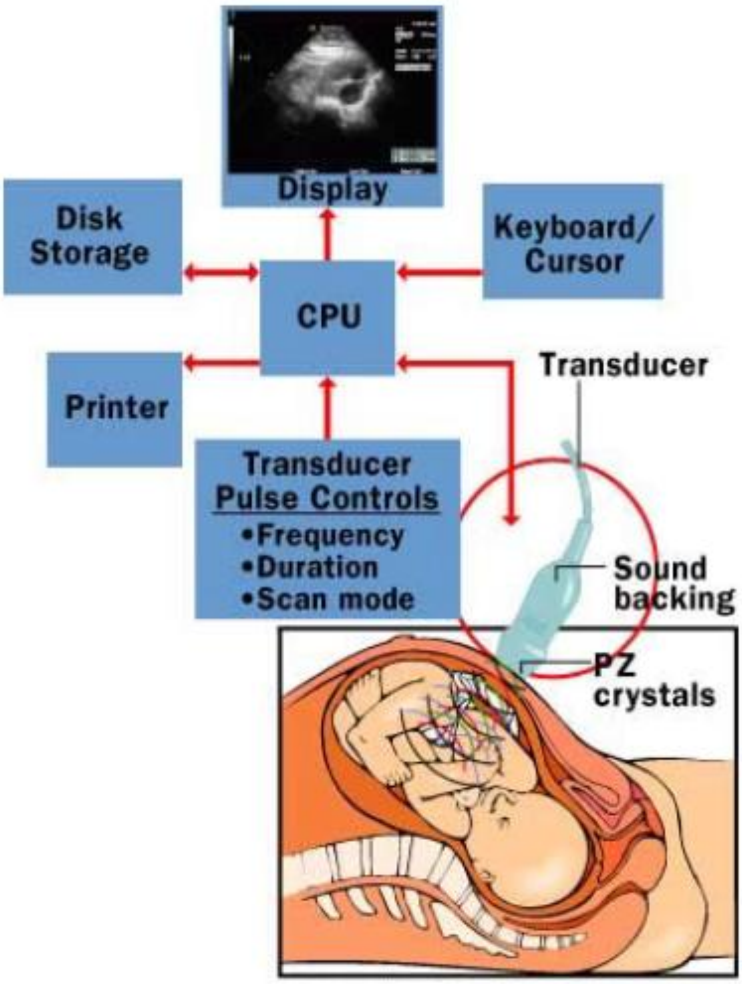


Figure 2.10: The parts of an ultrasound machine (Freudenrich, 1998)

2.4 The way ultrasound works

2.4.1 Piezoelectric crystals

Ultrasound transducers contain many piezoelectric crystals which are interconnected electronically and vibrate when an electric current is applied. According to Chan and Perlas (2011) the phenomenon called the piezoelectric effect was originally described by Jacques and Pierre Curie in 1880 when they subjected a cut piece of quartz to mechanical stress, so generating an electric charge on the surface. The Curie brothers discovered that the piezoelectric effect makes the transducers generate and detect ultrasound in air and water (Pollet, 2012). Chan and Perlas (2011) state that these sound waves, which mechanically vibrate, produce alternating areas of compression and rarefaction when propagating through body tissues. Sound waves can be described in terms of their frequency (measured in cycles per second or hertz), wavelength (measured in millimetres), and amplitude (measured in decibels).

A thin layer of a synthetic piezoelectric material is built to vibrate at a reverberating frequency in a required range. This is where the ultrasound comes from. As the pressure wave of a returning ‘echo’ hits the transducer surface, a voltage is recorded. The size of this voltage is related directly to the quantity of energy transmitted by the echo and will determine the brightness level stored from this location and displayed on the monitor (see Figure 2.11). This construction of sensitive crystal elements must be handled carefully (BMUS, 2011:44-49).

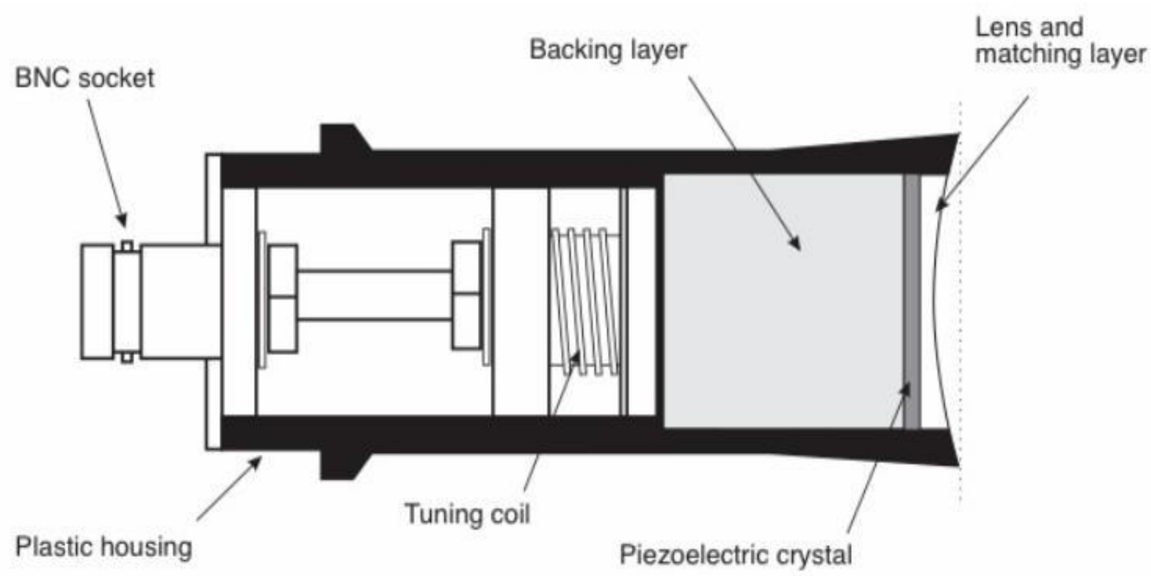


Figure 2.11: Piezoelectric crystals in typical transducer (Panagiota, 2011)

2.4.2 Performance of ultrasound machines

Freudenrich (1998) describes, in six points, how ultrasound machines generally perform. Below are the stated points.

A. The transducer probe is the device that transmits sound pulses of frequencies as high as 1 to 5 MHz into the body.
B. The high frequency sound waves penetrate through the body and reach a boundary between tissues such as between fluid and soft tissue, or soft tissue and bone.
C. The common occurrence is that some sound waves are reflected back to the probe and others penetrate further, reaching another boundary and reflecting back.
D. The transducer probe receives the waves that bounce back and transmits them to the central processing unit.
E. The central processing unit then calculates the distance between the transducer probe and the tissue or organ by utilizing the speed of sound in the tissue and the time taken for each echo to return.
F. The display screen then converts that information from the central processing unit into a two-dimensional image like the one shown in Figure 2.12 below.
The probe can be shifted along the surface of the body and angled to acquire several views.

Figure 2.12: Ultrasound image of my baby's foetus (16 weeks)

2.5 Producing ultrasound images

According to the British Medical Ultrasound Society Safety Group [BMUS] (2011:44-49), diagnostic ultrasound utilizes the pulse-echo principle to construct a two-dimensional image of anatomical structures. This is essentially similar to what bats use to snatch insects through echo-location. A pulse of sound leaving the transducer travels into the patient until it encounters an 'acoustic' interface. A proportion of the sound energy redirects to the transducer and this return echo is detected (Figures 2.13 and 2.14). If the speed of sound is known and the time taken for the echo to return is measured, the depth of the reflecting interface can be calculated.

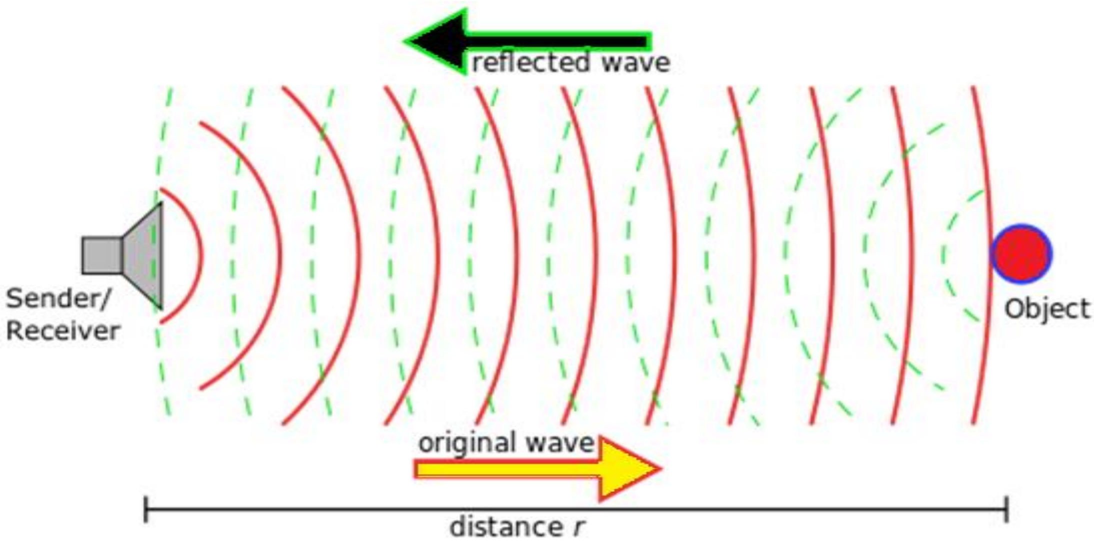


Figure 2.13: The transmitted and reflected wave

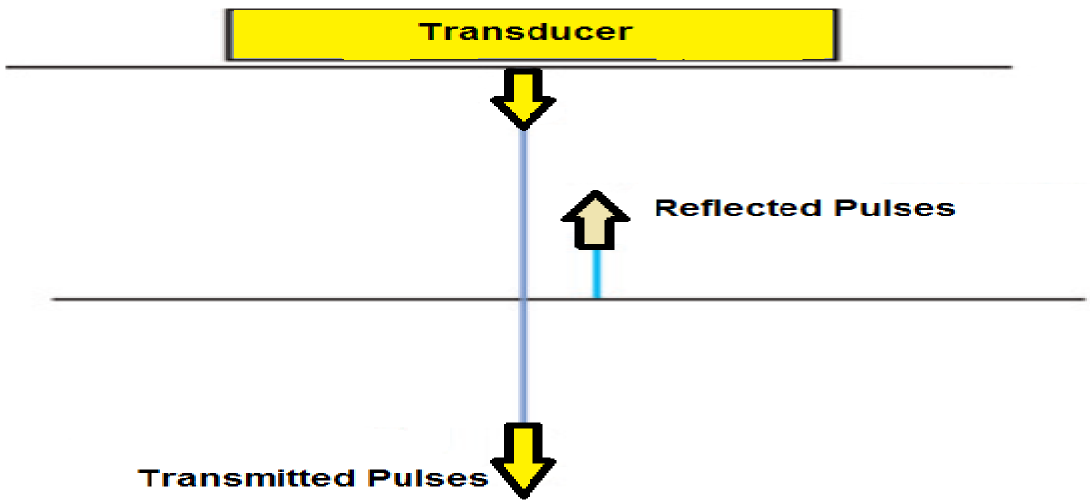


Figure 2.14: Calculating the depth of the reflecting interface by using time taken for echo to return at the speed of sound

2.5.1 Transmission and reflection-based ultrasound

The ultrasonic system provides an image to the users by calculating the change in an ultrasound wave when it spreads through the body. The ultrasound system can calculate the propagation of the ultrasound wave in a medium by two methods:

Transmission: The image is created according to the amount of wave that is transmitted through the body.

Reflection: The production of an image is structured by reflected waves from different parts of the body.

2.5.1.1 Transmission ultrasound imaging

Every part of the body absorbs a certain amount of ultrasound wave energy. The transmission ultrasound imaging system (TUIS) uses this principle and measures the amount of wave happening to the receiver to produce an image as shown in Figure 2.15 (Sanei, 1998; Ermert et al., 2000).

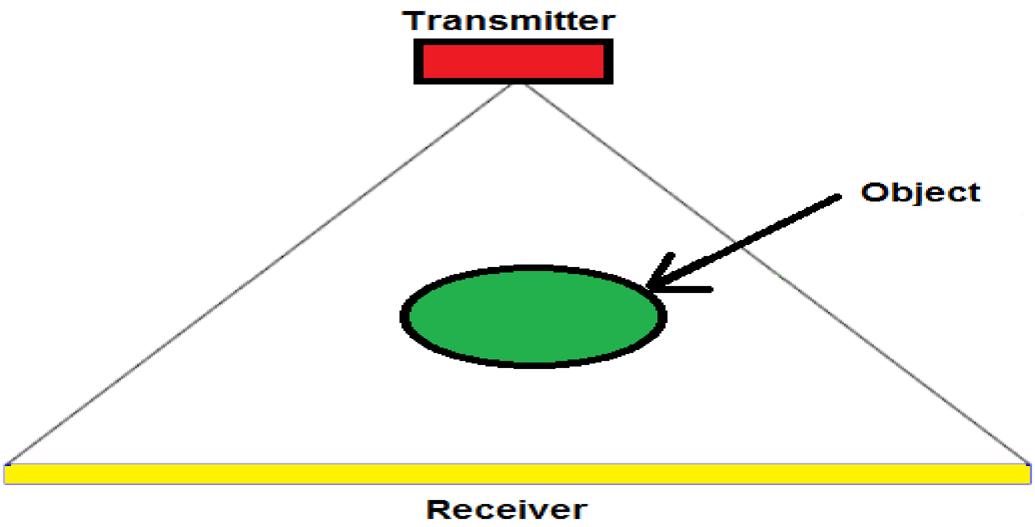


Figure 2.15: Simplified transmission ultrasound system.

2.5.1.2 Reflective ultrasound imaging

The speed of an ultrasound wave is different between one part and another in the body. That means, when an ultrasound wave arrives at the interface of two parts of the body, a little part of the incident energy will be reflected back. The magnitude of the reflected ultrasound relies on the relative resistance of the two parts of the body (Ahmadian, 2001). The magnitude is calculated by using the following formula:

$$A_{reflected} = \left|\frac{Z_2 - Z_1}{Z_1 + Z_2}\right| \times |A_{\text{incident}}| \tag{2.13}$$

where Z_2 is the resistance of the body part that the sound is trying to go through.

Z_1 is the resistance of the medium through which the sound wave is trying to go back. In Figure 2.16 (a-b) the simple way of the reflective ultrasound system is shown.

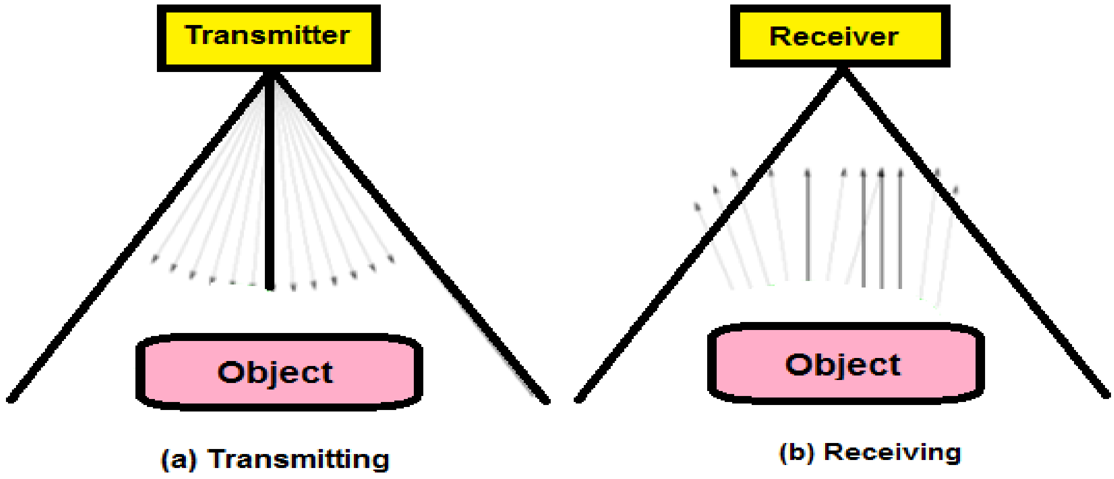


Figure 2.16: A simple diagram of the reflective ultrasound system, adapted from Ahmadian, 2001

2.6 The law of reflection and refraction

2.6.1 The law of reflection

The definition of the law of reflection is that the reflected and incident waves are in a plane and the angles of incidence and reflection are the same (see Figure 2.17) (Ahmadian, 2001):

$$\Theta_1 = \Theta_3 \qquad (2.14)$$

Where $\boldsymbol{\Theta_1}$ is the incident angle and $\boldsymbol{\Theta_3}$ is the reflection angle.

2.6.2 The law of refraction

The definition of the law of refraction is that the refracted and incident waves are in a plane and the angles of incidence and reflection are related to each other by the following equation:

$$n_1 \sin \Theta_1 = n_2 \sin \Theta_2 \qquad (2.15)$$

where $\boldsymbol{\Theta_1}$ is the incident angle and $\boldsymbol{\Theta_2}$ is the refraction angle (see Figure 2.14).

$\boldsymbol{n_1}$ is a dimensionless constant called the index of refraction for medium 1.

n_2 is the index for refraction of medium 2.

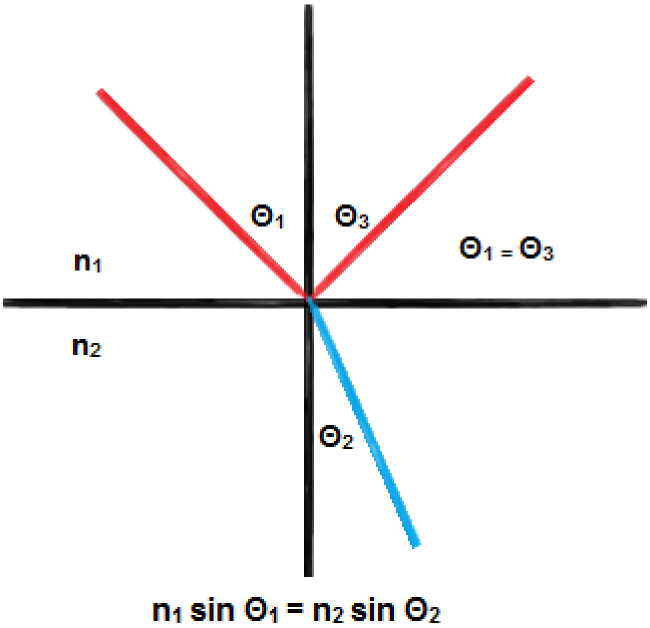


Figure 2.17: The law of reflection and refraction.

The indicator of refraction for the medium relies on the velocity of the wave in the medium. It is especially calculated according to the wave speed in a reference medium. There is no reference medium for electromagnetic waves and it will be the air for sound (as long as the reference medium is the same for calculating both the **n_1** and **n_2** so **it** does not matter which medium it is). Assuming the velocity of a wave in the medium is (v) and the velocity of a wave in the reference medium is (c), then the index of refraction can be calculated as follows (Ahmadian, 2001):

$$n = \frac{c}{v} \tag{2.16}$$

By replacing the value of the refractive index from this equation to equation (2.15), the formula will be as follows:

$$n_1 \sin \Theta_1 = n_2 \sin \Theta_2$$

$$\frac{c}{v_1} \sin \Theta_1 = \frac{c}{v_2} \sin \Theta_2$$

$$\frac{1}{v_1} \sin \Theta_1 = \frac{1}{v_2} \sin \Theta_2$$

$$v_2 \sin \Theta_1 = v_1 \sin \Theta_2 \tag{2.17}$$

2.6.3 Total reflection

By referring to the formula 2.14 we will see the relationship between incident angle and refraction angle. One may try to find the refraction angle and rewrite this equation as follows:

$v_2 \sin \Theta_1 = v_1 \sin \Theta_2$

$\sin \Theta_2 = \frac{v_2 \sin \Theta 1}{v_1}$

$\sin \Theta_2 = \frac{v_2}{v_1} \sin \Theta_1$

$$\Theta_2 = \sin^{-1} \left(\frac{v_2}{v_1} \sin \theta_1\right) \qquad (2.18)$$

By looking to the formula (2.15), Θ_2 does not have any value except if $\frac{v_2}{v_1} \sin \Theta_1$ is between -1 and 1. Whether that value of $\frac{v_2}{v_1} \sin \Theta_1$ is greater than 1 or less than -1, then there will not be any refracted wave and all of the wave will be reflected back. The lower angle that total reflection occurs at can be calculated as follows (Ahmadian, 2001):

$\left|\frac{v_2}{v_1} \sin \Theta_1\right| \leq 1$

$\frac{v_2}{v_1} |\sin \Theta_1| \leq 1$

$$|\sin \Theta_1| \leq \frac{v_1}{v_2} \qquad (2.19)$$

That means the velocity of the wave (v) is always a positive value so $\frac{v_2}{v_1}$ and $\frac{v_1}{v_2}$ will be positive values too.

2.7 Constructing the image

BMUS (2011:44-49) states that each pulse of sound transmitted into the individual produces a stream of returning echoes from multiple reflecting and scattering targets at several depths in the tissue. The mechanical energy carried by each echo is transformed into electrical energy by the piezoelectric crystals within the transducer. These values are then stored in the ultrasound machine's computer memory as a single 'scan line' of data. The voltage values are used to determine the brightness levels allocated to points in a vertical line on the image to represent the interfaces at corresponding depths in the patient. By firing pulses of sound in sequence from multiple adjacent crystals across the face of the transducer, numerous contiguous scan lines can be generated and a single brightness mode (B-mode) 'frame' of information produced to represent a two-dimensional anatomical cross-section (BMUS, 2011:44-49).

2.8 Types of ultrasound devices

Many different types of diagnostic ultrasound devices are commonly used. These include the two-dimensional ultrasound, the three-dimensional ultrasound, the four-dimensional ultrasound and the Doppler ultrasound. The basic difference between the devices and tests is the type of transducer that is used.

2.8.1 A-mode

A-mode (amplitude mode) is considered the simplest kind of ultrasound device, and the simplest mode to display the ultrasound data which is helping the users to understand all other modes of ultrasound (Ahmadian, 2001). In this kind of ultrasound unit, the echoes appear like peaks. It is a one-dimensional (1-D) technique and has limited applicability. The echoes are shown on the screen in the form of a graph and plotted as a function of depth by only one transducer, which scans a beam inside the body of the patient. Therefore the distances between the different structures can be measured. It is usually used in scanning eyes (Bowra & Mclaughlin, 2006; Longe, 2002). Figures 2.18 and 2.19 show a sample A-mode display.

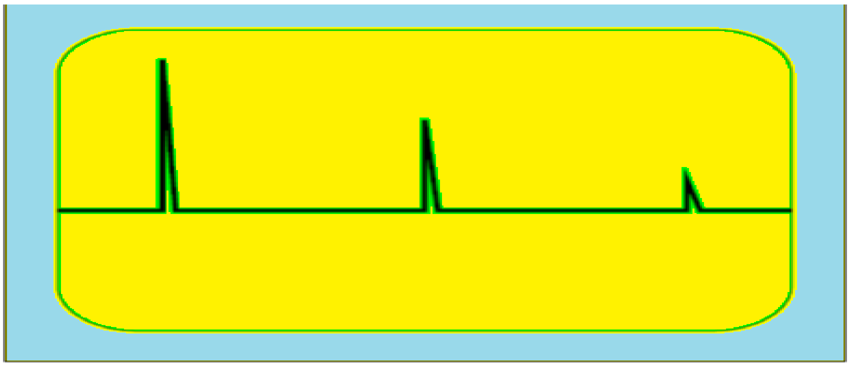


Figure 2.18: Specimen of A-mode display.

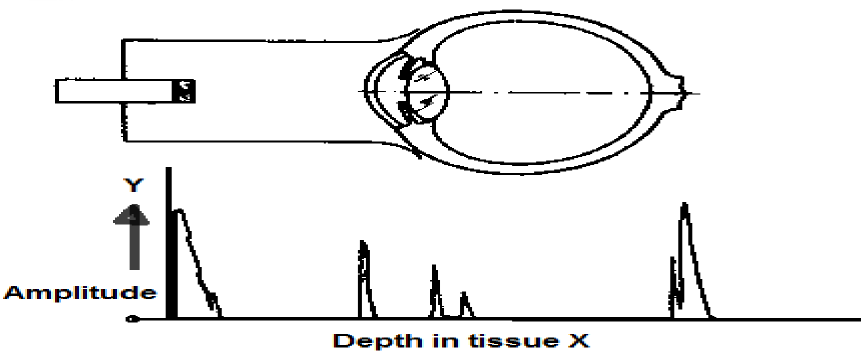


Figure 2.19: Diagram of an A-mode display (Panagiota, 2011)

2.8.2 M-mode

This is another way of displaying movement (motion mode). In this mode of ultrasound transmission, the pulses are sent in quick succession by the probe and the scrolling in this mode can be horizontal and vertical. Over time, scans will be recorded to describe movement, such as the movement of heart valves. These kinds of devices are commonly used in echocardiography (Bowra & McLaughlin, 2006; Longe, 2002). The frame average for this kind of scan is very high, for example, 600 frames per second (fps) (MeDicken, 1991). See figures 2.20 and 2.21.

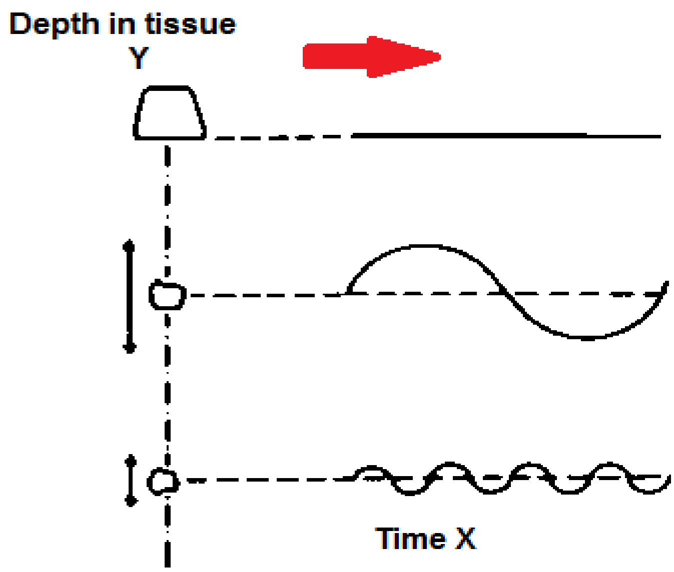


Figure 2.20: Diagram of an M-mode display (Panagiota, 2011).

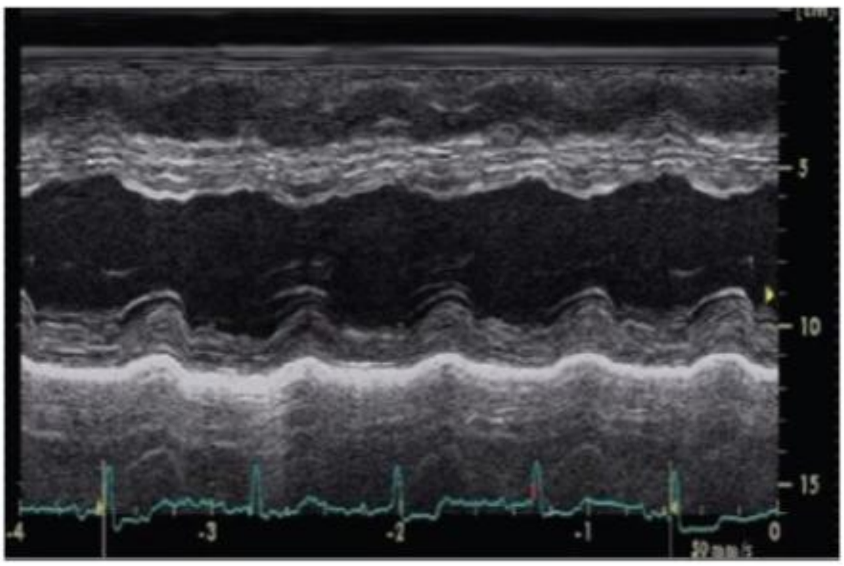


Figure 2.21: A sample M-mode display (Ahmadian, 2001).

2.8.3 B-mode or two-dimensional ultrasound (2DUS)

In the 1980s a real revolution happened in the world of ultrasound. It is called the Real time scanner, which means live imaging (two-dimensional or B-Mode), by which the life of the actual foetus could be identified, including movements, actions, heartbeat and breathing in the mother's womb. The first effective device in this field was in 1985 in Germany (Hazem, 2006). Figures 2.22 and 2.23 show an image and representation of B-Mode.

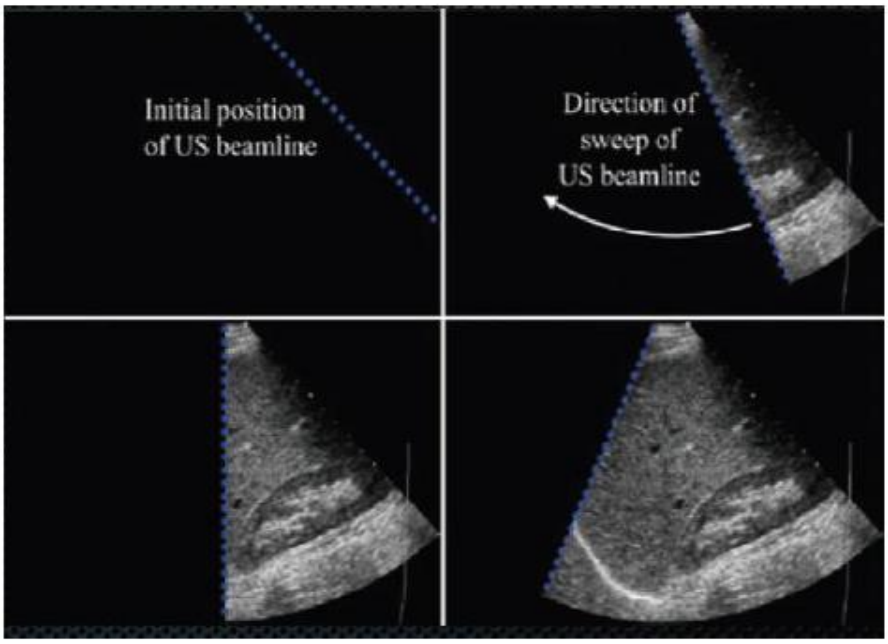


Figure 2.22: A sample B-mode display (Ahmadian, 2001).

Figure 2.23: Two-dimensional (2D) my baby ultrasound image–week 25

2.8.4 Three-dimensional ultrasound (3DUS)

When we talk about 3D, we mean that depth is shown but not that movement is shown. 3D needs a therapist effort to rotate the captured image to take the third dimension, and this takes some time as is shown in Figures 2.24 and 2.25.

Figure 2.24: Three-dimensional (3D) image (width and depth and height).

Figure 2.25: Three-dimensional (3D) images (Ahmadian, 2001)

The first to develop this technique was Olaf von Ram and Stephen Smith at Duke University in 1987. The only dissimilarity between 3D and 2D ultrasound is that in 3D, the waves are emitted from many angles and reflected waves are processed then by sophisticated computer programs resulting in a composite image with size 3D for members of the foetus on the screen. Three-dimensional imaging allows a person to see the width and length and height of images in the same way as 3D movies, but without movement. This technique allows for visualization of the foetal physiognomy with amazing accuracy (Hofer, 2005). A person can observe the depth in the images and see more details, which makes it more impressive and clearer than the conventional 2D (Hofer, 2005). In three-dimensional imaging, the specialist passes the probe device over the mother's womb just like 2D imaging, but the computer will take multiple images which are produced in 3D on the screen. Because the resulting images are in 3D, it is possible to detect any defect in the face, such as cleft lip, and in any other part of the body (Layyous, 2013). According to Hofer (2005), the three-dimensional visualization of foetal facial features improves the diagnosis of malformations.

According to Sheiner, Hackmon, Shoham-Vardi, Pombar, Hussey, Strassner and Abramowicz, (2007, 29:326-328), three-dimensional (3D) ultrasound is gaining popularity in prenatal diagnosis and non-medical facilities, for non-diagnostic purposes. 3D has been used for diagnostic purposes in the foetus. Guindi, Dreyfus, Carles, Lambert, Herlicoviez and Benoist (2013) investigated the value of 3D ultrasound in the prenatal assessment of fetal cardiovascular anomalies through offline diagnosis and/or second opinion. They found that 3D ultrasound is very useful for the prenatal diagnosis and management of congenital heart diseases.

2.8.5 Four-dimensional ultrasound (4DUS)

4D symbolizes the shortcut to the four-dimensional imaging. The fourth dimension is time (Olivia, 2011). It is the latest technology in ultrasound. Often 4D is referred to as 3D + T, or real-time 3D, or RT3D, to explicitly separate the time-varying component from the spatial dimensions (Spekowius & Wendler, 2006). These authors further state that 4D ultrasound allows for a richer description of pathology that can often be lost with traditional two-dimensional (2D + T) imaging.

This type of imaging is helpful in the diagnosis and detection of structural defects in the foetus, such as contortions and other abnormalities of the hands, legs and spine. Four-dimensional imaging technology (4DIT) assists health practitioners also in establishing the age of the foetus, foetal development, and the evaluation of multiple pregnancy and high risk pregnancy. Ultrasound has been proven to help in the tests used to detect polyps in the lining of the uterus, and uterine fibroids and ovarian tumours (Layyous, 2013).

Figure 2.26: Four-dimensional (4D) scan with movement (Layyous, 2013).

2.8.6 Doppler ultrasound

The Doppler Effect upon which Doppler ultrasound is based is named after Christian Johann Doppler, who first described it in 1842 (Sohn, Voigt & Vetter, 2004). It states that the frequency heard by the ear depends on whether a noise is moving toward or away from the observer. From the difference in the frequency between them we can calculate the speed of these organs accurately such as the speed of blood flow from the heart to the blood vessels and arteries as is shown in Figure 2.27 (Hazem, 2006).

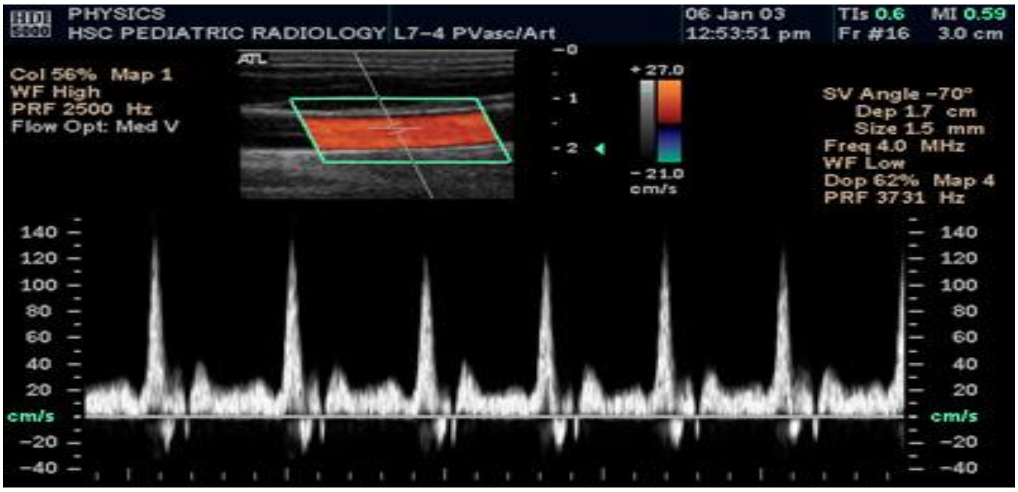


Figure 2.27: Medical spectral Doppler of common carotid artery

According to Sohn, Voigt & Vetter (2004), the Doppler Effect is utilized in diagnostic medical procedures to measure the velocity of blood flow in blood vessels. It is possible to improve the image of waves by using Doppler effects, which is used to study the flow of the blood in blood vessels, so it is useful to use it in cardiovascular studies. Doppler ultrasound is used usually in the second half of pregnancy for suspected intrauterine growth restriction, pregnancy-induced hypertension, intrauterine death, preeclampsia, abnormalities in foetal heart rate, and suspicion of a cardiac condition (Sohn et al., 2004).

2.9 Use of ultrasound

Ultrasound has been used in lots of different areas (Huntsville, 2003). Ultrasound devices have been used to detect objects and measure distances. Some animals use ultrasound to locate prey and obstacles, such as bats and porpoises (Novelline and Squire, 1997). Ultrasonic imaging technology is used in human and veterinary medicine. The Canadian Guidelines for the Safe Use of Diagnostic Ultrasound (2001) stipulate that the use of diagnostic ultrasound to obtain information about function or structure in human beings should be restricted to situations in which the medical benefit that may accrue from the diagnostic data outweighs any foreseeable risk. Most such situations are limited to clinical examinations of the ill or potentially ill patient, or pregnant women.

2.10 Production of waves

Scientists have invented whistles and other devices to produce ultrasound. A waves adapter which converts electrical energy into ultrasound is considered one of the most commonly used devices. Some of these converters include a special disk of material, quartz or ceramic material, and when you shed an electrical signal on the disk it will vibrate at high speed, causing ultrasound (Hasri, 2012).

Many of the converters can turn ultrasound into electrical energy. Such transformers produce ultrasound and at the same time turn the echoes into electrical signals. The strong echoes make electrical impulses which are stronger than those caused by the weak echoes. The computer can register data of intensity of electrical impulses and counter-trend echoes. The computer can then provide us with information about the material that reflected ultrasound. Some of these computers convert data received by the image on the screen (Hasri, 2012).

Generators of modern ultrasound generate waves with a frequency of a few GHz (1GHz = 10^9 Hz) by converting high-frequency alternating currents into mechanical vibrations. Detection of these waves are usually done using piezoelectric crystals or by means of light, where one can benefit from the diffraction of light to make these visible waves. Figure (2.28) shows a valve based electronic circuit used to detect ultrasound. The crystallization synthesized piezo device (Q) is sensitive to the frequency of vibration of ultrasonic waves that it is required to detect , which is connected to the circuit of the Triode electrodes (Hasri, 2012).

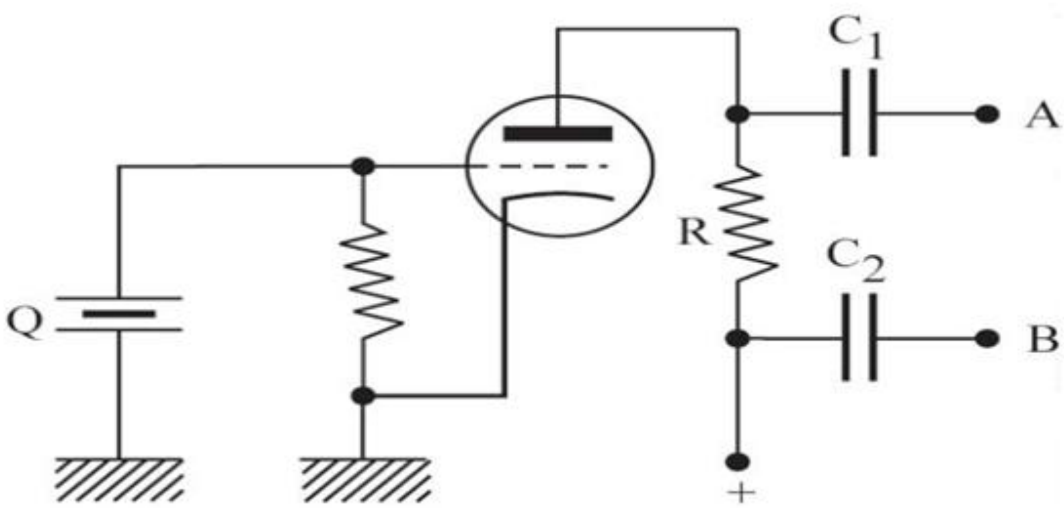


Figure 2.28: Electronic circuit to capture ultrasound (Hasri, 2012)

2.11 The working principle of the circuit

The piezo detector picks up ultrasound and turns it into electrical vibrations, the transistors Q1 and Q2 will amplify these electrical signals, and then it will move on to the integrated circuit U1 circuit through pin 14. The integrated circuit will compare the phase between the captured signal and the signal generated by the IC, which can control its frequency by breaker latency R9. The circuit will give a frequency equal to the difference between the captured frequency and the generated frequency at pin 2. The transistor Q3 will amplify the differential of the signal, and the signal will be transmitted through the transformer T1 to the headsets as audible frequency (Hasri, 2012). This is shown in Figure 2.29.

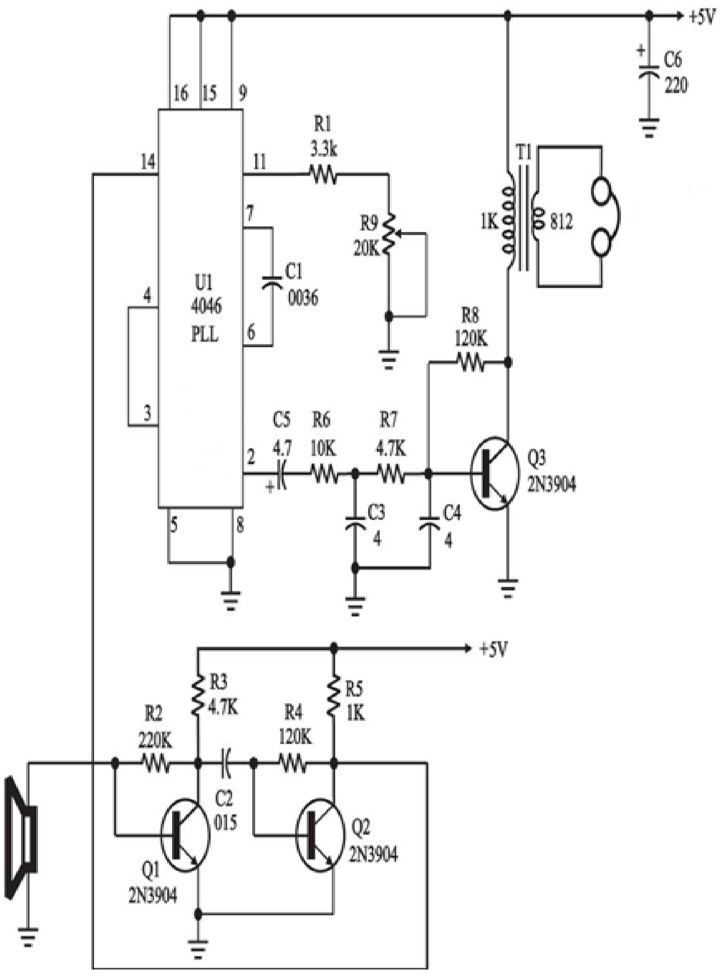


Figure: 2.29 Modern electronic circuit to capture ultrasound and convert it into audible sound waves (Hasri, 2012)

2.12 Summary

This chapter provides an overview of the physics of ultrasound. Characteristics and applications of ultrasound imaging technology are discussed. The laws of reflection and refraction, constructing the image, types of ultrasound, production of waves, and using of ultrasound are provided.

CHAPTER THREE

ACOUSTIC OUTPUT INDICES AND ITS BIOEFFECTS

3.1 Introduction

While ultrasound (US) is supposed to be totally safe, it is a form of energy. Diagnostic ultrasound (DUS) has the prospect of effects on living tissues it crosses, such as bio-effects. The two most important mechanisms for effects are thermal and non-thermal, also called mechanical. These two main mechanisms are indicated on screen by two indices: the thermal index (TI) and the mechanical index (MI), to express the potential for a rise in temperature at the ultrasound's focal point and the probability of harm from the mechanical effects such as cavitation. It is important to understand bio-effects of acoustic output during ultrasound scanning in obstetrics. This study identifies the need for users of ultrasound to understand thermal and mechanical indices appearing on ultrasound screens. Some users do not use the indices and others do not know or are unaware of their importance.

3.2 Acoustic safety and exposure control

Before 1976, there were no specific values for acoustic output of diagnostic ultrasound equipment (Nelson et al., 2009:139-150). In 1976, the US Food and Drug Administration (FDA) started regulating medical devices, including ultrasound to be no more than 94 mW/cm^2 (Sheiner et al., 2005:1665-1670), and finally, it put in place four (4) application-specific exposure limits (peripheral vascular, 720 mW/cm^2; cardiac, 430 mW/cm^2; fetal and others, 94 mW/cm^2; and ophthalmic, 17 mW/cm^2) (AIUM, 2004: 723-726). This level of output was set according to the medical devices used in the market, and the clear safety of ultrasound at the time (Nelson et al., 2009:139-150).

Several epidemiological studies conducted in the 1980s and 1990s, searched evidence of a range of possible effects on the foetus due to exposure to diagnostic ultrasound (BMUS, 2010:110-118). Until 1992, the FDA instructions were based on maximum allowable values of the intensity levels of ultrasound, which was dependent on the application. These included lower values allowing for exposure to the most delicate tissues. From 1992, manufacturers were presented two paths for approval (BMUS, 2010:110-118). Track 1 (Table 3.1) was equivalent to control levels of the value of each application. It is worth mentioning, that some of the mechanical effects have been described in animals with exposure more than the upper limit (MI=1.9) imposed by the FDA (Dalecki, 2004:229-248).

Table 3.1 FDA Track 1 maximum permitted values of intensity and MI

Application	ISPTA (mW/cm2)	MI
Peripheral vascular	720	1.9
Cardiac	430	1.9
Fetal and other	94	1.9
Ophthalmic	17	0.23

Spatial peak temporal average intensity (I_{SPTA}) is the time averaged value of Intensity, measured at the point in the ultrasound field where it is at its maximum.

In 1991, there were noticeable changes in the regulations concerning allowable upper limits of the acoustic output levels (AOL) of diagnostic ultrasound to be 720 mW/cm^2 for all applications (including obstetrical, i.e. an increase of a factor of almost 8); this was except for ophthalmic application, which was set at 50 mW/cm^2 (Jacques 2008:17:22). Track 2 (Table 3.2) allowed manufacturers to use the highest output levels, in return for providing an on-screen display of thermal (TI) and mechanical (MI) safety indices (BMUS, 2010:110-118).

Table 3.2 FDA Track 3 maximum permitted values of intensity, MI and TI

Application	$\mathbf{I_{SPTA}}$ (mW/cm2)	MI	TI
All applications except Ophthalmic	720	1.9	6.0
Ophthalmic	50	0.23	1.0

FDA, Food and Drug Administration; MI, mechanical index; TI, thermal index; I_{SPTA}, Spatial peak temporal average intensity

Since 1992, ultrasound devices have the ability to work with acoustic outputs of up to 720 mW/cm^2 with a specific acoustic output under full control and direction of the operator and with the expectations that techniques that are As Low As Reasonably Achievable (ALARA) will be used. Implementation of the output display standard (ODS) puts responsibility for the safety of the patient and compliance with the principle of ALARA fully on the users of ultrasound (Nelson et al., 2009:139-150).

3.3. Diagnostic ultrasound (DUS)

According to Sheiner, Shoham-Vardi and Abramowicz (2007) diagnostic ultrasound is widely used in obstetrics and is perceived as risk-free. It is also used for various therapeutic medical applications including sonophoresis (ultrasonic transdermal drug delivery), dentistry, eye surgery, body contouring, breaking kidney stones and eliminating blood clots (Ahmadi et al., 2012).

3.4 Acoustic output indices (AOI)

Diagnostic ultrasound (DUS) is an imaging modality that is useful in a wide range of clinical applications, and in particular, prenatal diagnosis (BMUS, 2010). It is considered very safe for a foetus (Abramowicz, 2002; Hershkovitz et al., 2002). However, data regarding effects on living tissues, e.g. bio-effects, are still inconclusive (Hagi & Khafaji, 2013; Cavicchi & O'Brien, 1984; Child et al., 1990). As a form of energy, ultrasound has the probability to have bio effects that cause damage on living tissues if used incorrectly. The two most probable mechanisms for these are heating and cavitation (AIUM, 2000; Abramowicz, 2002; NCRP, 2002; AIUM, 2009).

The cavitation mechanism includes the existence of gaseous bubbles in an air-water interface (Herskovits et al., 2002). The vibration of bubbles is caused by ultrasound waves through alternation of positive and negative pressures. However, it has not been documented in mammalian foetuses, since there is not air-water interface, which is needed for the cavitation mechanism (Nyborg, 1965).

The normal temperature of human body is commonly considered to be 37˚Celcius (±0.5 -1˚C). Temperature in the human foetus is higher than body temperature of the mother by 0.3 to 0.5 ˚C during the complete pregnancy but in the third trimester temperature of the foetus is higher by 0.5 ˚C than its mother (O'Brien, 1992). These mechanisms are referred to on the screen of the device by two of the indicators: The thermal index (TI) and the non-thermal index called also the mechanical index (MI) (Jacques, 2008). The output display standard (ODS) consists of two indicators MI and TI (Nelson et al., 2009).

● The two most important indicators of acoustic output are:

3.4.1 Thermal index (TI)

The thermal index (TI) shows the probability of temperature increase along the ultrasound beam (Sheiner et al., 2007; AIUM Technical Bulletin, 2004). It is the ratio of the total acoustic energy to the energy required to raise the temperature of the tissues by 1 °C (Sheiner et al., 2005: 1665-1670). It is assumed that with modern ultrasonic devices, there is no rise in temperature; usually only a small rise which does not exceed (Abramowicz et al., 2000:594-596). Manufacturers are required to display MI and TI on the screen (Jacques, 2008:17-21).

The thermal index (TI) can be calculated as 'the ratio of current acoustic power output from the transducer (W) to the power required to cause a maximum tissue temperature rise of 1 °C (W_{deg}) by the following formula' (BMUS, 2010:110-118).

$$TI = \frac{W}{Wdeg} \quad (3.1)$$

The AIUM Technical Bulletin (2004), states that there are three specific thermal indices: the soft tissue thermal index (TIS), the bone thermal index (TIB) and the cranial bone thermal index (TIC). The TIS is used to provide data on increase in temperature in homogeneous soft tissue, the TIB provides data on increase in temperature in bones at or near the focus of the beam, and the TIC provides data on increase in temperature at or near the surface, such as during a cranial exam.

The TIS, TIB and TIC are measured and calculated by using many different thermal models according to three conditions of the beam, firstly whether the beam is scanned, for instance B-mode and Colour Doppler. Secondly whether the beam is un-scanned for instance M-mode and Pulsed Doppler. Thirdly whether the effective beam aperture is greater or less than 1 cm^2.

TI in the simplest thermal model is given by the equation:

$$TI = \frac{\mathrm{Wf}}{210} \quad (3.2)$$

Where (W) is the acoustic power from the transducer, measured through a 1 cm aperture and (f) is the frequency (BMUS, 2010:110–118). This model applies to both TIS and TIB for scanned modes and TIS for non-scanned modes where the aperture is < 1 cm2.

In un-scanned modes, TIB is given by the formula:

$$\mathrm{TIB} = \min\left[\frac{\sqrt{\mathrm{WITA}}}{50}, \frac{W}{4.4}\right] \quad (3.3)$$

Here, (W) and (I_{TA}) are the acoustic power and temporal average intensity according to the depth of the bone surface. The two terms in the bracket are calculated and that which gives the minimum value is used (BMUS, 2010:110–118).

In 1992, the National Electrical Manufacturers Association (NEMA) and the American Institute of Ultrasound in Medicine (AIUM) established a voluntary standard which is termed the output display standard (ODS). This was intended to be used for on-screen labelling of diagnostic ultrasound devices (AIUM Technical Bulletin, 2004). The bulletin states that higher acoustic output ultrasound systems using the ODS have been on the market since 1993. End users are able to keep the patient exposure to as low as possible, while retaining high image quality (the ALARA principle, as low as reasonably achievable). The above can be accomplished by using the information displayed on the screen in the form of biologically relevant exposure indices: the TI and the MI devices (AIUM Technical Bulletin, 2004). Harm free use of these devices can be accomplished only through the end users' knowledge and the application of the ALARA principle (AIUM Technical Bulletin, 2004).

3.4.2 Mechanical index (MI)

The mechanical index (MI) shows the probability of the ultrasound producing cavitation in tissues in the presence of gaseous bubbles in an air-water interface (O'Brien & Siddiqi, 2001; Abramowicz, Kossoff, Marsal & Ter- Haar, 2000). It is therefore displayed in B-mode imaging (Holland et al., 1996: 917-925). It also expresses the possibility of ultrasound inducing tissue cavitation (O'Brien & Siddiqi 2001:29–48).

Its value is permanently updated by the operator, according to the control settings, using the formula:

$$MI = \frac{P-0.3}{\sqrt{f}} \qquad (3.4)$$

Where (f) is the Pulse Centre frequency and (P-0.3) is the maximum value of peak negative pressure anywhere in the ultrasound field (BMUS, 2010: 110-118).

According to Sheiner, Shoham-Vardi and Abramowicz (2007:319-325), cavitation can be either back-and-forth movements of bubbles (stable cavitation) or growth and implosive collapse of these bubbles (inertial or transient cavitation). According to the AIUM Technical Bulletin (2004), the MI can range up to 1.9 for all uses except ophthalmic, which has a maximum MI limit of 0.23. The index levels do not indicate that a biological effect is actually happening, but only informs users regarding the possibility of a biological effect. This is the reason it is vital to implement the ALARA principle, using the smallest possible TI and MI values, while keeping the quality of the scan as high as possible (AIUM Technical Bulletin, 2004).

The power outputs of clinical devices have been rising, so the potential for thermal and non-thermal damage may be greater (Sheiner et al., 2007:319-325). In addition, to increase diagnostic capabilities of clinical ultrasound, the outputs of machines for foetal applications have been increased (Sheiner et al., 2007:319-325).

3.5 Bio-effects of ultrasound

3.5.1 Introduction

According to Szabo (2004), clinical uses of ultrasound are known to have the potential to create two major types of bio-effects: heating and cavitation. Although there is no conclusive evidence of the harm of ultrasound in humans, regulatory bodies advise on users using precautionary measures in routine ultrasonography (Joy et al., 2006). It is suggested that ultrasound can heat tissues as during propagation, energy is lost to absorption (Szabo, 2004). The energy is converted to heat. Szabo (2004) further stipulates that the direct contact of the transducer creates the direct transfer of heat by conduction. A conglomeration of multiple factors causes safety thresholds to be exceeded and can lead to harmful thermal and mechanical bio-effects.

Miller (2008) reported on safety assurance in obstetrical ultrasound. He reports that safety assurance for diagnostic ultrasound in obstetrics began with a tacit assumption of safety allowed by an American federal law enacted in 1976 for then-existing medical ultrasound equipment. The implementation of the 510(k) pre-market-approval process for diagnostic ultrasound resulted in the establishment of guideline upper limits for several examination categories in 1985 (Miller, 2008). The author further states that obstetrical category has undergone substantial evolution from initial limits (i.e, 46 mW/cm2 spatial peak temporal average [SPTA] intensity) set in 1985.

Thermal and mechanical exposure indices, which are displayed onscreen according to an Output Display Standard, were developed for safety assurance with relaxed upper limits. In 1992, with the adoption of the output display standard, the allowable output for obstetrical ultrasound was increased in terms of both the average exposure and the peak exposure. Miller (2008) further states that there has been little or no subsequent research with the modern obstetrical ultrasound machines to systematically assess potential risks to the foetus using either relevant animal models of obstetrical exposure or human epidemiology studies. Miller concludes that there is no specific reason to suspect that there is any significant health risk to the foetus or mother from exposure to diagnostic ultrasound in obstetrics. This assurance of safety supports the prudent use of diagnostic ultrasound in obstetrics by trained professionals for any medically indicated examination (Miller, 2008).

3.5.2 Thermal bio-effects

According to Abramowicz, Barnett, Duck, Edmonds, Hynynen and Ziskin (2008), processes that can produce a biological effect with some degree of heating (i.e, about 1°C above the physiologic temperature) act via a thermal mechanism. An increase in tissue temperature is the most worrying bio-effect associated with diagnostic ultrasound in obstetric practices (Joy et al., 2006). The transducer itself can be a source of heat by direct contact with the body (Szabo, 2004). Joy, Cooke and Love (2006) suggest that ultrasound devices, especially the pulsed spectral Doppler, produce a fixed ultrasound beam which, when directed to a fixed ultrasound target tissue, cause a significant rise in temperature within a relatively short time. Once a transducer is placed on the body and is acoustically loaded, the energy is released to propagate into the body and not the transducer, and the normal mechanism of body cooling through perfusion reduces the heating considerably (Szabo, 2004).

For most healthy people, the skin can detect small changes in temperature; however, the communication of this sensation may not be possible for the ill and the very young (Szabo, 2004). Because the temperature contribution is very localised to the surface and smaller than the absorption contribution, it is often neglected in temperature elevation estimates (Szabo, 2004). According to Miller (2008), thermal bio-effects depend on the temperature elevation and its duration. The temperature elevation produced by ultrasound depends on the special peak temporal average (SPTA) intensity, the ultrasound frequency, the dwell time along the beam axis, the width of the beam, the tissue properties, the individual patient, and other minor factors.

3.5.3 Mechanical bio-effects

The principal non-thermal (mechanical) interactions deal with the generation, growth, vibration and possible collapse of micro-bubbles within tissue (Ng, 2002). Bly & Van Den Hoff (2005) state that radiation force, streaming and cavitation are the main factors in mechanical effects. Cavitation requires small, stable gas bubbles to be present in the tissues, and involves implosion (collapse) of the bubbles caused by the ultrasound. The sudden collapse results in mechanical damage and possible formation of free radicals. Two types of cavitation exist: stable cavitation refers to the creation of bubbles that oscillate with sound beams; transient cavitation refers to the process in which the oscillation grows so strong that the bubbles collapse violently, producing very intense, localized effects (Ng, 2002).

The focus of attention for mechanical effects is the shifting from naturally occurring nucleation sites in the body to ultrasound contrast agents (Szabo, 2004). These encapsulated agents vary considerably in their response to ultrasound, depending on the gas and shell materials (Szabo, 2004). Miller (2008) states that for ultrasound, bio-effects occur only above thresholds and increase from zero severity with increasing exposure above the threshold with certainty (not probability) for specific conditions. The occurrence of cavitation for a given cavitation nucleus depends on the PRPA, which is a pulse-peak parameter thereby related to the spatial peak pulse average (SPPA) intensity of the 510(k) guidelines (which is not displayed on screen), and the ultrasonic frequency. Mechanical effects are unlikely to occur in obstetric ultrasound because of the absence of gas bodies or the use of contrast media.

3.5.4 Cavitation

Acoustic cavitation is defined as the influence of an ultrasonic wave on the creation, growth, oscillation and collapse of bubbles known as gaseous cavities in a liquid channel. When a sound wave propagates through a liquid, it forms expansion (negative-pressure) and compression (positive-pressure) half cycles. High pressure in the sound wave, can cause the distance between liquid molecules to become more than the critical molecular distance necessary to hold the liquid intact. This may lead to the liquid breaking down and bubbles (gas-filled cavities) being formed (Brennen, 1995).

The ultrasonic pressure wave can influence the populace of pre-existing bubbles in the liquid medium at pressures that are low. At such pressures *de novo* formations of bubbles is impossible. At these pressures, a number of forces are applied to a pre-existing bubble by the acoustic field. When the bubble radius is similar in size to the wavelength, the bubble is trapped in the spatial distribution of compression and expansion of the acoustic field. This leads into the episodic changes in dimension. According to Leighton (1998), the interface of the bubble-liquid routine for fairly little pressure amplitudes is a linear oscillator having a normal resonance frequency. Accordingly, bubbles with a natural resonance frequency corresponding f will go through maximum oscillations for an acoustic wave with frequency f transmitting in a liquid medium including different bubble sizes. Considering water under normal atmospheric pressure, the following is the linear resonant radius (R_r) formula for spherical air bubbles resonating at frequency f :

$$R_r = \frac{3.28}{f} \; ; \; R_r \leq 0.01 \qquad 3.5$$

f is measured in *kHz* and R is measured in mm. The surface tension of the liquid is ignored, making this formula less applicable for high frequency ultrasound (Wu & Nyborg, 2006). The oscillation of bubbles in reaction to the acoustic wave is known as stable cavitation. It takes place at low to moderate pressure amplitudes which are less than ~1 MPa and have an inverse dependence on frequency (Carvell & Bigelow, 2011). A radically oscillating bubble within a liquid medium can enlarge in an acoustic pressure field because of rectified diffusion. In this course, a quantity of the liquid proximate to the bubble diffuses through the boundary layer and is converted into vapour inside the bubble during the expansion half cycle, because of the pressure decrease inside the bubble. Some vapour diffuse out in the subsequent contraction half cycle, in response to the increase of pressure in the bubble. This diffusion is 'rectified' since the area of the surface of a bubble in the expanded condition is a lot larger than in the contracted condition providing a greater area for diffusion of the gas into the bubble than for diffusion out of it. Rectified diffusion favours bubble development on subsequent oscillations due to the swell of gas within the bubble (Polat et al., 2011). The bubble encounters speedy growth over a small number of cycles followed by a collapse in the course of the positive half cycle, if this above scenario proceeds rapidly. According to Wells (1977), this phenomenon is termed inertial or transient cavitation. The collapsing bubble can either create a shock wave in the bulkiness of the liquid or a micro-jet near a boundary (Crum, 1999). This depends on the position. During bubble collapse, elevated temperatures reaching several thousand degrees Kelvin occur were bubbles are and may trigger the formation of free radicals (Wells, 1977).

The beginning of short-lived cavitation depends on acoustic pressure amplitude, frequency, and the size of the bubble for a free spherical bubble in a specific liquid. The preliminary magnitude of a bubble has an optimal range and can experience inertial cavitation at the threshold pressure amplitude of a wave with frequency (f). This optimal magnitude is calculated as R_r /3 where R_r represents the radius of the bubbles resonating at frequency (f) as presented by Crum (1999). The lower the wave frequency during inertial cavitation, the higher the time the bubble has to grow by rectified diffusion in the expansion half cycle, and accordingly an increased violent disintegration occurs during the following compression half cycle. The effect of transient cavitation is additionally important at lower ultrasonic frequencies (Odegaard et al., 2005).

Inertial cavitation is a threshold phenomenon, distinguished by a particular value beneath which the negative pressure amplitude is lacking for the implosion of gas bubbles. The thresholds for inertial cavitation follows a pattern which relies on the frequency with continuous wave ultrasonic exposure ranging between 20 and 500 kHz1 which can be calculated by:

$$P_t = A + Bf^n \tag{3.6}$$

A and B have positive values. A study by Urick (1983) found similar outcomes from an experimental study. It was reported monotonous increase in threshold with frequency, for continuous exposure of aerated water at room temperature in this frequency range (Urick, 1983).

3.6 Measurements of acoustic output during scanning

3.6.1 First, second and third-trimester

Sheiner et al. (2005) quantified acoustic output as measured by mechanical and thermal indices during routine obstetric ultrasound examinations. They collected data on duration of the examination and specific duration spent at each MI and TI. Thirty-seven (37) patients were recruited to the study.

The number of examinations that were evaluated in the first trimester was 11, 14 in the second trimester, and 12 in the third trimester. The average duration of examination in the first three months was (8.9) minutes. The average mechanical index (MI) was 0.73 (range, 0.3 – 1.3), and the average thermal index (TI) was 0.34 (range, 0.1 – 1.7).

Table 3.3 Comparison of MI and TI during Each Trimester of Pregnancy

Trimester	Mechanical index (MI)	Thermal index (TI)	Examination Duration, min
First Mean (range)	0.73 (0.3-1.3)	0.34 (0.1-1.7)	8.9
Second Mean (range)	1.04 (0.5-1.5)	0.28 (0.1-2.4)	31.8
Third Mean (range)	1.06 (0.2-1.5)	0.32 (0.1-2.4)	16.3

Output levels during routine obstetric ultrasound examinations, as expressed by (TI) and (MI) index are usually low (Sheiner et al., 2005).

The average duration of examination in the second-trimester was (31.8) minutes. The average mechanical index (MI) was 1.04 (range, 0.5 – 1.5), and the average thermal index (TI) was 0.28 (range, 0.1 – 2.4). The average duration of examination in the third-trimester was (16.3) minutes. The average mechanical index (MI) was 1.06 (range, 0.2 – 1.5), and the average thermal index (TI) was 0.32 (range, 0.1 – 2.4) as described in Tab 3.3 (Sheiner et al., 2005).

They found a statistically significant difference across trimesters with regard to the durations of examination and MI ($P < .001$), and there were no statistically significant differences in TI across trimesters.

3.6.2 Two, three and four-dimensional ultrasound (2D, 3D & 4D)

Sheiner et al. (2007) compared acoustic output indices in 2D and 3D/4D ultrasound in obstetrics. They used three different commercially available machines. A total of 40 ultrasound examinations were evaluated. Average thermal index (TI) during the three-dimensional examinations (3D) and four-dimensional (4D), were similar to the thermal index during B-mode scanning or two-dimensional (2D). The mechanical index (MI) during the 3D examination was significantly lower than in the 2D B-mode ultrasound, and significantly lower than in the 4D ultrasound exam, but there were no statistically significant differences of TI or MI between the three devices (see Table 3.4) (Sheiner et al., 2007: 326-328).

Table 3.4 Acoustic output indices in 2D and 3D/4D ultrasound in obstetrics

Characteristic	B-mode (2D)	(3D)	(4D)	P
TI [mean ± SD (rang)]	0.28 ± 0.1 (0.1-0.7)	0.27 ± 0.1 (0.1-0.6)	0.24 ± 0.1 (0.1-0.5)	0.343
MI [mean ± SD (rang)]	1.12 ± 0.1 (0.7-1.3)	0.89 ± 0.2 (0.5-1.3)	1.11 ± 0.2 (0.7-1.3)	0.018*

Comparison between AOI in 2D & 3D/4D ultrasound in obstetrics (Shiener et al., 2007, 326-328).

3.6.3 Colour Doppler and pulsed wave

In 2007, The American Institute of Ultrasound in Medicine (AIUM) published a study about the evaluation of acoustic output during clinical ultrasound examinations, as expressed by the thermal and the mechanical index, during the second half of pregnancy and comparing acoustic outputs between B-mode and Doppler examinations. The study was conducted by Sheiner et al. (2007:71-76).

In that study, patients with suspected foetal growth problems who were undergoing Doppler examinations of the foetal circulation in addition to B-mode sonography were selected. Examinations were taken between 21 and 40 weeks' gestation, and data were collected by an obstetrician. A total of 63 examinations including Doppler examinations in 63 patients were evaluated. Acoustic output, as indicated by the output indicators, during the ultrasound examinations are shown in Table 3.5.

Table 3.5 Acoustic output indices in B-mode, Colour Doppler and Pulsed Wave

Characteristic	B-mod (n = 190)	Colour Doppler (n = 31)	Pulsed Wave (N = 118)	P*
TI				
Mean ± SD	0.3 ± 0.1	0.8 ± 0.1	1.5 ± 0.5	<.O1
Range	0.1-0.7	0.6-1.2	0.9-2.8	
MI				
Mean ± SD	1.1 ± 0.1	1.0 ± 0.1	0.9 ± 0.2	<.O1
Range	0.2-1.3	0.8-1.2	0.2-1.2	

An increase TI can be achieved when performing Doppler studies in obstetrics ultrasound [Sheiner et al., 2007, 71-76].

The mean duration ± SD was 17.6 ± 8.6 for the total examination. Doppler studies continued an extra 0.9 ± 0.8 minute. There were 190 alterations of the TI during B-mode examinations, 118 during pulsed Doppler examinations and 31 during colour Doppler examinations. In pulsed wave Doppler examinations the TIs were significantly higher (mean, 1.5 ± 0.5) and colour Doppler examinations (mean, 0.8 ± 0.1) when compared with B-mode nosography (0.3 ± 0.1). The 190 B-mode MI differences (mean, 1.1 ± 0.1) were comparable with the 31 colour Doppler examinations (mean, 1.0 ± 0.1) but higher than the 118 pulsed wave Doppler MI differences (mean, 0.9 ± 0.2; P <.O1).

3.6.4 General ultrasound scanning

Hagi and khafaji (2013) quantified acoustic output as measured by mechanical and thermal indices during different scans (abdominal, obstetric, transvaginal and other small part scans). They collected data on duration of the examination and specific duration spent at each MI and TI. 408 scans were conducted at King Abdul-Aziz University Hospital (KAUH). The values of TI and MI for each scan type were compared to those from the survey conducted by BMUS-UK. About ten ultrasound machines where used in that study and all of them were manufactured by Philips. The results of this study were very close to the benchmark acoustic parameters that were based by BMUS. Acoustic output, as indicated by the output indicators, during the ultrasound scans are shown in Table (3.6) including the benchmark that was conducted by BMUS.

Table 3.6 Benchmarking of general ultrasound scans

Scan type / parameter	**Benchmark (BMUS)**	**KAUH STUDY**
Abdominal		
TI	0 – 1.2	0.2 – 1.3
MI	0.4 – 1.6	0.2 – 1.3
Obstetric		
TI	0.1 – 2.5	0.2 – 1.3
MI	0.2 – 1.6	0.3 – 1.5
Transvaginal		
TI	0.1 – 0.4	0.2 – 0.8
MI	0.4 – 1.0	0.6 – 1.3
Small part		
TI	0 – 0.3	0.1 – 0.9
MI	0.4 – 0.9	0.4 – 1.3

AOI in different scans as conducted at KAUH (Hagi and khafaji, 2013).

Table 3.7 The maximum mean of TI and MI used for different scans.

Scan type	BMUS		KAUH	
	Mean TI_{Max}	Mean MI_{Max}	Mean TI_{Max}	Mean MI_{Max}
ABDOMINAL	0.31	1.1	0.78	1.22
OBSTITREC	0.44	0.9	0.55	1.13
SMALL PARTS	0.15	0.6	0.23	0.74
TRANSVAGINAL	0.23	0.7	0.51	1.04

Maximum levels of TI and MI as reported at KAUH (Hagi and khafaji, 2013)

According to Hagi and Khafaji (2013), five different scans were performed. The study has established the existing practice at KAUH and the results enhanced that the acoustic output indices related to TI and MI levels could reach 1.3 during routine scanning even though the mean stayed within the limits of the guidelines that were established by BMUS. The maximum TI and MI during each patient scan as measured at KAUH are indicated in Table (3.7) and Figure (3.1) and (3.2).

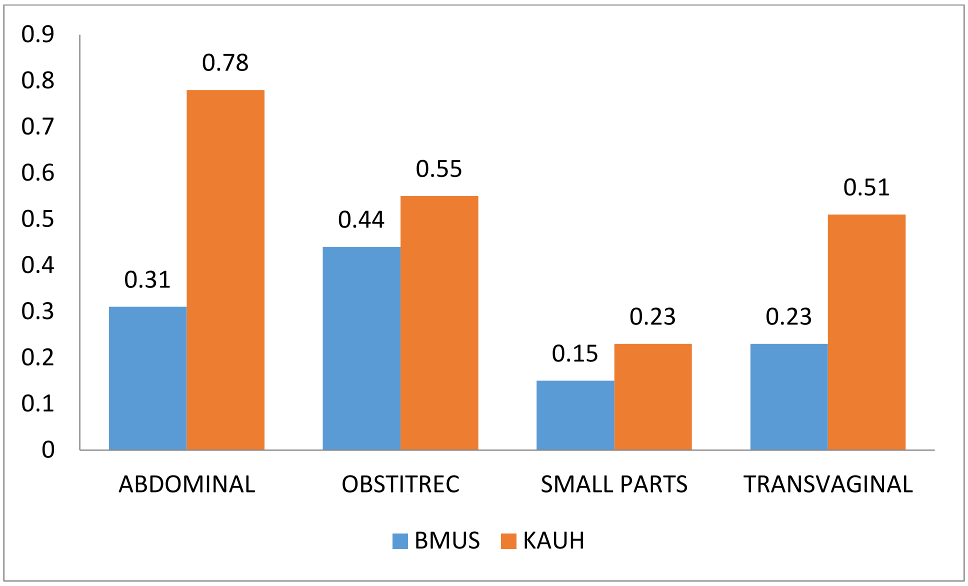


Figure 3.1: Mean maximum of TI used for all scan types (Hagi and khafaji, 2013).

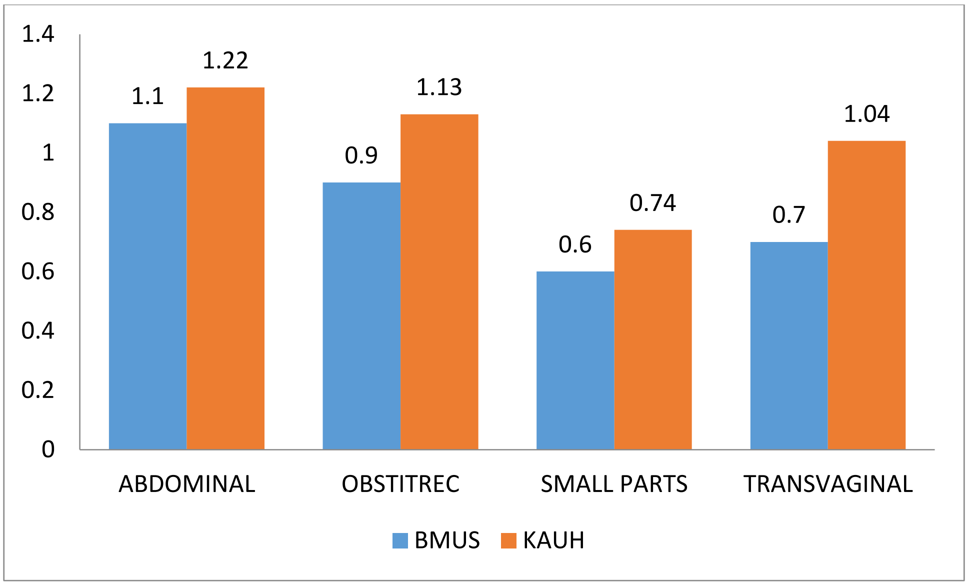


Figure 3.2: Mean maximum of MI used for all scan types (Hagi and Khafaji, 2013)

3.6.5 Nuchal translucency (NT) ultrasound scanning

According to Nicolaides et al. (1992) and Nicolaides et al. (2005), the definition of Nuchal translucency (NT) is the subcutaneous aggregation of liquid in the foetal neck that can be produced by ultrasound. When the foetus is at age between 11+0 and 13+6 weeks' gestation, this measurement can be used as a screening test for chromosomal abnormalities. If there is an Increase in NT, that indicates a measurement up to the 99th centile, or 3mm. After 14 weeks, any increase in NT can be resolved, but in some situations it develops into nuchal edema or cystic hygromas. The measuring technique of NT is I established, including right training of sonographers and external quality assurance (Nicolaides et al., 1992) (Nicolaides et al., 2005).

Sheiner and Abramowicz (2005) quantified acoustic output as measured by mechanical and thermal indices during foetal Nuchal translucency (NT) ultrasound examinations. They collected of data on duration of the examination and specific duration spent at each MI and TI. Fifty (50) ultrasound Nuchal translucency NT examinations were evaluated for the study. The NT involved the foetus at age between (11+0) and (13+6) weeks' gestation as part of a screening test for foetal chromosomal abnormalities, and includes comparatively stable ultrasound scanning of the foetus.

Table 3.8 The maximum mean of TI and MI used for different scans.

Characteristic	**Values**
TI [mean ± SD (rang)]	0.2 ± 0.1 (0.1 ± 0.7)
MI [mean ± SD (rang)]	1.1 ± 0.1 (0.7 ± 1.3)
NT	1.4 ± 0.4 mm

AOI as measured by TI & MI during foetal TN US examinations (Sheiner & Abramowicz, 2005).

The number of variations of the TI during the examinations was (109). The average duration of ultrasound examination was (11.6 ± 4.2) minutes. The average thermal index (TI) was (0.2 ± 0.1) (range, 0.1 – 1.7). The average gestational age was (12.3 ± 0.6) weeks (Sheiner & Abramowicz, 2005).

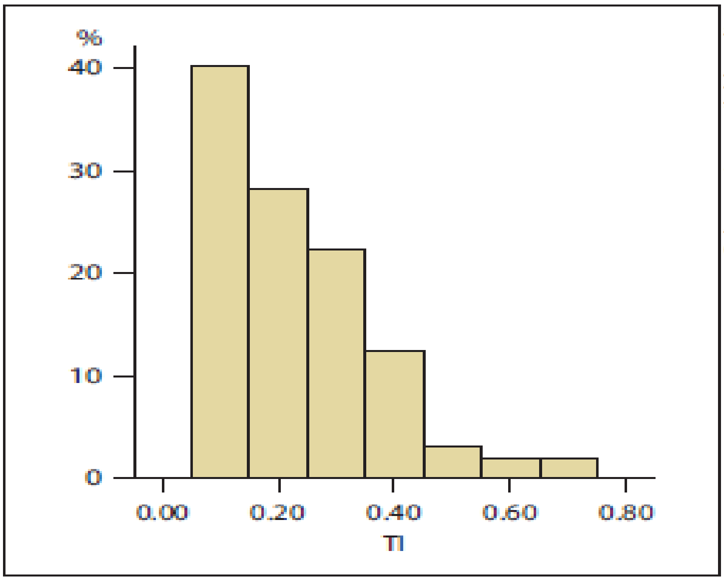


Figure 3.3: Distribution of TI variations during the NT examinations (Sheiner & Abramowicz, 2005).

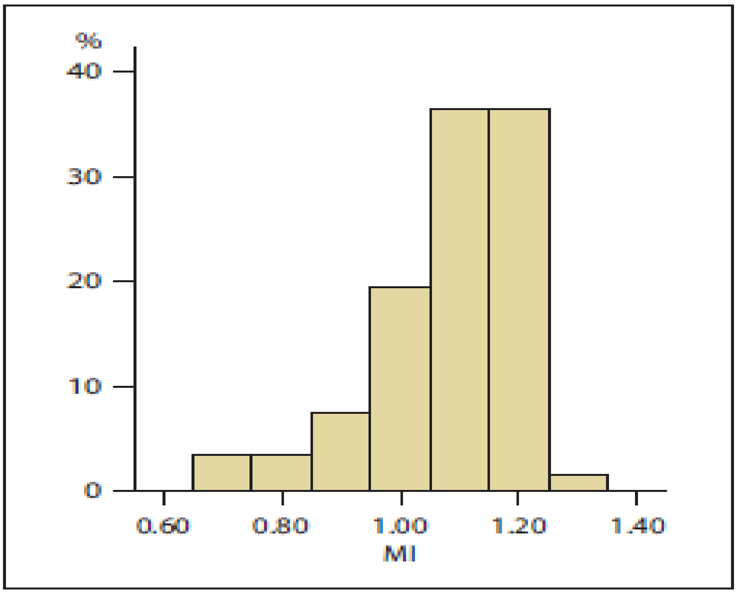


Figure 3.4: Distribution of MI variations during the NT examinations (Sheiner & Abramowicz, 2005).

3.7 Bio-effect of ultrasound on endothelial cells

Only a few studies have investigated the effects of ultrasound stimulation on endothelial cells. In a study by Hsu and Huang (2004), 1 MHz, pulsed 1:4, and four different spatial-average temporal-peak intensities (0.5, 1.0, 1.6, and 2 W/cm2) of ultrasound were used to stimulate endothelial cells for 10 minutes per day. The aim of the present study was to evaluate the effects of ultrasound stimulation in cell proliferation, ex-tracellular matrix secretion, nitric oxide and calcium concentration of endothelial cells. The results showed that ultrasound (intensity 1.6–2.0 W/cm) treatment after 6 days enhanced the nitric oxide (NO) and Ca^{2+} release from the endothelial cells but did not promote cell growth. In addition, ultrasound stimulation changed the cellular morphology and orientation, and increased extracellular matrix secretion from endothelial cells.

ALMahrouki, Karshafian, Giles and Czarnota (2012) investigated ultrasound bio-effects in which the levels of genes in endothelial cells can be significantly altered by ultrasound-stimulated micro-bubble exposure. These were compared with established effects of radiation on endothelial cells at a gene level. Human-endothelial cells were exposed to ultrasound and micro-bubbles, radiation or combinations of ultrasound, micro-bubbles and radiation. Gene expression analyses revealed an up-regulation of genes known to be involved in apoptosis and ceramide-induced apoptotic pathways, including sphingomyelinase (SMPD2), an enzyme involved in lipid modification (UGT8), cytochrome c Oxidase (COX6B1), Caspase 9 and mitogen activated protein kinase 1 (MAP2K1) with ultrasound-stimulated micro-bubble exposure but not SMPD1. This was supported by immunohistochemistry and morphologic changes examined with cell microscopy, which showed changes in SMPD1 gene product in cells with micro-bubble exposure. This supports the hypothesis that ultrasound-stimulated micro-bubbles can induce significant bio effect-related changes in gene expression and can affect ceramide signalling pathways in endothelial cells, leading to apoptosis.

Useful information on bio-effects has come from in vitro, in vivo, theoretical, epidemiological, and therapy research. An early assessment by the AIUM resulted in the landmark 'Statement on Mammalian in Vivo Ultrasonic Biological Effects' of August 1976 which states that 'In the low megahertz frequency range there have been no demonstrated significant biological effects in mammalian tissues exposed to intensities below 100 mW/cm2' (Miller, 2008).

3.8 Knowledge of use of ultrasound, of practitioners in obstetrics and gynaecology

A survey was conducted on 120 end users of ultrasound (Sheiner, et al., 2007:319-325). These end users included obstetricians, gynaecologists, sonographers and nurses or nurse practitioners. The main aim of the study was to determine end users' knowledge regarding safety aspects of diagnostic ultrasound during pregnancy and assess end users' attitudes toward the use of ultrasound in low-risk pregnancies. Half of the end users thought that the number of ultrasound examinations in low-risk pregnancy should be limited to 1 to 3. Approximately 70% criticized the use of 'keepsake/entertainment' ultrasound. About 3% of the participants were familiar with the term thermal index. The authors reported that only 17.7% knew the nature of the thermal index. About 22% were familiar with the term mechanical index, but only 3.8% described it properly. Almost 80% of these professionals did not know the location of acoustic indices. Only 20.8% were aware that they are displayed on the sonographic monitor during the examinations. End users with higher knowledge of safety issues thought that there should be limitations on the number of ultrasound examinations in low-risk pregnancies.

3.9 Users' lack of knowledge

Evidence shows that there is a lack of knowledge amongst health care users of ultrasound regarding acoustic output of machines and safety issues during pregnancy (Sheiner, et al., 2007). The authors further state that, as a form of energy, ultrasound has the potential to have bio-effects.

3.10 Summary

This chapter discusses the acoustic output as measured by thermal (MI) and mechanical (MI) indices during different ultrasound scanning in obstetrics. Electrical power and the relationship between applied acoustic power is inferred. Bio-effects and safety of ultrasound during pregnancy are reviewed, acoustic safety and exposure control, and diagnostic ultrasound are also looked at. Measurements of acoustic output overview are given as well as acoustic output indices in the literature review.

CHAPTER FOUR

METHODOLOGY

4.1 Introduction

This chapter provides a detailed description of the methodology used to answer the research question. A research methodology helps one to specify how the researcher intends to find a solution or solutions to a problem and the steps that are necessary to do so (Goddard & Melville, 2007). This chapter provides details of the approach which was taken, the instrument used for data collection, data collection procedure, data analysis plan, population and sample, ethical issues and how the findings will be disseminated. The main aim of this study is to evaluate end user knowledge regarding the safety of ultrasound.

4.2 Methodology

This study uses a quantitative research methodology. Quantitative research is a means of testing objective theories by examining the relationship among variables (Cresswell, 2009). These theories can be measured using instruments so that numbered data can be analysed using statistical procedures.

4.3 Research design

A descriptive cross-sectional study in the form of observation and a survey was employed. The study took place in September and October 2014. Descriptive studies are used to merely describe the phenomenon. The researcher does not manipulate any variables as in experimental designs and makes no effort to determine the relationship between variables (Brink, Van der Walt & Van Rensburg, 2012). Surveys are a type of descriptive study design which is quick to administer and is given at one point in time. Through a survey, a researcher can obtain information on the knowledge of end users on the safety of ultrasound.

4.4 Setting

The study was conducted at public and private hospitals located in the Western Cape. These hospitals are Groote Schuur Hospital, New Somerset Hospital (Department of Obstetrics and Gynecology), Christian Bernard Hospital and the Foetal Assessment Centre, Kingsbury Hospital.

4.4.1 Groote Schuur Hospital

Groote Schuur Hospital is one of the largest public teaching hospitals in South Africa and is famous for being the institution where the first human heart transplant took place, conducted by a surgeon named Christian Barnard. The hospital provides tertiary care and instruction in all the major branches of medicine and health sciences.

4.4.2 New Somerset Hospital (Department of Obstetrics and Gynaecology)

New Somerset Hospital is a 330 bed regional general specialist hospital for the metro west district of the Cape Metro pole in the Western Cape. It offers a range of general specialist services to a population of more than half a million people. Services include a 24hr emergency Centre, specialist paediatric, surgical, medical, orthopaedic, obstetrics and gynaecology departments.

4.4.3 Christian Barnard Hospital

The Christian Barnard Memorial Hospital is a private hospital based in Cape Town, South Africa, and is part of the Net care Group of private hospitals. The hospital is a large facility and has 247 beds and 14 theatres, and performs a wide and varied range of procedures. The hospital has several departments including; dentistry, dermatology, plastic surgery, general surgery, neurosurgery, orthopaedics, paediatrics and obstetrics and gynaecology.

4.4.4 The Foetal Assessment Centre, Life Kingsbury Hospital

Life Kingsbury Hospitals is a member of Life Healthcare, one of the largest private hospital groups in South Africa, operating 63 acute care facilities across the country. Facilities at the institution include 134 beds and 7 theatres, a 9 bed general intensive care unit, equipped with leading diagnostic and monitoring facilities, a 5 bed high care unit, a radiology facility, with a comprehensive range of sophisticated diagnostic equipment including CT scanner, a 25 bed maternity unit and the Foetal assessment unit. The Foetal assessment unit provides patients with experienced medical care in specialized obstetric and gynaecological imaging, using the latest imaging technology.

4.4.5 Tygerberg Hospital

Tygerberg Hospital is a tertiary hospital located in Bellville, Cape Town, South Africa. The hospital was officially opened in 1976 and is the largest hospital in the Western Cape and the second largest hospital in South Africa, with the capacity for 1899 beds. It acts as a teaching hospital in conjunction with the Stellenbosch University's Health Science Faculty. To become a patient at Tygerberg, a person must be referred by a primary or secondary health care facility. Over 3.6 million people receive health care from Tygerberg, either directly or via its secondary hospitals, such as Paarl and Worcester Hospital. During the normal working day there are about 10,000 people on hospital grounds.

4.5 Population, sampling and sample size

A population is a complete set of people with a specific set of characteristics who are the subject of research interest (Goddard & Melville, 2007; Hulley, Cummings, Browner, Grady & Newman, 2007). A sample is a subset of the accessible population that participates in a study (Hulley et al., 2007). A good choice of subjects serves the vital purpose of ensuring that the findings in the study accurately reflect what is going on in the population of interest (Hulley et al., 2007). The population consisted of all professionals who use ultrasound at the enrolling institutions. Convenience sampling of 18 end users was selected from the hospitals. These included physicians, nurses, sonographers and radiographers, and gynaecologists.

4.6 Inclusion criteria

The study included physicians, nurses, sonographers and radiographers, and gynaecologists working at the hospitals with at least one year of working experience of using ultrasound for diagnostic purposes in pregnant women.

4.7 Instrumentation

An adapted version of a questionnaire was used for data collection. The questionnaire had been used by Sheiner, Shoham-Vardi and Abramowicz (2007) on end user knowledge regarding the safety of ultrasound. The questionnaire consisted of 17 questions. The questions addressed general demographic information, familiarity with ultrasound bio-effects and knowledge regarding the safety of ultrasound, in closed ended questions.

4.8 Ethical clearance

Ethical clearance was obtained from the Cape Peninsula University of Technology Ethics committee. Furthermore, permission was sought from the institution for the study to be conducted there. Informed consent was obtained from each individual prior to completing the questionnaire. Anonymity was assured. No identifying information was included on the questionnaire or data extraction form.

4.9 Data collection

After permission was granted to conduct the research at the hospitals, the researcher approached the receptionists to identify the potential participants. He then introduced himself and the research project to the potential participants. For those that were willing to participate, informed consent was obtained before the questionnaires were handed to the participants. Participants were provided with questionnaires by the researcher, and he collected the completed questionnaires. Values of acoustic output indices (MI and TI) in ultrasound were gathered from the ultrasound machines in the previous studies and compared between 2D and 3D. The 2D and 3D values from those studies were then compared to those of the BMUS. The focus was on 2D and 3D ultrasound during routine obstetric ultrasound examinations.

4.10 Data analysis

After collection of data, they were entered in Excel and double checked for any errors. Data were analysed descriptively and presented in tables as frequencies and means. Statistical analyses were performed using the SPSS package (SPSS Inc., Chicago, IL). The chi-square test was used for categorical variables.

4.11 Dissemination of findings

Findings will be disseminated via publication in a peer reviewed accredited journal. A presentation at a conference will also be done. A workshop will be convened to include professionals that use ultrasound in obstetric units.

CHAPTER FIVE

Design of 2D and 3D arrays for medical ultrasound imaging

5.1 Introduction

Real time 3-D ultrasound imaging provides a full view of internal tissue formations and flow information. Volumetric ultrasound has minute devices which include endoscopes or intra-cavital probes which offer unique chances for directing surgeries or minimally invasive therapeutic procedures. The advancement and clinical usefulness of 3-D ultrasound imaging has been comprehensively evaluated over the years (Fenster et al., 2001; Salgo, 2007). The main focus of 3-D ultrasound imaging research is transducer design, array signal processing, and image visualization. According to Houck et al. (2005) and Houck et al. (2006), volumetric imaging systems make use of 2-D transducer arrays which have hundreds of elements, and require data acquisition probes which have integrated front-end electronics and a few electrical connections. One of the challenges of real-time 3-D imaging is difficulties in fabricating and interconnecting 2-D transducer arrays (Oralkan et al., 2003; Wygant et al., 2005). The other is challenges in acquiring and processing data from a huge number of ultrasound channels (Thomenius, 1996: Brunner, 2002). Conventional phased array (CPA) imaging uses all array elements in transmit and receive. CPA has the most excellent and possible image quality for a given array, and is thus considered the gold-standard. CPA is difficult to apply in hardware for large arrays and in particular for 2-D arrays that consist of thousands of elements as a result of the large number of active elements. Furthermore, the outcomes of great numbers of scan lines in volumetric imaging are low frame rates and/or view angles as a result of the finite speed of sound. The real-time imaging is restricted as the following (Karaman et al., 2009):

$$\left(\frac{\#ofFrames}{Second}\right)\times\left(\frac{\#ofFirings}{Frame}\right)\times\left(\frac{2\times \mathrm{Im}\,ageDepth}{Speedofsound}\right)\geq 1 \qquad 5.1$$

As an illustration, a 64×64-element CPA system can generate a single 90^0, 15-cm-deep pyramidal volume image in 1.6 s. To decrease the front-end complexity and enhance data acquisition rate, a variety of array processing techniques based on synthetic aperture (Nock & Trahey, 1992; Kim & Song, 2004), sparse arrays (Davidsen et al., 1994; Austeng & Holm, 2002), parallel beam-forming (Smith et al., 1991; Hergum et al., 2007), rectilinear scanning (Yen et al., 2000; Yen & Smith, 2002; Daher & Yen, 2006), phased sub-array processing (Karaman & O'Donnell, 1998; Johnson et al., 2005), coded excitation (Misaridis & Munk, 2004; O'Donnell & Wang, 2005), micro beam-formers (Savord & Solomon, 2003), configurable arrays (Fisher et al., 2007), and separate transmit and receive arrays (Savoia et al., 2007) have been proposed.

In classical synthetic aperture (CSA) imaging a sole active element is stepped across a huge transducer array at consecutive data acquisition steps by channel multiplexing. The figure is reconstructed through synthetic beam-forming by means of the collected A-scan data. CSA has low signal-to–noise ratio (SNR), poor contrast resolution and artifacts as a result of tissue and transducer motion. The SNR functioning can be enhanced by transmitting from numerous adjacent elements with defocusing phases to develop a strong, virtual element (Frazier & O'Brien, 1998; Nikolov & Jensen, 2000). To develop the contrast resolution, a small active receive sub-array with a minor increase in the front-end complexity can be utilized (Gammelmark & Jensen, 2003). Vulnerability of CSA imaging to tissue and transducer motion can be lessened by a variety of motion estimation and compensation procedures (Hazard and Lockwood, 1999). In 3-D CSA imaging, the great number of firing occurrences (data acquisition steps) confines the frame rate and effectiveness of motion compensation. The foundation of sparse array processing is aperture under sampling by means of sporadic or random sampling, and is utilised extensively to simplify the front-end by reducing the active channel count (Johnson et al., 1993).

Generally, the aim of sparse array design is to realize a needed beam pattern via a subset of array elements through optimization techniques. Studies have reported on 2-D sparse arrays for 3-D imaging (Davidsen et al., 1994; Austeng & Holm, 2002). Periodic sparse arrays experience grating lobe artifacts. Random sparse arrays supply the grating lobe energy to the side lobes, resulting in a rise in typical side lobe levels. The sparse array design appears to be an economical solution if the contrast resolution requisite in a specific application can be met by the set active element count. Another challenge of 2-D sparse array optimization besides accomplishing an acceptable image quality with a tolerable active channel count, there are also complexities in real-time volumetric scanning due to the large number of firings (Austeng & Holm, 2002).

According to Smith et al. (1991) and Hergum et al. (2007), matching beam-forming is recommended to meet real-time frame rate necessities in volumetric imaging. A transmit beam with a broad key lobe is generated by utilizing a sub-array, and an amount of parallel, narrow receive beams extending over the main lobe of the transmit beam are formed by using a huge receive array. On the other hand, several simultaneous narrow spread beams at diverse angles can be made by the use sub-arrays. It can also be made by a periodically under-sampled array, or by firing superimposed steered beams from a great array. This results in the reducing of the number of firings by the quantity of parallel beams at the expense of the reduction of beam condition. As stipulated by Kim and Song (2004) and Wall and Lockwood (2002), rectilinear scanning expands the principle of linear scanning to 3-D imaging. The authors further suggest that each linear array on a 2-D array is used to develop a plane beam, in rectilinear scanning, and image lines on that plane are rebuilt by parallel beam-forming using a 2-D receive array. The utilization of separate transmit and receive arrays in acquiring data makes the front-end hardware complexity simple, and facilitates the synthesis of various transmit–receive array configurations. A range of studies have utilized this method for volumetric scanning with different array shapes (Kim & Song, 2004; Wall & Lockwood, 2002; Austeng & Holm, 2002).

Karaman and O'Donnell (1998) and Johnson et al. (2005) state that the phased sub-array approach merge the principles of phased array and synthetic aperture imaging to lower the system intricacy by reducing the active channel count. The low-resolution sub-array images are produced by scanning the space with a tiny beam count similar to the sub-array size. This is similar to CPA processing. These low-resolution images are laterally up-sampled, interpolated, weighted, and logically added to create the final high-resolution image. The sub-array-dependent 1-D interpolation filters are likely to function well when applied for narrowband systems. On the other hand, wideband imaging commands 2-D filters for beam interpolation (Johnson et al., 2005).

For almost all kinds of beam-forming, coded excitation may be utilized for increasing the SNR and the deepness of penetration and the rate of the frame (O'Donnell & Wang, 2005). To improve the frame rate, one has to generate non-interfering wave-fronts in the image space by firing coded signals that do not correlate from array elements. Accordingly, echo signals are capable of being decoded for instantaneous reconstruction of numerous scan lines. Production of economical uncorrelated codes with practical lengths and efficient decoding formats to reduce the dilapidation in axial resolution are main difficulties to use the capable advantages of coded excitation style for escalating frame rate (Karaman et al., 2009).

Combination of a quantity of the electronics with the transducer array allows miniaturization of the front-end and channelling the electrical links of a 2-D array which has thousands of elements into a lessened number of channels. This permits the realization of configurable arrays by utilizing switching matrix circuits and sub-array micro-beam formers (Savord & Solomon, 2003; Fisher et al., 2007). These methods are exceedingly hopeful for 3-D and portable 2-D imaging functions, where the miniaturization of the array front-end is required. There are currently three-dimensional high-tech systems whose foundation is sub-array micro-beam (Houck et al., 2005, Houck et al., 2006). According to Gill and Klas (2007) and Salgo, (2007), systems like these use completely sampled piezoelectric matrix arrays (these have almost 3000 elements) yet make use of only 128 channels of an ordinary scanner, can produce fine size images in real time, or broader volume images by time gating (4–8 cardiac cycles). Evidence on CMUT-based imaging systems suggests that front-end circuits can be integrated with CMUT arrays using flip-chip bonding techniques (Wygant et al., 2008; Wygant et al., 2005), as well as monolithic silicon processing.

5.2 Two dimensional array

The full 2D arrays are the most superior arrays in ultrasound imaging. They match to an extension of the conventional 1D array to the lateral and elevation directions. The elements of a 2D array probe are aligned on a normal grid and plotted out of an expanse (the pitch) fewer than a mid-wavelength to circumvent grating lobes apparition. This inter-element space restriction is the spatial sampling condition. This limitation results into a huge number of tiny elements. The equal of a 1D probe of 128 elements has 128x128 = 16,384 elements in 2D. Linking such an excessive figure of elements is a technical difficult as the quantity of channels in a large number of the present ultrasound scanners does not surpass 256. Although the scanners make possible the link of these elements, its fulfilment will demand too huge electrical connecting cables ensuing in a weighty and non-appropriate probe for everyday practice operation. As a result, the key concern which should be addressed is the elements reduction techniques (Diarra, 2010).

5.3 Processing techniques of two-dimensional (2D) array

5.3.1 Overview

The quality of pulse-echo array system image can be measured by the co-array function which is also termed the effective aperture, which matches the convolution of the transmit, and receive arrays (Thomenius, 1996; Chiao & Thomas, 1996; Lockwood et al., 1998; Hoctor & Kassam, 1990)

$$C(n_x, n_y) = A_T(n_x, n_y) \otimes A_R(n_x, n_y) \tag{5.2}$$

In the equation above, the indexes n_x and n_y are discrete variables which represent locations of 2-D array elements (see Figure5.1). $C(n_x,n_y)$, $A_T(n_x,n_y)$ and $A_R(n_x,n_y)$are the 2-D transmit array, receive array, and co-array functions, respectively.

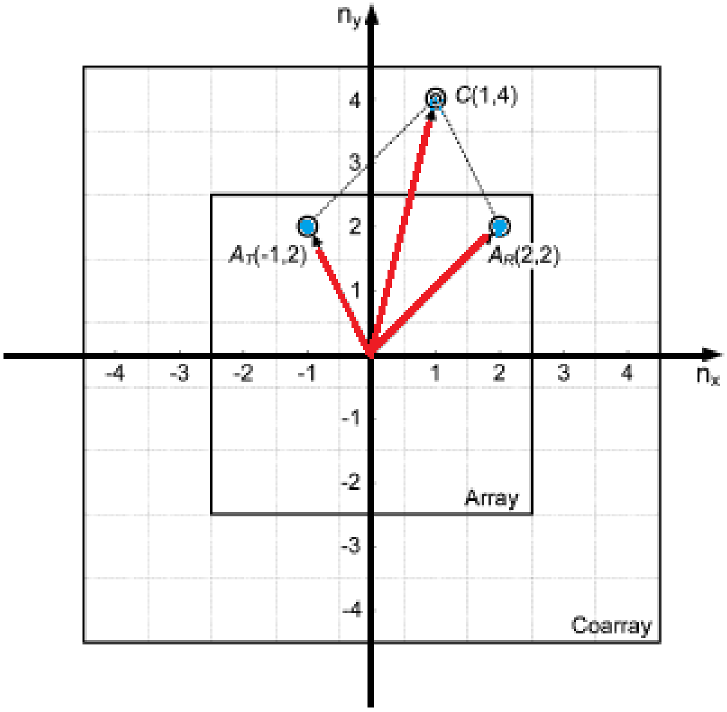


Figure 5.1 Transmit and receive element combination produces a co-array element.

The far-field, nonstop wave point spread function (PSF) of the system of the array imaging can be estimated by the Fourier transform of the co-array

$$H(\alpha,\beta)=F\{C(n_x,n_y)\}=F\{A_T(n_x,n_y)\}\times F\{A_R(n_x,n_y)\}$$

$$(n_x,n_y)\xleftrightarrow{F}(2\alpha,2\beta);\alpha=\frac{\pi d}{\lambda}\sin\theta_x;\ \beta=\frac{\pi d}{\lambda}\sin\theta_y \qquad 5.3$$

Considering the formula above, λ represents the wavelength, d the inter-element distance and θ_x and θ_y are the angles in azimuth and elevation directions respectively, (see Figure5.2).

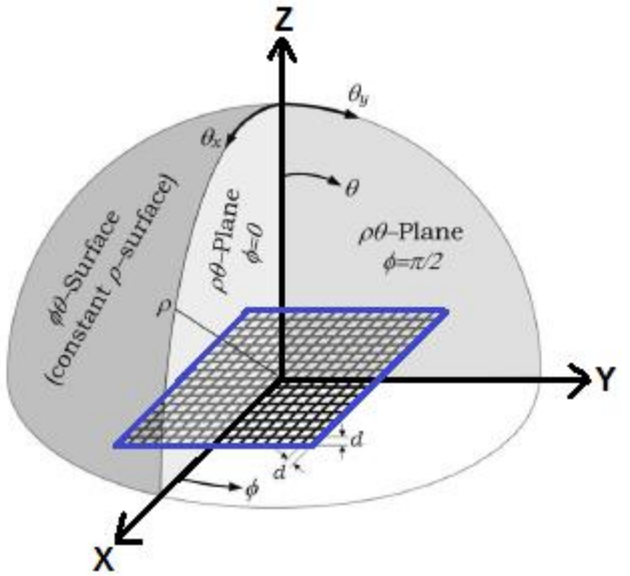


Figure 5.2: Reference geometry utilised for the theoretical and simulated point spread functions (Karaman et al., 2009).

Take notice that the Fourier transform relation is amid the separate aperture space and the continuous image space represented by the duo variables, (n_x , n_y) and $(2\alpha, 2\beta)$, respectively.

Every amalgamation of a transmit element and a receive element generates a co-array element. A co-array element's spatial position equivalent to the total of position vectors of the transmit and receive elements (see Figure 5.1).

$$\overrightarrow{(n_{x,C}, n_{y,C})} = \overrightarrow{(n_{x,T}, n_{y,T})} + \overrightarrow{(n_{x,R}, n_{y,R})} = \overrightarrow{(n_{x,T}+n_{x,R}),(n_{y,T}+n_{y,r})} \qquad 5.4$$

Thus, dissimilar mixtures of transmit and receive elements in the convolution operation may be part of the cause of the same co-array elements. Taking into consideration the Fourier relation involving the aperture and image spaces, every sample of the co-array matches to a spatial frequency. The numerous combinations causative to the equivalent co-array element in fact corresponds to the redundancy in the spatial regularity. In the creating of arrays, it is intended to develop a co-array which is modestly redundant in spatial frequency content. As elaborated by Karaman et al., (2009), such a co-array secures the entire spatial frequency content with a lowest amount of transmit/receive element pairs.

Volumetric scanning using 2-D arrays necessitates very large amounts of scan lines which are also known as firings. In pulse-echo imaging utilising an N×N element array (N>>1) having an inter-element spacing of d, the number of firings (scan lines) to form a pyramidal volumetric structure together with an angle of ($\theta_x \times \theta_y$) is giving by the following formula;

$$B_x \times B_y \geq \left(\frac{4Nd}{\lambda} \sin(\frac{\theta_x}{2}) \right) \times \left(\frac{4Nd}{\lambda} \sin(\frac{\theta_y}{2}) \right) \quad 5.5$$

Take notice of the fact that the beam count in each aspect ought to be scaled by 2 when one-way response is taken into account. To create a 90^0 volumetric frame with pulse-echo CPA imaging with d=λ/2, the lowest number of firings is $\left(\sqrt{2} \times N\right) \times \sqrt{2N}$. On the other hand, the frame rate is conversely proportional to the size of the array and/or the amount of signal firing/receiving steps as denoted by (1). The firing count in addition, ought to be kept small enough to meet real-time imaging requirements in array processing.

5.3.2 Array formations of two-dimensional (2D)

Array configurations linked to reduce or minimum spatial frequency redundancy describes four. The designs differ as they explore diverse trade-offs in relation to image quality and the front-end complexity. In order to make some differences, CPA and CSA are deemed as the reference methods providing the best image quality and the simplest front-end, respectively. The two-way PSF of CPA with N×N square array, $H_{CPA}(\alpha, \beta)$ (Johnson et al., 1993), can be expressed by utilising the continuous wave, paraxial and far-field approximations. The formula is presented below;

$$H_{CPA}(\alpha, \beta)\, \alpha \left(\frac{\sin(\alpha N)}{\sin(\alpha)} \times \frac{\sin(\beta N)}{\sin(\beta)} \right) \times \left(\frac{\sin(\alpha N)}{\sin(\alpha)} \times \frac{\sin(\beta N)}{\sin(\beta)} \right) \quad 5.6$$

Where,

$\alpha = (\pi d / \lambda) \sin(\theta_x),$

$\beta = (\pi d / \lambda \sin(\theta_y)$

θ_x , θ_y represent the angles in azimuth and elevation directions respectively, (Figure 5.2) (Smith et al., 1991). In like manner, point spread function of the CSA is calculated by:

$$H_{CSA}(\alpha, \beta)\, \alpha \left(\frac{\sin(2\alpha N)}{\sin(2\alpha)} \times \frac{\sin(2\beta N)}{\sin(2\beta)} \right) \quad 5.7$$

It is vital to know that the first and second terms in the point spread function representations provided above and below, tally with the transmit and receive responses of the array, respectively. All analytical point spread function expressions are returned to normal by the two-way response of a single array element provided below by:

$$h_e(\alpha,\beta)\alpha\left(\frac{\sin(\alpha)}{\alpha}\times\frac{\sin(\beta)}{\beta}\right)\times\left(\frac{\sin(\alpha)}{\alpha}\times\frac{\sin(\beta)}{\beta}\right) \qquad 5.8$$

To simplify in origination, the analytical point spread functions of the four array designs given below are estimated by being presumptions that the general elements are utilised in transmit and in receive. Figure (5.3) offers the transmit, receive and co-array functions schematics for diverse array patterns. Every bar in the array functions stand for an element's amplitude. The amplitude of every array function is stabilized to harmony. The transmit and receive arrays are constituted over a 16×16-element square array, and the consequent co-array magnitude is 31×31. The stepping of the dynamic element in CSA above the array in consecutive firings is denoted by the arrows (Karaman et al., 2009).

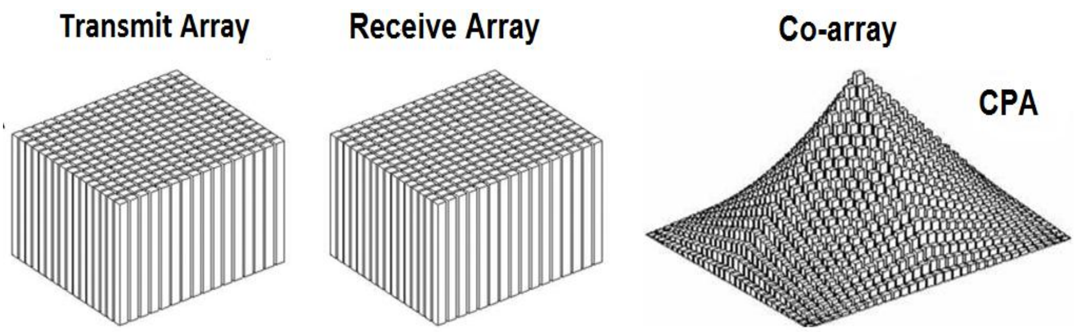


Figure 5.3: Scheme of transmit, receive and co-array functions of CPA.

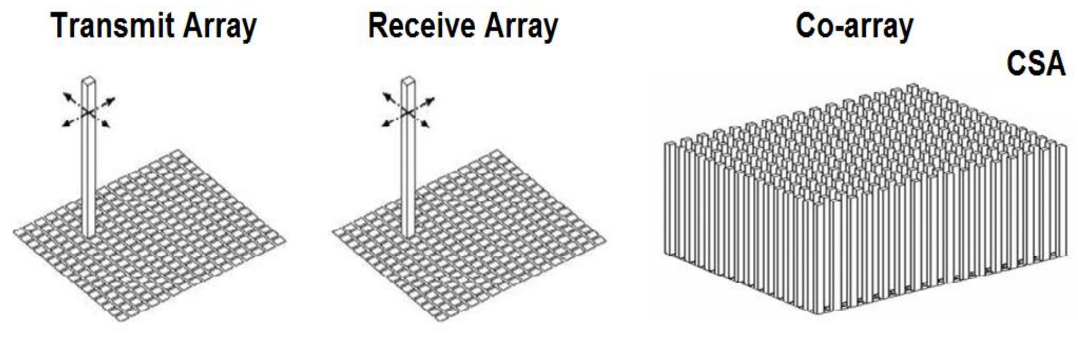


Figure 5.4: Scheme of transmit, receive and co-array functions of CSA.

5.3.2.1 X-Shaped Transmitter and Full Receiver (XT-FR) of 2-D

The configuration below shows that the transmit array is a cross-shaped aperture formed by two diagonals of the 2-D transducer array, while the entire array is utilized in receive (See Figure5.5).

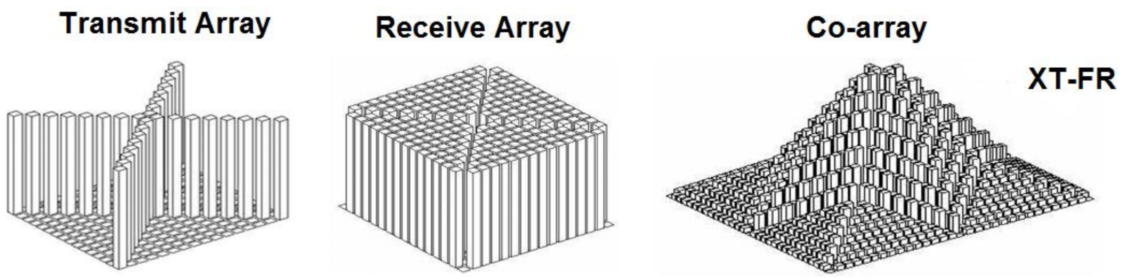


Figure 5.5: Scheme of transmit, receive and co-array functions of TX-FR.

Bearing in mind that the transmit elements are also used in receive, The PSF of this configuration can be approximated by:

$$H_{XT-FR}(\alpha,\beta)\alpha\left(\frac{\sin[(\alpha-\beta)N]}{\sin(\alpha-\beta)}+\frac{\sin[(\alpha+\beta)N]}{\sin(\alpha+\beta)}\right)\times\left(\frac{\sin(\alpha N)}{\sin(\alpha)}\times\frac{\sin(\beta N)}{\sin(\beta)}\right) \qquad 5.9$$

Note therefore that term one of the responses of the two diagonal Linear arrays correspond to the sum of responses as opposed to the second where the term is a one way response of a square array. Figure5.6 displays the Computed PSF of XT-FR.

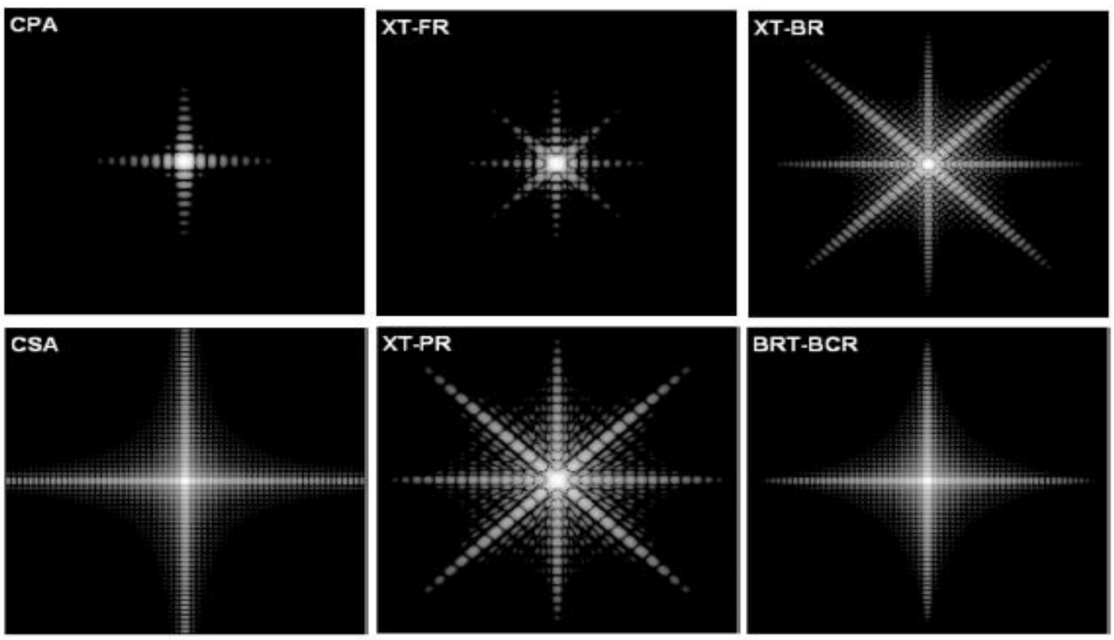


Figure 5.6: The Computed PSF of XT-FR (Karaman et al., 2009).

5.3.2.2 X-Shaped Transmitter and Plus-Shaped Receiver (XT-PR) of 2D

The transmit array is a cross-shaped narrow opening which is formed by two vertical linear arrays which are oblique of the 2-D transducer array as seen in this configuration, whereas the plus shaped aperture created by two vertical linear array pairs is the receive array (see figure 5.7).

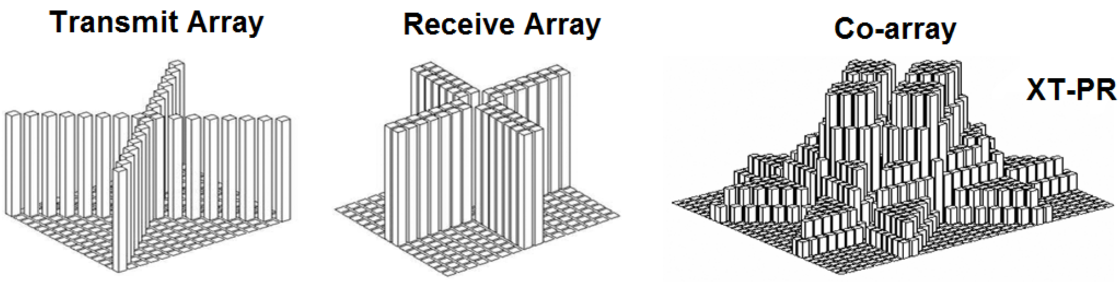


Figure 5.7: Scheme of transmit, receive and co-array functions of TX-PR.

Approximation of the outline of the use of the four central transmit elements used in receive of the PSF of this configuration can be implemented by:

$$H_{XT-PR}(\alpha,\beta)\alpha\left(\frac{\sin[(\alpha-\beta)N]}{\sin(\alpha-\beta)}+\frac{\sin[(\alpha+\beta)N]}{\sin(\alpha+\beta)}\right)\times\left(\frac{\sin(\alpha N)}{\sin(\alpha)}\cos(\alpha)+\frac{\sin(\beta N)}{\sin(\beta)}\cos(\beta)\right) \quad 5.10$$

Take note of the reaction of the two diagonal linear arrays that correspond to the first term as opposed to the response of the plus shaped receive array which corresponds to the second term. Also take note that the association between the vertical and horizontal arms comprising of two central rows and columns respectively are cosine factors in the second term. Figure 5.6 illustrates the computed PSF plot of XT-FR (Ramm et al., 1991).

The XT-PR design can be deemed as an addition of the basic array configuration which is termed the Mills cross array. In this array the transmitter and receiver are perpendicular linear arrays as stated by Kim and Song (2004). Smith et al. (1991) and Ramm et al. (1991) investigated the XT-PR array configuration using a plus-shaped transmitter and a single row and column and cross-shaped (diagonals) receiver for phased array volumetric imaging.

5.3.2.3 X-Shaped Transmitter and Boundary Receiver (XT-BR) of 2-D

The X-Shaped Transmitter and Boundary Receiver (XT-BR) of 2-D configuration uses the diagonal essentials of the 2-D transducer aperture in transmit and the boundary elements in receive (see Figure 5.8).

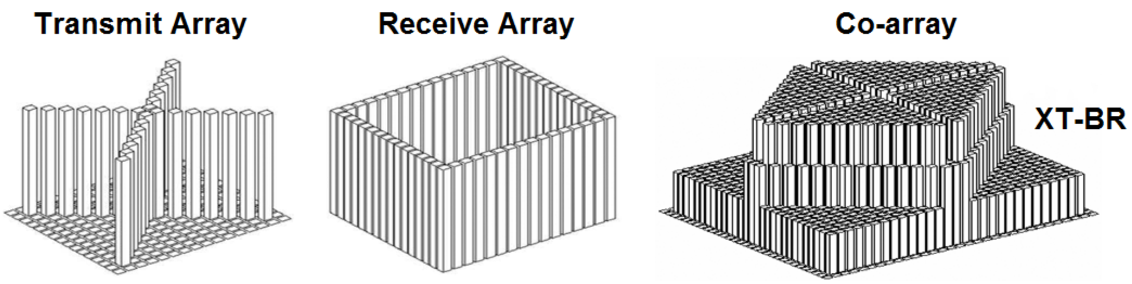


Figure 5.8: Scheme of transmit, receive and co-array functions of TX-BR.

The PSF of this array design is represented by formula below:

$$H_{XT-BR}(\alpha,\beta)\alpha\left(\frac{\sin[(\alpha-\beta)N]}{\sin(\alpha-\beta)}+\frac{\sin[(\alpha+\beta)N]}{\sin(\alpha+\beta)}\right)\times\left(\frac{\sin(\alpha N)}{\sin(\alpha)}\cos(\beta N)+\frac{\sin(\beta N)}{\sin(\beta)}\cos(\alpha N)\right) \quad 5.11$$

Here the initial expression is similar to that formula (5.9) and (5.10), and the second expression is the one-way reaction of a square boundary array, estimated by the addition of the reactions of two horizontal and two vertical linear arrays (the corner elements are regarded as the general elements). The calculated PSF of XT-BR is shown in Fig. 5.6. Kozick and Kassam (1993) in their study studied a rectangular boundary array with dissimilar weighting systems employed both as the transmitter and receiver. The XT-BR examined here has two differences from the earlier configurations: it uses an X-shaped array in transmit and a boundary array in receive, and engages fan-beam processing for volumetric scanning.

5.3.2.4 Boundary-Rows Transmitter and Boundary-Columns Receiver (BRT-BCR) of 2D

Boundary-rows transmitter and boundary-columns receiver (BRT-BCR) of 2-D array design utilizes two boundary rows (the outmost horizontal linear arrays) in transmit and two boundary columns (the outmost vertical linear arrays) in receive, and generates an identical co-array without redundant spatial frequency (Figure 5.9).

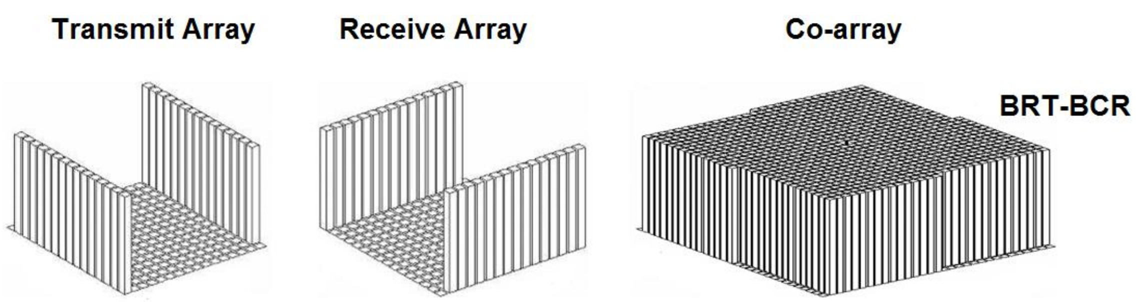


Figure 5.9: Scheme of transmit, receive and co-array functions of BRT-BCR.

The estimated PSF of this scheme matches multiplication of the summation of reactions in the second term of (5.11).

$$H_{BRT-BCR}(\alpha,\beta)\alpha\left(\frac{\sin(\alpha N)}{\sin(\alpha)}\cos(\beta N)\right)\times\left(\frac{\sin(\beta N)}{\sin(\beta)}\cos(\alpha N)\right) \quad 5.12$$

The computed, continuous-wave, far-field PSF of BRT-BCR is depicted in Figure 5.9. The BRT-BCR configuration is fundamentally an expansion of a normal Mills cross array. It has two spatially orthogonal N-element, linear arrays, employed as the transmit and receive arrays, and generates a (N×N)-element co-array which is not redundant and has unvarying amplitude (Kim & Song, 2004). The two-way PSF of the standard Mills cross array is matches the one-way PSF of an entirely populated N×N–element array; $H_{Mills\text{-}Croos}$ is comparable to $H_{BRT\text{-}BCR}$ in (5.12) with no cosine terms. Taking into account an element transducer array, BRT-BCR utilises the two N-element boundary horizontal linear arrays in transmit and the two -element boundary vertical linear arrays in receive, and generates a co-array with magnitude of (2N-1) × (2N-1) (Karaman et al., 2009).

It can therefore be deduced that the size of the co-array of BRT-BCR is twice that of the Mills cross array. This is owing to making double the transmit and receive elements or increasing by multiplying 4 times, the firings from N active channels. Kozick and Kassam (1993) have previously investigated The BRT-BCR with diverse weighting schemes. Here we review this array configuration to develop its frame rate by employing the fan-beam scanning, and contrast it with the other array configurations.

5.3.3 Fan-Beam Processing

The transmit fan-beams is utilized for real-time volumetric scanning. It is produced by the linear arrays to lessen the firing count. According to Karaman et al. (2009), A subset of elements on a 2-D transducer array selected alongside a line, forming a “linear array,” generates a fan-shaped beam (fan-beam), narrow in one dimension and broad in the other. The beam width which is narrow on the scanning plane is established by the length of the linear array. The wide beam width orthogonal to the scanning plane, on the other hand is made resolute by the element pitch. In volumetric scanning, a plane of the volumetric field is insonified by a fan-beam, and then the image pixels is reconstructed on that plane by means of parallel receive beam-forming. This procedure is reiterated for each plane of the volumetric field by means of steered fan-beams (Austeng & Holm, 2002). The fan-beam course of action can be executed utilising any of the array configurations illustrated. Exemplary, fan-beam scanning employing the XT-BR array configuration is shown in Figures 5.10.

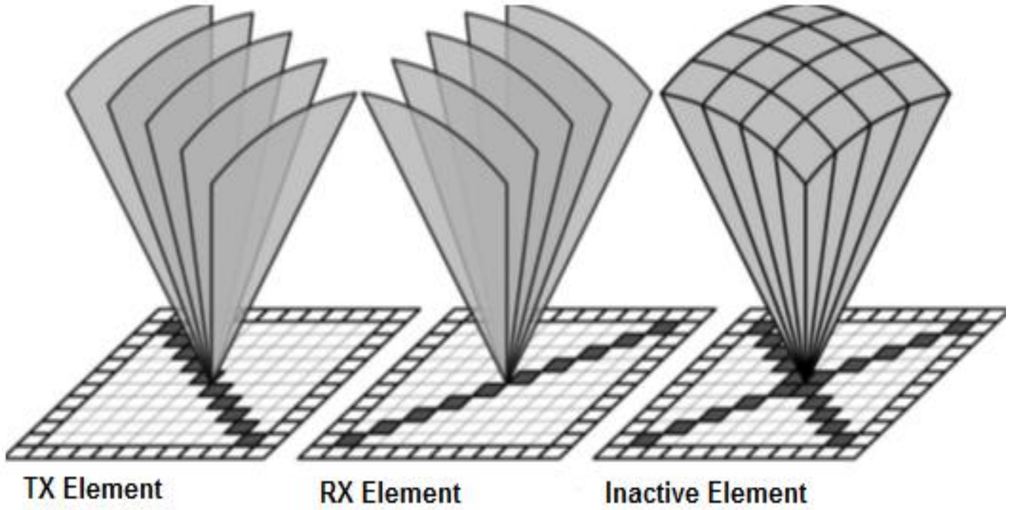


Figure 5.10: fan-beam processing using XT-BR array configuration (schematic of volumetric scanning).

Take note that the selected transmit 2-D sub-array array ought to be decomposable into linear arrays, and information acquirement must be repeated for every transmit linear array. The complete image is produced when data from these acquisitions are added consistently.

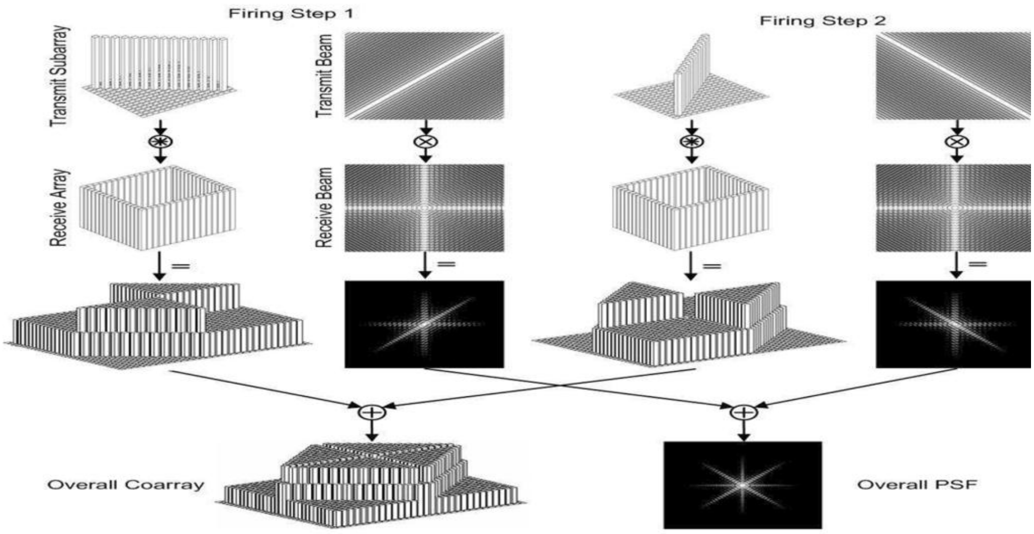


Figure 5.11: fan-beam processing using XT-BR array configuration (coherent processing).

$$h_{FB}(\alpha,\beta)\alpha\,\frac{\sin(\beta N)}{\sin\beta}\times\left(\frac{\sin(\alpha)}{\alpha}\times\frac{\sin(\beta)}{\beta}\right) \qquad 5.13$$

This is applicable where the subsequent expression is the one-way response of an individual element. For illustration, the replicated wide-band transmit beam patterns of three diverse linear array configurations on a 2-D array are shown in Figure 5.11, where the parameters provided in Table 5.1 were utilised in the models. The one-element broad diagonal linear array creates grating lobes in its one-way beam pattern as illustrated in Figure 5.12

Table 5.1: Simulation Parameters of three diverse linear array configurations on a 2-D array (Karaman et al., 2009)

Array size	32 × 32 Elements
Frequency	5 MHz
Element Pitch	$150\mu m$ ($\lambda/2$ at 5 MHz)
Excitation Pulse	Gaussian with 80% FBW
Sampling frequency	250 MHz
Transmit focus/ Target location	$F_{\#}$ of 4
Ultrasound velocity	1540 m/s

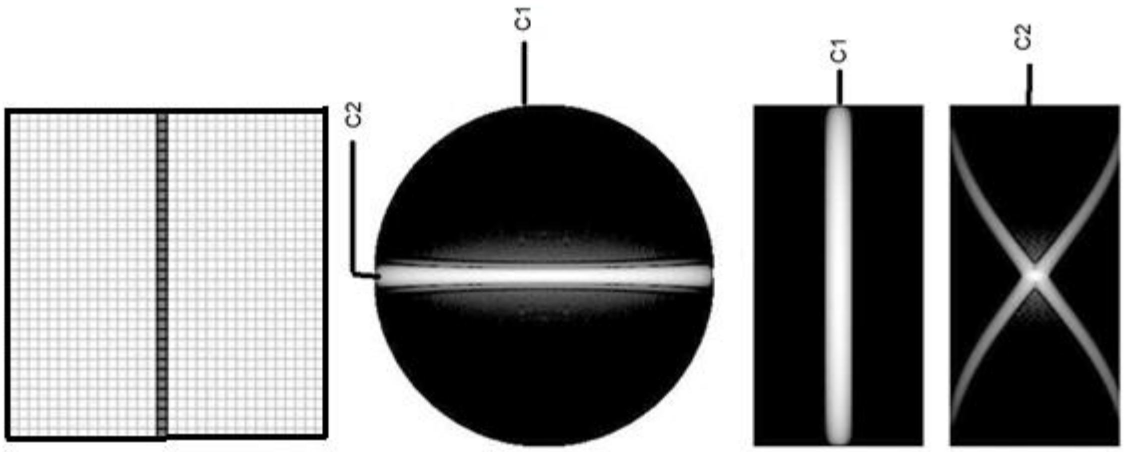


Figure 5.12: One-element wide diagonal.

This is dissimilar to a one-element wide horizontal or vertical linear array (Figure 5.13). These grating lobes arise from the aperture under-sampling. This is because the inter-element distance along the diagonal linear array on a 2-D array with λ/2-element spacing, is $\sqrt{2\lambda}/2$. As shown by the simulations in the following section, the grating lobes can be contained to a tolerable level by the receiver array. A multi-element wide diagonal linear array (whose inter element-spacing turn out to be s $\sqrt{2\lambda}/4$ can create a fan-beam devoid of any grating lobes at the cost of lessening beam angle.

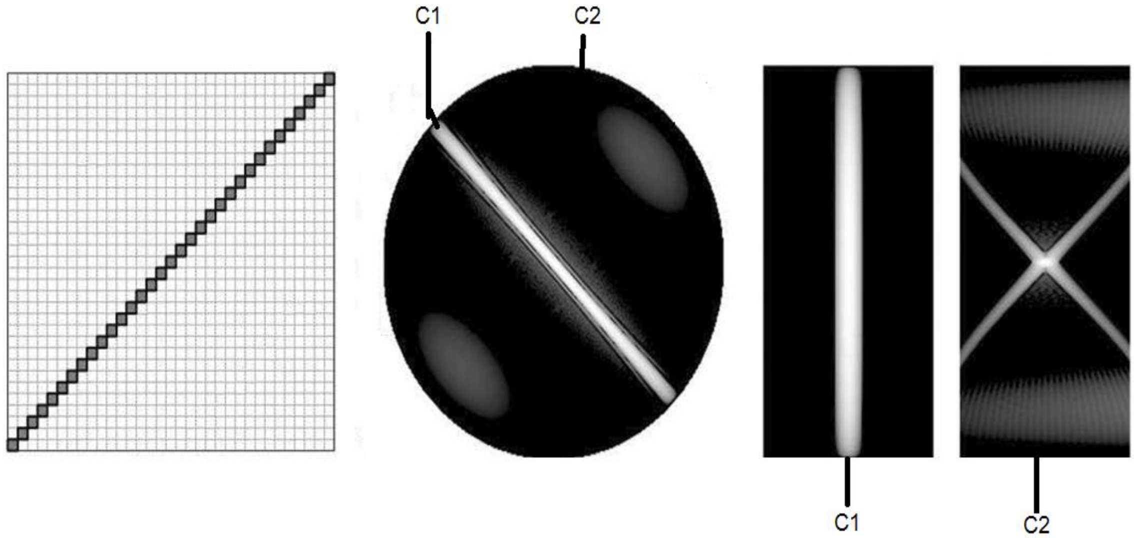


Figure 5.13: Three-element wide diagonal.

The reaction of a three-element wide diagonal array is shown in Figure 5.14 to provide an example. Daft et al. (2007) provides a solution to this by suggesting that this obstacle can be managed by defocused excitation of the multi-element wide diagonal linear arrays.

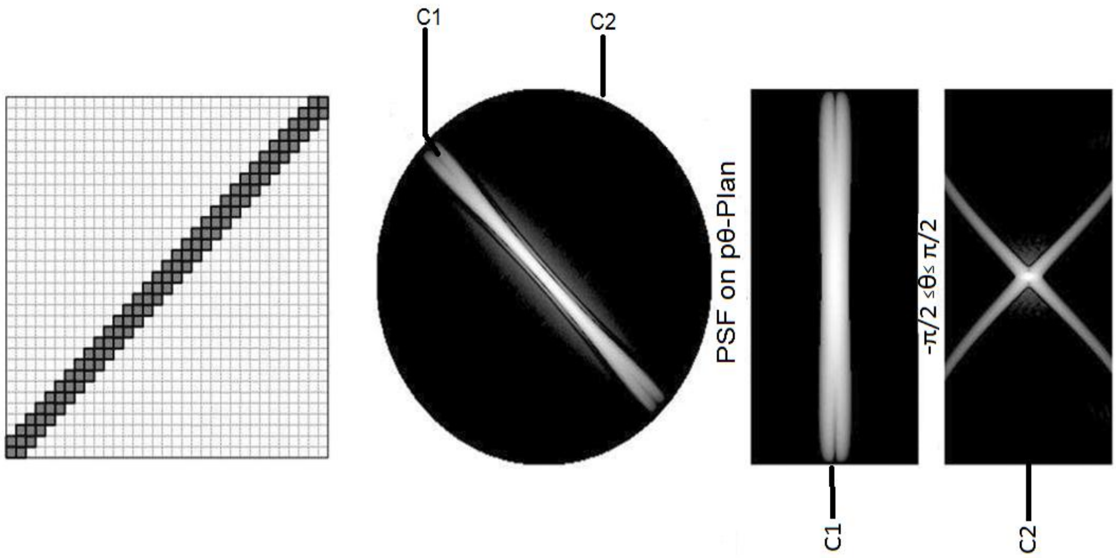


Figure 5.14: Linear arrays on a 32×32-element 2-D array.

In fan-beam development using an N × N element array (N>>1) having an inter-element spacing of d , the quantity of firings to create a pyramidal size with an angle of

$(\theta_P \times \theta_P)$ is $B_P \geq K\left(\frac{2Nd}{\lambda}\sin(\frac{\theta_P}{2})\right)$ 5.14

The letter (K) represents the amount of linear arrays creating the transmit array. This is accomplished by executing parallel receive beam-forming to compute the image pixels on the plane insonified by the transmit fan-beam. To create a 90^0 volumetric frame with $d = \lambda/2$, the least quantity of firings is calculated using the formula $K \times (\sqrt{2} \times N)$. In short, fan-beam development lessens the firing count from $O(N^2)$ to O(KN) as stated by Karaman et al. (2009). Fan-beam development consists of (K) successive firings for the reconstruction of pixels on a cross-sectional image plane, and therefore swells the vulnerability to tissue motion by a factor of K.

In the BRT-BCR array configuration, the image volume can be scanned by firing from only one of the transmit rows each time, or alternatively by firing the two rows at the same time. In the second case each firing produces a comb-shaped fan-beam as shown in Figure 5.15, and therefore two successive firings are needed to generate interleaved fan-beams.

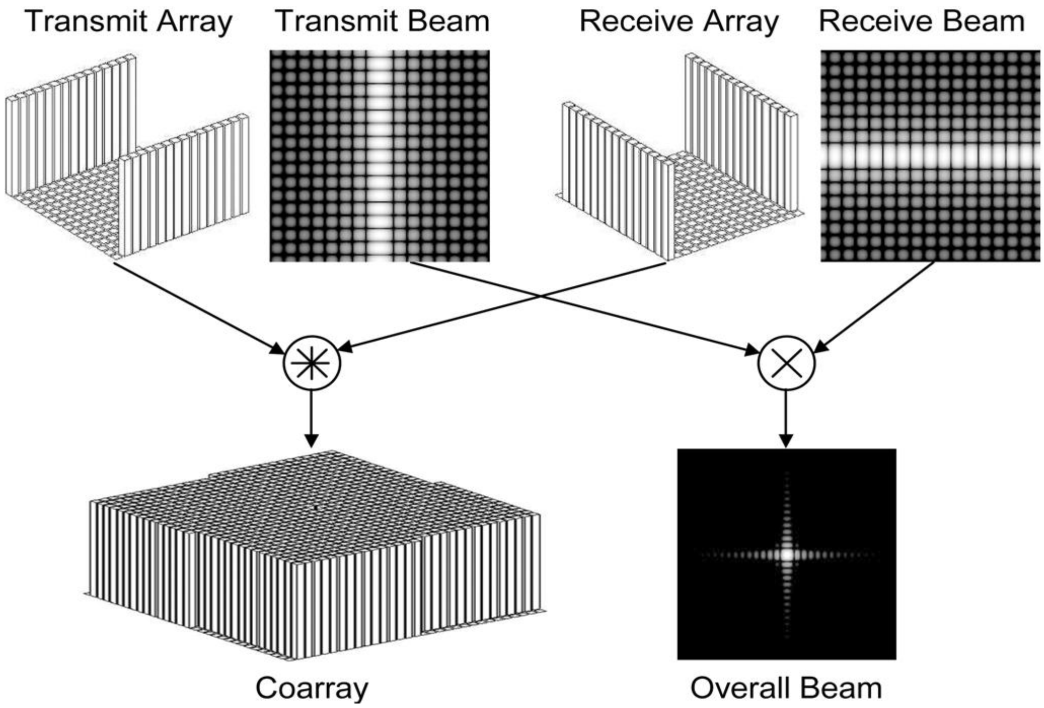


Figure 5.15 Concurrent firing from both rows of the transmit array in BRT-BCR, produces a comb-shaped fan-beam. (Karaman et al., 2009).

5.4 Analysing the Two-Way Response of 2D Sparse Periodic Designs

It is essential to ensure that the transmit response has zeros at the occasion of grating lobes in the receive response and vice versa when creating 2-D sparse periodic arrays (Austeng & Holm, 2002). Smith et al.. (1991) examined a number of configurations of

Mills cross arrays developed in this manner by simulating the two-way responses. Lockwood et al. (1996) and Lockwood and Foster (1996) investigated the effective orifice of sparse periodic arrays and employed the Vernier method to create 2-D Vernier arrays. The design is such that the receiver is built as a periodic array consisting of elements distributed uniformly all over the aperture with spacing p × d.
P represents the sparseness factor and d represents the inter-element spacing. The transmitter is designed in a similar way with element spacing (P-1)×d (Austeng & Holm, 2002).
A first-order estimation to the pulse echo reaction, W_{Pulse} (u, v), at a chosen central range, or in the far field, is the multiplication of each layout's continuous wave (CW) (Smith et al., 1991).

$$W_{pulse}(u,v) \approx W\frac{Tx}{CW}(u,v) \times W\frac{Rx}{CW}(u,v) \qquad 5.15$$

In the above formula, $u = \sin\phi\cos\theta$, $v = \sin\phi\sin\theta$, ϕ is azimuth angle and θ is the elevation angle. The location of grating lobes can be established approximately by assessing the CW response of every layout. The design technique can be additionally made simple because, for rectangular regular sparse periodic layouts, the reaction of the CW can be established by assessing the response of a 1-D array with the same aperture and periodicity as reported by Austeng and Holm (2002). The binary weights of a layout with periodicity P_x in x-direction and P_y in y-direction is shown with the following formula:

$$w(x,y) = w(x) \times w(y) \qquad 5.16$$

The CW response of this array can be separated and is proportional to

$Wcw(u,v) = W^{x}_{cw}(u) \times W^{y}_{cw}(v)$ (Johnson and Dudgeon, 1993) 5.17

The coordinate system can be turned around, and the identical method can be ensued for 2-D layouts with symmetry along the diagonals. Because the response can be split, the worst-case side-lobes will take place in directions matching the axes of symmetry of the layout and is equivalent to $\max_s [w_x(s), w_y(s)]$ (Austeng & Holm, 2002).

Lim (1990) states that the Fourier projection slice theorem suggests that a slice through the 2-D CW response can be established by projecting the 2-D element distribution on a line on the same course as the needed slice. In each course, is an equivalent 1-D array, a projection in that course. The level of the side-lobes and grating lobes in the response of the weighted array is usually inferior at the cost of a wider main-lobe, but the location of the grating lobes and zeros in the uv area is, nonetheless, similar (Austeng & Holm, 2002). A number of such arrays and their responses are illustrated in

Figure 5.16. The responses illustrate the covering of the simulated far-field CW beam pattern when supposing omnidirectional point elements. The method is only an estimate for arrays with circular footprint, but it provides a signal of the side-lobe pattern along the worst-case directions in the radiation model. The extra decline in side-lobe levels generated by the circular footprint includes an extra advantage (Austeng & Holm, 2002).

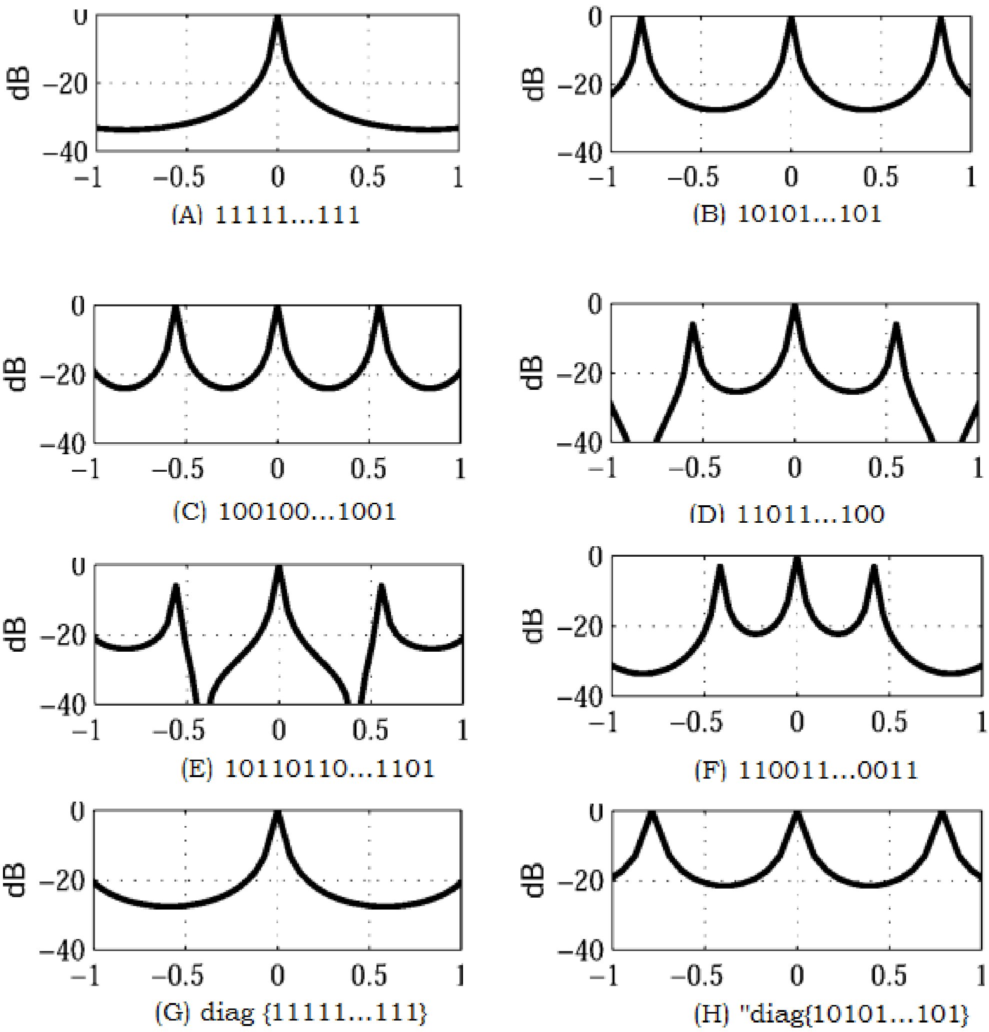


Figure 5.16 Different typical arrays and their responses (Austeng & Holm, 2002).

5.5 Basic characteristics of 3D ultrasound

5.5.1 Techniques of beam-forming

The universal name utilized to define the various methods used to merge single elements of an ultrasound array to create an image is beam forming. Beam forming can be made with by having the beam focalized or not. Thomenius (1996) reports that beam forming can be performed analogically or numerically in the temporal or in the frequency field. Beam forming uses various methods in current classical ultrasound imaging equipment and the most common is the “delay and sum” technique (Diarra, 2010).

5.5.1.1 Time range of beam forming (delay and sum)

The delay-and-sum beam forming technique shown in Figure 5.17 is the mainly used in current imaging scanners. It comprises of including delays (τ_n) on the probe single elements excitation ensuring that their responses arrive at the same time at the intended area which is named the focal point (Diarra, 2010).

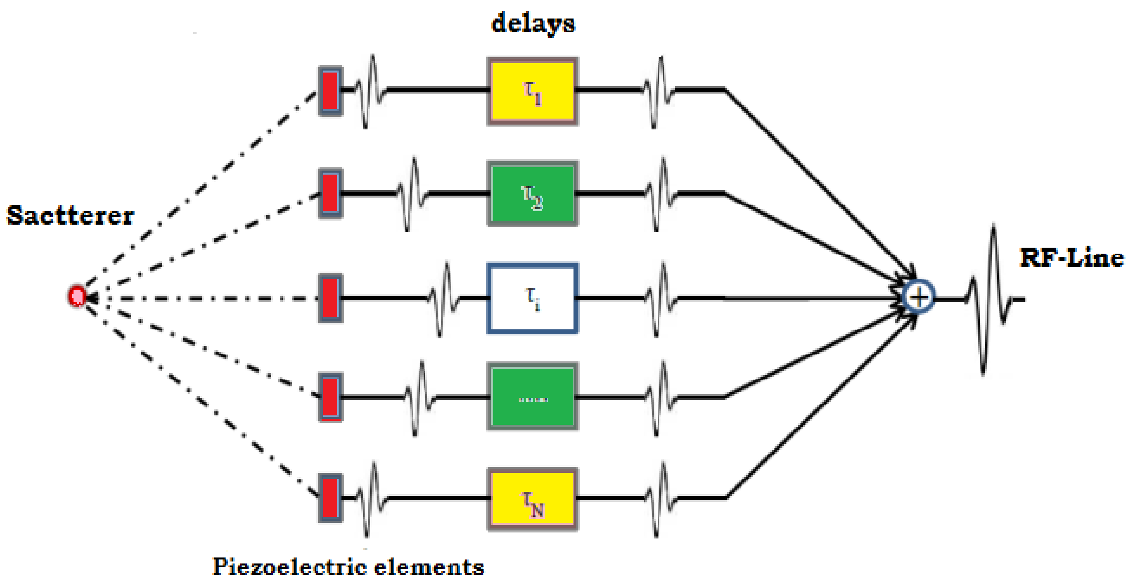


Figure 5.17: The delay-and-sum beam-forming technique.

The pressure summation provides an elevated intensity indicator which offers a superior image resolution and element penetration deepness in the medium delved into. In this method, linear scanning is prepared by employing the holdup on a collection of elements for every image line while in phased scanning the delay or hold up is made to the entire probe. In this technique, the beam is executed in the equal time for all frequencies (Diarra, 2010). To attain an extra identical beam, particular apodization coefficients can be directed to the array elements. The general apodization functions utilized are the windowing functions such as Hanning, Hamming, Blackman, etc… but any other adapted apodization function can be used. The default apodization is the rectangular window whereby all elements contain similar coefficient values as stated by Diarra (2010).

5.5.1.2 Frequency range of beam forming

The frequency range beam forming is a substitute to time domain beam forming. The frequent use of it has mainly been in 2D imaging (Mucci, 1984: Maranda, 1989) to take advantage of the swiftness of Fourier transform. There are two main clusters in frequency beam-forming. These include the direct methods and the approached methods (Maranda, 1989). Both of these methods have been modified to the 3D imaging as observed in some studies (Dhanantwari et al., 2004; Murino and Trucco, 1994).

5.5.1.3 Parallel processing

The parallel processing technique is a hopeful method for real time 3D volumetric imaging. This method is applied by many researchers including those from Duke University in the USA. Duke University has one of the most sophisticated teams in the origin of 2D arrays for 3D imaging. They developed a parallel beam forming algorithm known as Explososcan (Shattuck et al., 1984; Smith et al., a & b1991). This algorithm allows performance of real time volumetric acquisitions. It contains a 256 channel beam former at transmission and reception, with the capacity to produce up to 30 volumes each second (Light et al., 2008) by forming 16 image lines at every individual transmission (Ramm and Smith, 1990). In industry, a thick array probe of 3000 elements formed by Philips (Sonos 7500) utilised at a frame pace of 20 volumes/second uses as well the parallel processing. The 3000 elements are incorporated on an ASIC in the head of the probe and the received signals are amassed together to be funnelled by 128 channels in the direction of the processing system (Savord & Solomon, 2003). Two methods: (configurable array and sub-array beam forming) are used to achieve this probe.

5.5.1.4 Configurable array

In the configurable array, any individual element can be actively attached to one next to it by bringing into action four switches which surround it and can be programmed (Figure 5.18). A comparable 1D probe can be achieved in any direction (lateral, diagonal, elevation) as shown in Figure 5.9, depending on the spot with exploring interest and a appropriate switch choice. Volumetric acquisition is comparatively easy in this configuration as array elements can be placed into action in any direction and the obtained signals are multiplexed in the probe head to evade the use of supplementary channels relate to a 1D probe. The method’s disadvantage is the noise created by the opening and shutting operations of the switches which depreciate the image signal-to-noise ratio (Diarra, 2010).

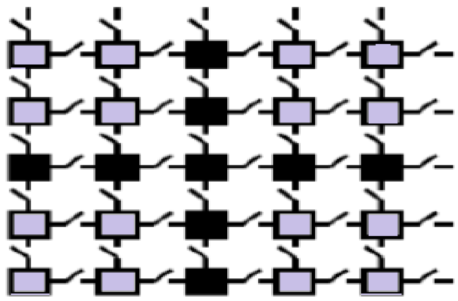


Figure 5.18: reconfigurable array. Gray elements are connected (Savord and Solomon, 2003).

5.5.1.5 Beam forming of sub-array

The sub-array beam forming technique operates as the conventional 1D beam forming except in two phases. Each sub-array (3000/128 elements) creates a 1D ultrasound beam which is then guided through the 128 channels in parallel (Figure 5.19).

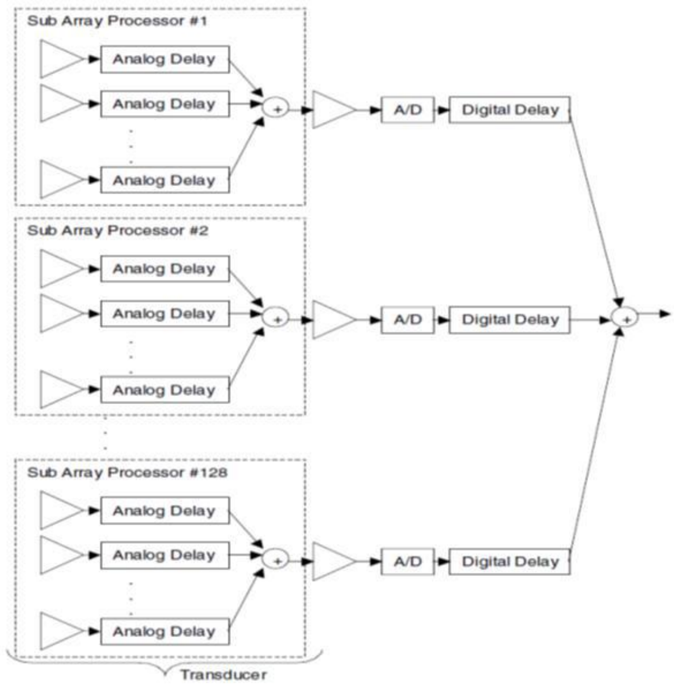


Figure 5.19: beam-forming using sub-arrays (Savord and Solomon, 2003).

This parallelization evades the employing of supplementary channels and decreases the system complexity in reception. With this configuration, the probe can reach an immense frame rate, 20 volumes/second for the Sonos 7500 (Diarra, 2010).

5.5.2 Reconstruction of 3D volume

The reconstruction of 3D volume is the method used to interpose conventional 2D slices to 3D-like structures. Both 3D mechanical and matrix arrays permit volumetric attainment but with unlike speed. The first 3D imaging was executed by the user's manual displacement of the 1D probe and is known as freehand 3D ultrasound imaging (Gee et al., 2002; Housden et al., 2008). Sophisticated reconstruction algorithms are suggested in literature to exact the indistinctness in the slice attainment but this method continues to be hard to employ normally. Motorized probes were then launched to automatize the 2D planes attainment and to sustain a steady scanning step amid dissimilar slices making the volume. These mechanical probes build amounts by obtaining several 2D images by means of a stepper or a nonstop current motor (seldom) whose speed is about 1 rad/s (or 60 degrees/s) for the majority of them (Pospisil et al., 2010) and this regulates the volume rate. In common, 3D mechanical probes generate 1 to 4 volumes/second (volume of 25 to 50 images, 50 to 100 lines /image) depending on the number of planes (explored sector) and the extent of penetration. Many 3D volume reconstruction methods with the mechanical probes have been made and the main methods are the pyramidal and the rotational techniques (Diarra, 2010).

The coordinates of the various planes in pyramidal volume imaging can be conveyed by means of the 3D rotation matrix R_x as observed in Figure 5.20. In this situation the x axis is fixed and the rotation is made about the y and z axis. This kind of scanning provides parallel planes in the elevation direction and allows the reconstruction of pyramidal quantities (Belohlavek et al., 1993). It is comparable to the technique used in 3D mechanical volume imaging. The angle θ is in the lateral direction (x axis) and φ in the elevation (y axis). The scanning is made in the sector range from $-\alpha/2$ to $\alpha/2$ (α being θ or φ) (Diarra, 2010).

$$R_X = \begin{pmatrix} 1 & 0 & 0 \\ 0 & \cos(\varphi) & -\sin(\varphi) \\ 0 & \sin(\varphi) & \cos(\varphi) \end{pmatrix} \quad \theta \qquad 5.18$$

In the 2D imaging, the coordinates of a plane are fixed

$$\begin{cases} x = d_{focus} * \sin(\theta) \\ y = 0 \\ z = d_{focus} * \cos(\theta) \end{cases} \qquad 5.19$$

These two equations (5.18, 5.19) provide the final illustration in the 3D pyramidal imaging

$$\begin{cases} x = d_{focus} * \sin(\theta) \\ y = d_{focus} * \cos(\theta) * \sin(\varphi) \\ z = d_{focus} * \cos(\theta) * \cos(\varphi) \end{cases} \qquad 5.20$$

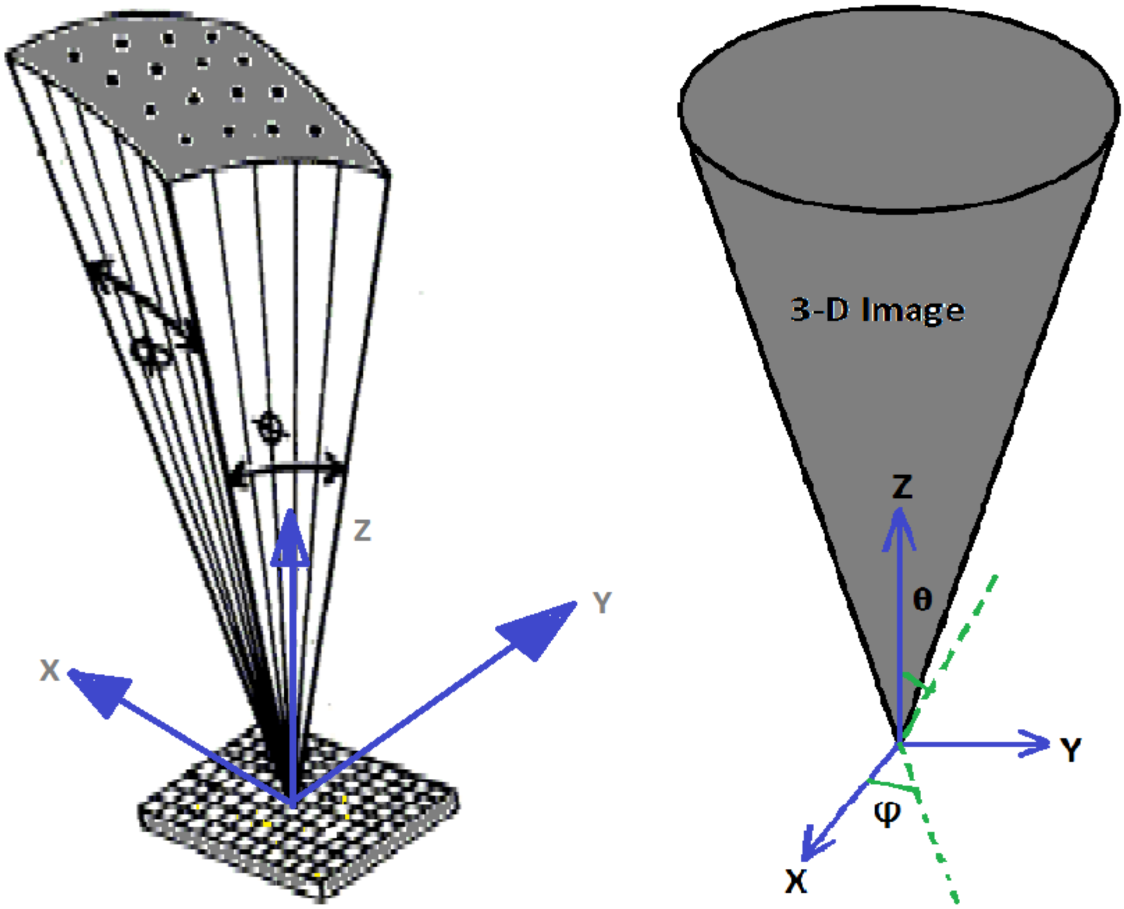


Figure 5.20: (A) the pyramidal 3D scanning strategies up dated from Belohlavek et al., 1993). (B) The rotational 3D scanning strategies up dated from (Tekes et al., 2011).

5.5.3 Intensive array and standard used element positioning

The dense array is the 2D array entirely packed where no lessening technique is employed. The dense array is also termed the fully sampled array. It comprises the reference array in every element quantity decrease studies (Diarra, 2010).

The mainly employed grid for the 2D arrays is the rectangular (or square) one (Figure 5.21a). This latter is simple to form because it is an absolute extension of the conventional 1D probe. Several other grids are suggested in literature including the circular one (Figure 5.21b). The circular elements nature offers an improved beam design in terms of grating lobes compared to the square grid but it expands the main lobe (Mendelsohn and Wiener-Avnear, 2002). Spiral configuration in Figure 5.21c was in addition tried in some studies with the conclusion of a minor beam pattern enhancement in comparison to the aforementioned configurations (Tweedie et al., 2009).

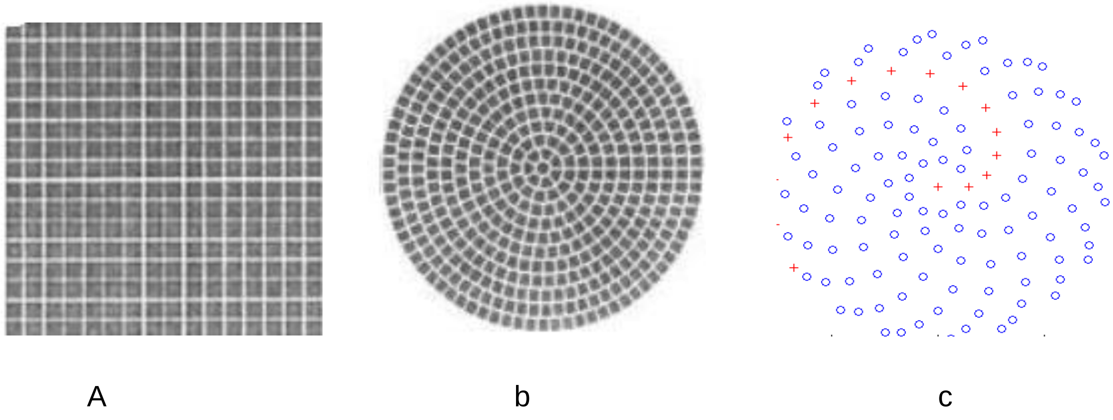


Figure 5.21: different elements configuration of 2D arrays (Diarra, 2010).

5.5.4 Element number reduction techniques

The element number reduction techniques form two main groups. One of the groups is one which successively utilizes a subset of elements to direct the entire array (synthetic aperture and row-column addressing). The second group entirely neutralizes some elements (edge element deactivation and sparse arrays). The latter group (the one studied in this work) offers improved viewpoints for real-time 3D imaging than the first one as it supplies 2D arrays entirely controllable by present scanners. These reduction techniques are not essential for small arrays utilised for viability studies stressing the efficiency of 2D array when compared to the 1D probe (Weber et al., 1994; Weber et al., 1999; Austeng and Holm, 2000; Eames and Hossack, 2008; Fuller et al., 2008).

5.6 Summary

Four reduced redundancy 2-D array configurations (XT-FR, XT-PR, XT-BR and BRT-BCR) for miniature 3-D ultrasonic imaging systems have been reviewed. 3-D scanning using fan-beams generated by the transmit linear arrays is discussed and the overall array response through coherent summation of the individual responses of each transmit–receive array pairs is presented.

CHAPTER SIX

THE KNOWLEDGE OF USERS REGARDING SAFETY OF ULTRASOUND DURING PREGNANCY IN HOSPITALS

This chapter provides a synthesis of the research findings. Data from questionnaires were entered into an Excel spread sheet. The data were then analysed descriptively. The findings are presented in figures, tables and narratively.

6.1 Introduction

A total of 30 users of ultrasound participated in this study. Eighteen of those completed the survey, for a response rate of 60%. Twelve (12) users did not respond, a non-response rate of 40%. The completed questionnaires were from five (5) different hospitals (including public and private) in Cape Town. Most of participants were sonographers, for a response rate of fifty per cent (50%) (n=9). The number of ultrasound examinations per day ranged between 4 and 42, with a mean of 18.

About sixty-one per cent (61%) (n=11) of the participants were from the private sector. Almost all the participants reported that ultrasound examinations were safe, for a response rate of 100% (n=17). Sixty five per cent (65%) (n=11) of the end users agreed that there should be limitations regarding the number of ultrasound examinations in low-risk pregnancies. About eighty-three per cent (83%) (n=15) of the participants did not agree with keepsake ultrasound examinations.

Approximately three-quarters (72%) of the participants agreed that they were familiar with the term thermal index (TI). These included a physician, a gynaecologist and a radiologist, but most of the participants did not answer the specific question regarding the TI correctly. Participants were also requested to respond whether they knew what MI was. Slightly less than half of the participants knew what the mechanical index was, for a response rate of 39% (n=11).

The majority (n=12) did not know that the acoustic indices TI and MI are displayed on the monitor of the ultrasound machine during the examinations. About seventy-eight per cent (78%) (n=14) of the participants did not observe these indicators during the examinations.

6.2 Socio-demographic information of participants

6.2.1 Workplace

Figure 6.1 shows the places of work where participants were working. The majority (n=11) of the participants in this study were from the private sector.

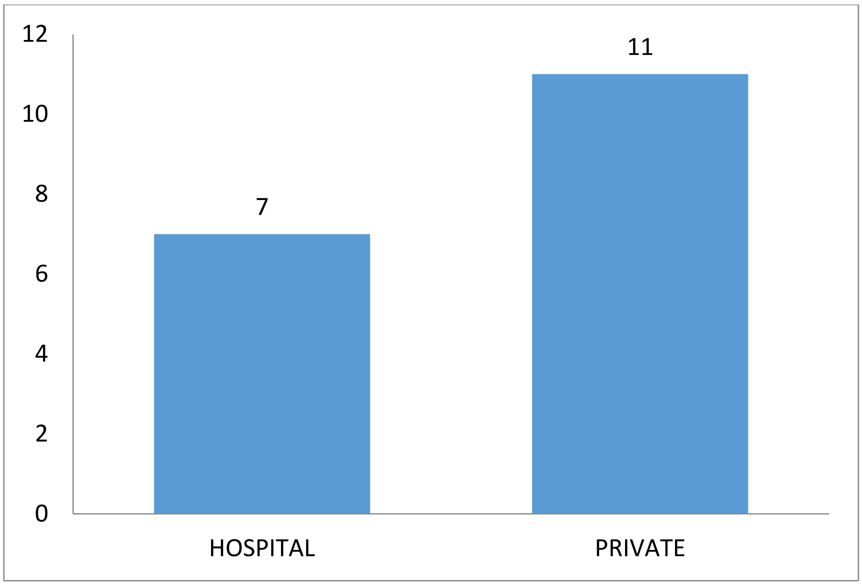


Figure 6.1: Place of work of participants by numbers.

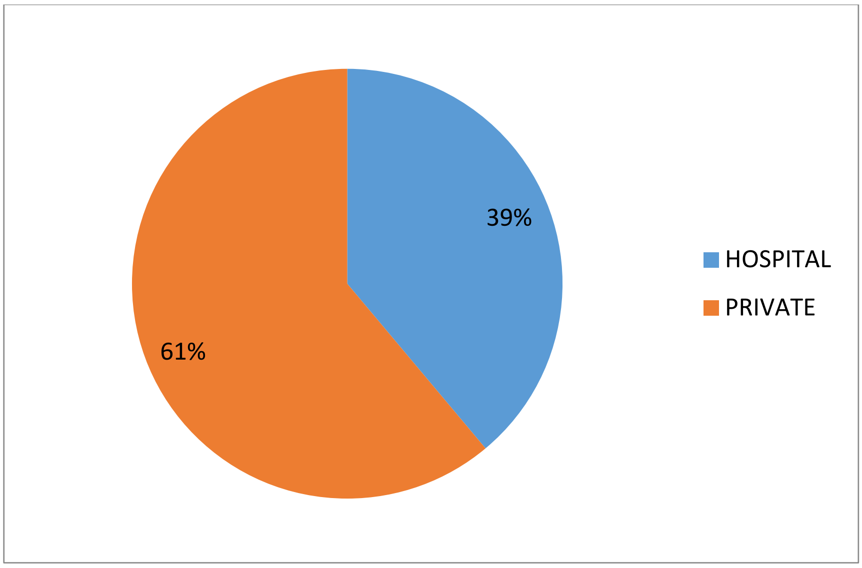


Figure 6.2: Place of work of participants by percentage.

6.2.2 Gender

The figures below (Figures 6.3 and 6.4) illustrate gender distribution among the participants. Seventy-eight per cent (78%) of the participants (n=14) were female.

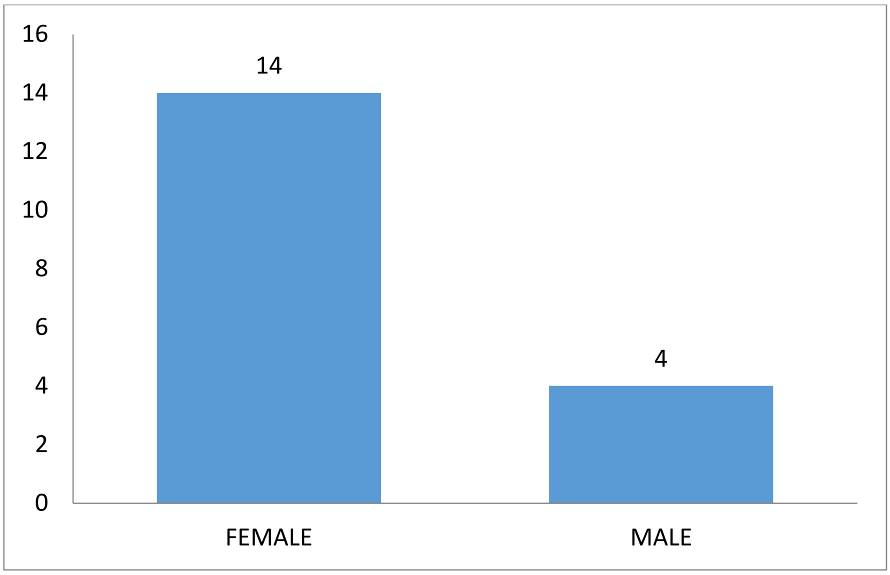


Figure 6.3 Gender of participants by numbers.

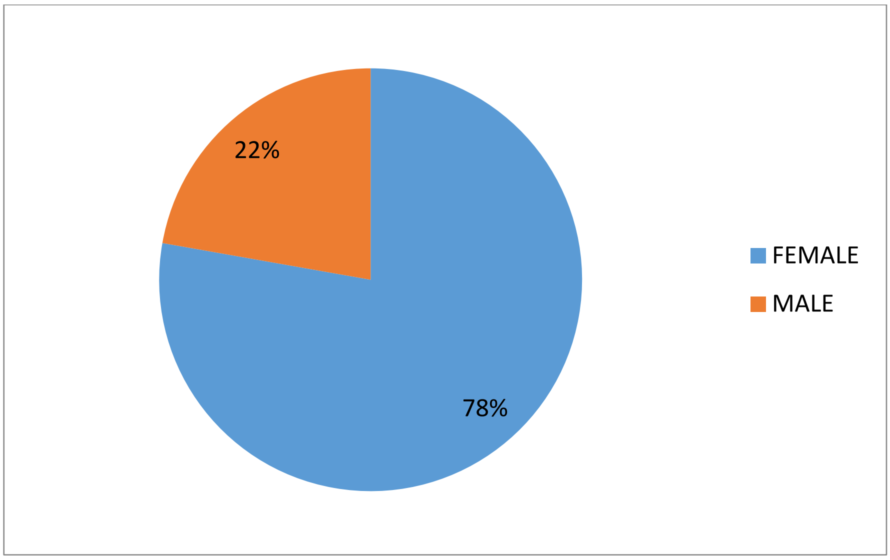


Figure 6.4 Gender of participants by percentage.

6.2.3 Profession

Various professions were represented amongst the participants. These included physicians, nurses, sonographers and radiologists. Figures 6.5 and 6.6 show the numbers of the professions represented. Fifty per cent (50%) (n=9) were qualified sonographers and were the majority. Almost twenty-two (22%) per cent (n=4) were physicians and only one, six per cent (6%) was a radiologist.

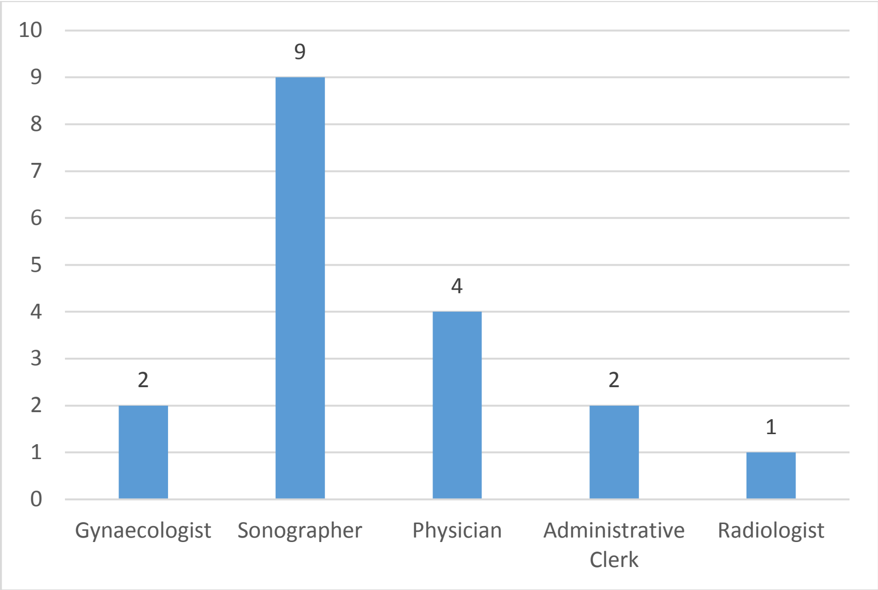


Figure 6.5: Professions of participants by numbers.

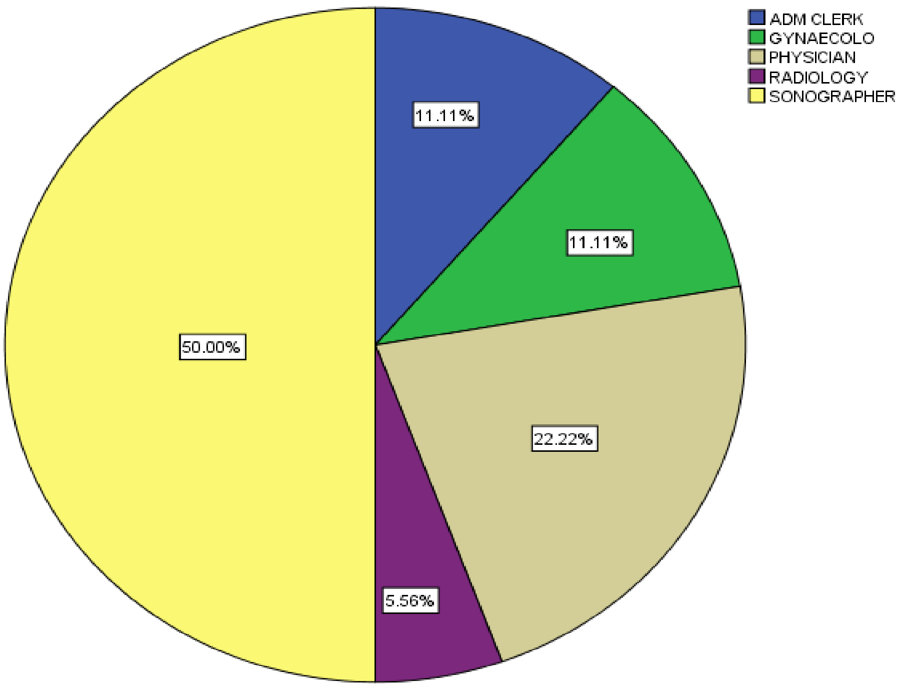


Figure 6.6: Professions of participants by percentage.

6.2.4 Years of professional experience

The average number of years of professional experience of participants was 14 years. The majority (n=8) of the participants had between 6 and 10 years of experience. Seven (7) had professional work experience of 13 to 20 years and none had experience of less than six years, as shown in Table 6.1.

Table 6.1: Years of experience in your profession

Years		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	6	3	16.7	17.6	17.6
	7	1	5.6	5.9	23.5
	9	1	5.6	5.9	29.4
	10	3	16.7	17.6	47.1
	13	1	5.6	5.9	52.9
	15	2	11.1	11.8	64.7
	19	1	5.6	5.9	70.6
	20	3	16.7	17.6	88.2
	25	2	11.1	11.8	100.0
	Total	17	94.4	100.0	
Missing	999	1	5.6		
Total		18	100.0		

6.2.5 Years of experience in sonography

Table 6.2 illustrates years of experience in sonography. Fifteen (15) participants responded to the question related to experience in the field of sonography. The average length of experience was 12 years. Six (6) participants had professional work experience of 2 to 10 years. Nine (8) had professional work experience of 12 to 25 years (Table 6.2).

Table 6.2: Years of experience in sonography

Years		Frequency	Percentage	Valid Percentage	Cumulative Percentage
Valid	2	1	5.6	6.7	6.7
	4	1	5.6	6.7	13.3
	7	2	11.1	13.3	26.7
	8	1	5.6	6.7	33.3
	10	1	5.6	6.7	40.0
	12	1	5.6	6.7	46.7
	13	2	11.1	13.3	60.0
	15	2	11.1	13.3	73.3
	16	1	5.6	6.7	80.0
	20	2	11.1	13.3	93.3
	25	1	5.6	6.7	100.0
	Total	15	83.3	100.0	
Missing	999	3	16.7		
Total		18	100.0		

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6.2.6 Average number of ultrasound examinations per day

The average number of ultrasound examinations that participants performed per day was 18. Most of the participants reported that they performed 11 to 20 ultrasounds per day at their institutions. Only two participants reported more than 30 ultrasound examinations per day.

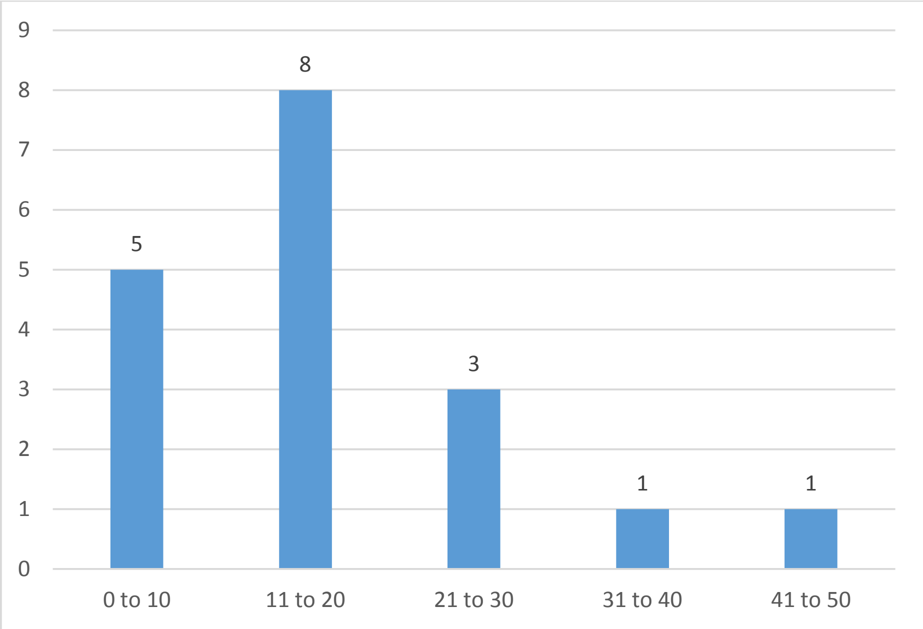


Figure 6.7 Ultrasound examinations per day.

6.2.7 Safety of ultrasound examinations

All participants reported that ultrasound examinations were safe, as can be observed in Figure 6.8.

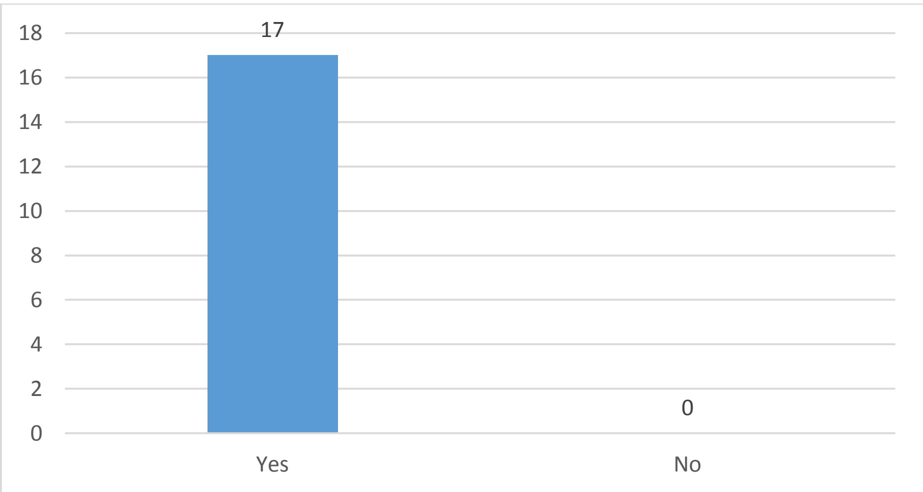


Figure 6.8 Safety of ultrasound examinations according to participants.

6.2.8 Limit of ultrasound examinations

Participants were asked if they thought there should be limitations regarding the number of ultrasound examinations ‘low-risk’ pregnant women should have during pregnancy. Eleven participants agreed that there should be a limit and five did not, as shown in Figure 6.9.

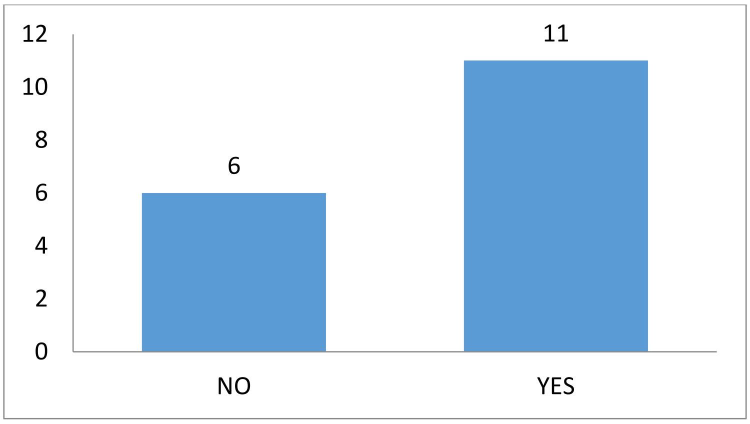


Figure 6.9 Limit in numbers of ultrasound examinations.

6.2.9 Number of ultrasound examinations for women during low-risk pregnancy

Many of the participants indicated that women experiencing ‘low-risk’ pregnancy should receive less than 4 ultrasound examinations. A common option was three examinations.

Table 6.3 Ultrasound examinations during low-risk pregnancy

Number of examinations	Participants
2	2
3	6
4	3
5	1
6	1
8	1
10	1
≥ 9	1
2 to 3	2

6.2.10 Adverse effects of ultrasound

Fourteen (14) participants stated that there are no adverse effects of ultrasound to the foetus and three (3) stated yes. Those that stated that there are adverse effects on the foetus gave several explanations.

The explanations of how ultrasound affects the foetus according to participants are as follows:

- The ultrasound waves heat up the foetus
- Thermal and non-thermal effects occur if scan times are longer
- Dependent on time scanned
- Overuse of Doppler can create heating
- If Doppler which is flawed is used, this could generate a heat focal point
- Depends on type of exam

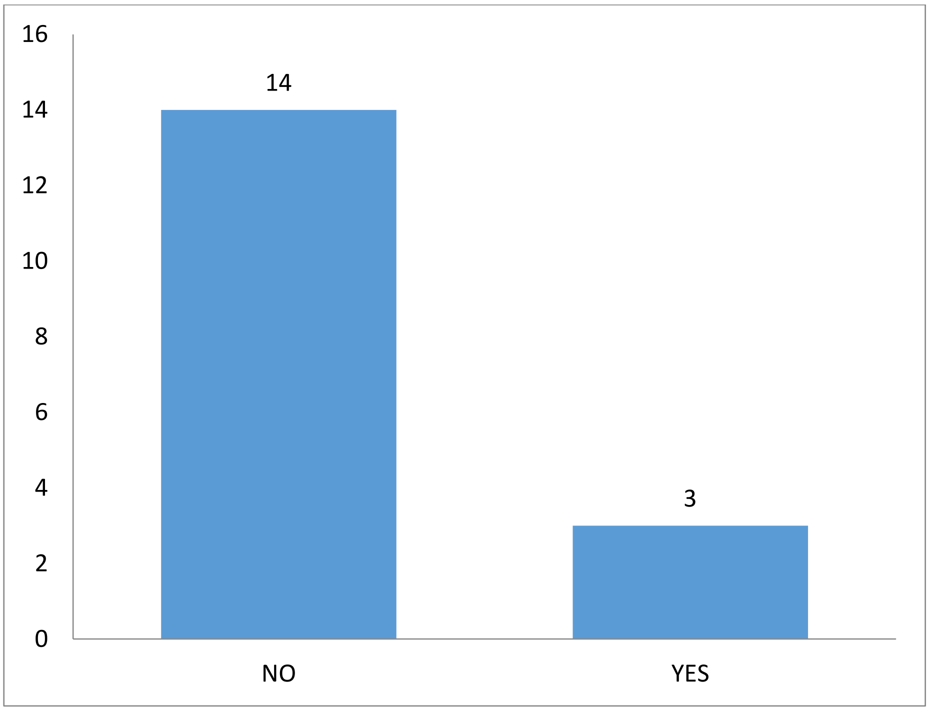


Figure 6.10: Adverse effects of ultrasound on the foetus.

6.2.11 Bio-effects on the foetus during ultrasound examinations

The majority of the participants (n=11) stated that there are no bio-effects to the foetus during ultrasound examinations and four (4) stated that there are. Three (3) participants did not respond to the question.

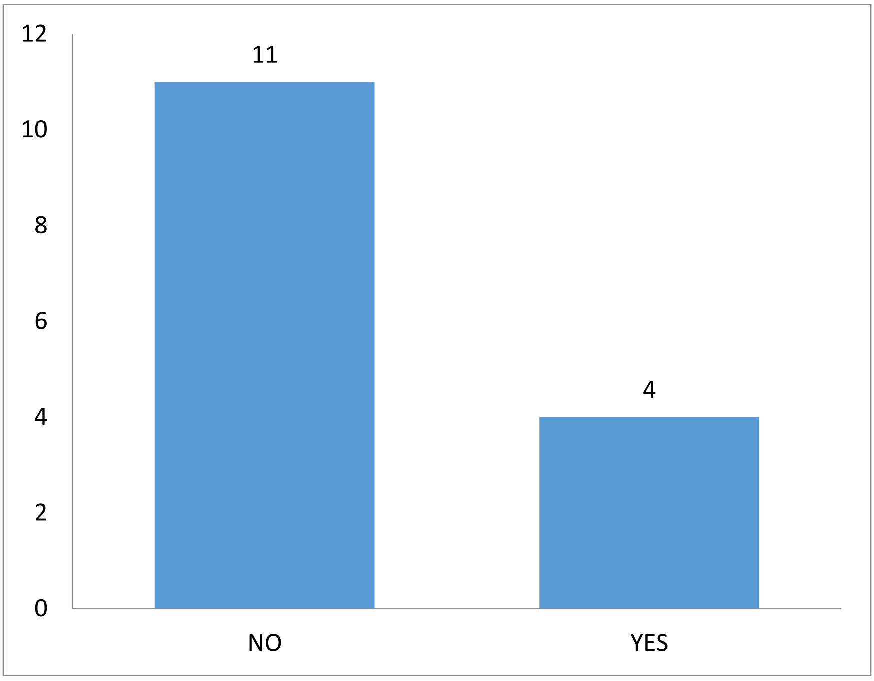


Figure 6.11 Bio-effects of ultrasound on the foetus.

6.2.12 Knowledge of thermal index

Participants were asked if they knew what the thermal index was. A large number of participants (n=13) stated that they knew what the term thermal index meant. Five (5) did not know what the thermal index is. These included a physician, a gynaecologist and a radiologist.

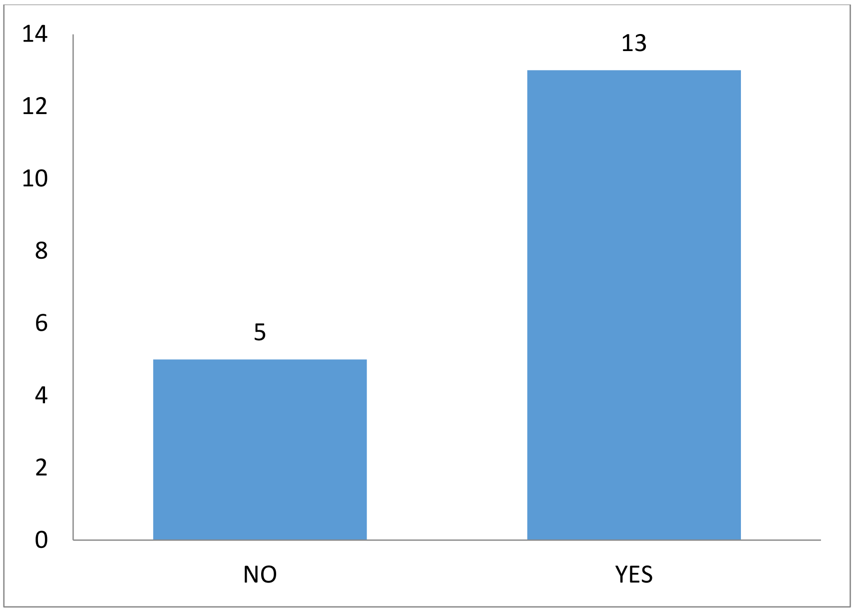


Figure 6.12: Knowledge of the thermal index.

6.2.13 Participant's definition of thermal index

Various meanings were provided as to what the thermal index is. Table 6.4 below lists the definitions as provided by the participants. Not all who stated that they knew what TI is gave a definition.

Table 6.4 Definition of Thermal Index (TI) as define by participants

Definition of Thermal Index (TI) as define by participants:
Tissue heating index.
Potential for u/s to increase temperature.
The heat increase in tissue of foetus.
Indicator of thermal risk during ultrasound.
Ratio of total acoustic power to that required raising a max temperature.
A heat focal point.
Increased heat gives increased mitosis and brain of rats.
Not sure.
Amount of heat generated during the exam.
Change in temperature.
Potential for heat generation by colour Doppler.

6.2.14 Knowledge of mechanical index

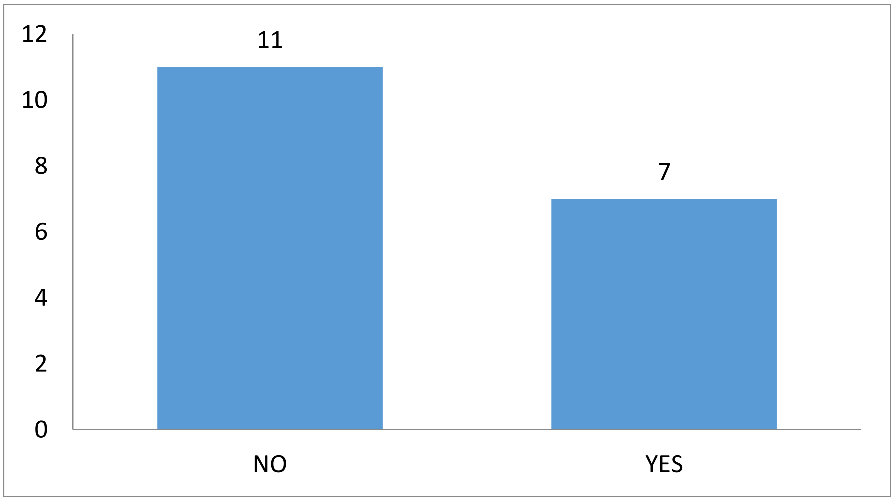


Figure 6.13 Knowledge of mechanical index.

Participants were requested to respond whether they knew what mechanical index was. Slightly less than half of the participants knew what mechanical index was. Seven (7) individuals stated that they knew what it was while eleven (11) did not as shown in Figure (6.13) above.

6.2.15 Participant's definition of mechanical index

Various definitions were provided by the participants. Table 6.5 lists the particular definitions. Of the eight individuals that stated that they knew what mechanical index was, one was not sure of the definition.

Table 6.5 Meaning of mechanical index

Definitions of Mechanical Index (MI) as mentioned by participants:
Estimates the degree of bio-effects on foetus.
Potential for u/s to induce non-thermal effects.
The estimation of degree of bio-effects on the foetus.
Level of mechanic effects.
Estimate of the maximum amplitude of the pressure pulse in tissue.
Not sure.
Risk of cavitation.

6.2.16 Location of MI and TI

Participants were asked if they knew the location of the thermal and mechanical indices. The majority (n=12) did not know the location of the indices. Three said that they knew the location and gave the correct location of the indices (see Figure 6.14).

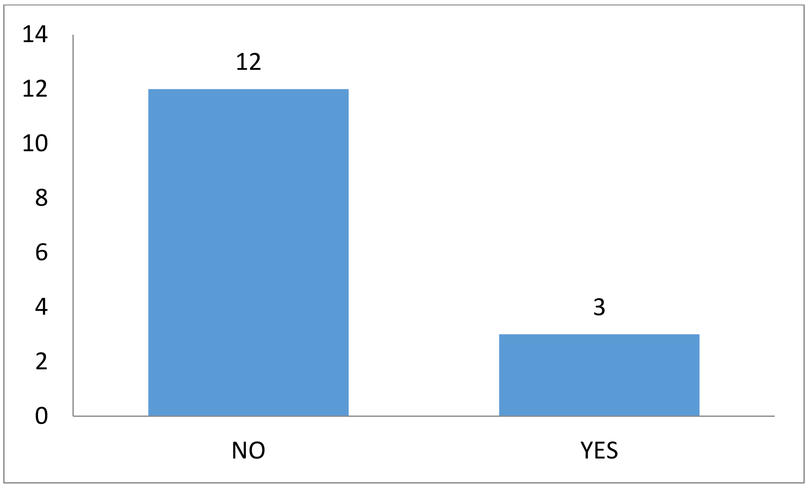


Figure 6.14: Knowledge of the location of thermal and mechanical indices.

6.2.17 Observation of indicators during ultrasound examinations

Sixteen (16) participants responded to the question on observation of indicators during ultrasound examinations. The majority of the participants (n=14) indicated that they did not observe indicators during ultrasound examinations. Only two (2) participants indicated that they did.

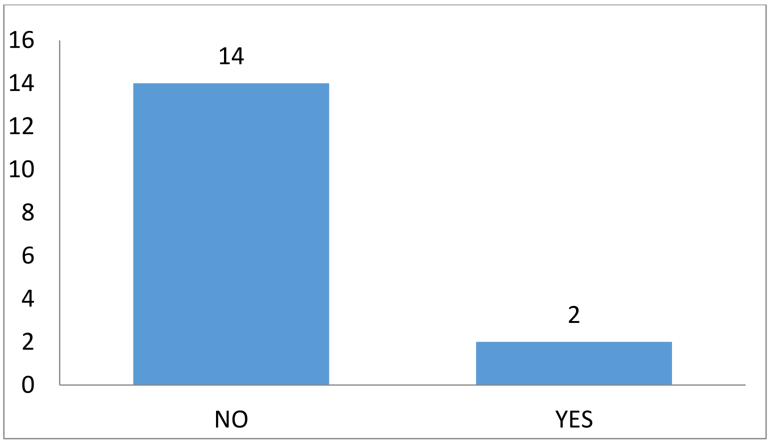


Figure 6.15 Observation of indicators during ultrasound examinations.

6.2.18 Rise in thermal and mechanical index

Respondents were asked to indicate if they knew what can cause the rise in the value of TI and MI. Figure 6.16 provides information on the responses. A total of thirteen (13) participants did not know what can cause a rise in thermal and mechanical index values. One participant did not respond to the question.

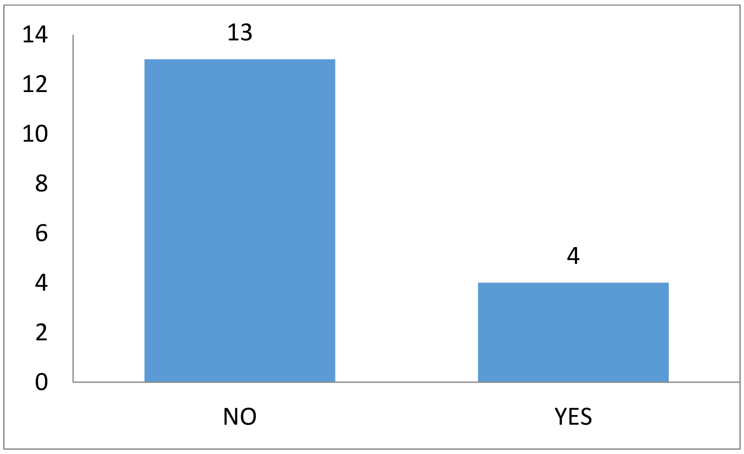


Figure 6.16 Knowledge of causes of rise in thermal and mechanical index values.

Table 6.6 below shows the specific information provided by participants as to what they believed can make the values of thermal and mechanical indices to rise. None of the participants provided a correct answer.

Table 6.6 Causes of rise in thermal and mechanical index values.

Causes of rise in TI & MI as mentioned by participants:
Colour flow mapping and Doppler. Long scan periods and increased power output of machine. Pulse wave Doppler and colour Doppler. Length of examination of TVS.

6.2.19 Rise in temperature for specific rise in thermal index values

For any particular value of thermal index, there is a specific rise in temperature. Participants were asked by how much the temperature would rise for a thermal index value of 1.0. None of the participants provided a correct answer. One participant did not respond. Eleven (11) indicated that they did not know and six (6) provided a wrong answer while the correct answer is 1.5. So thermal index (TI) value of 1.0 the temperature would rise to 1.5 C^0.

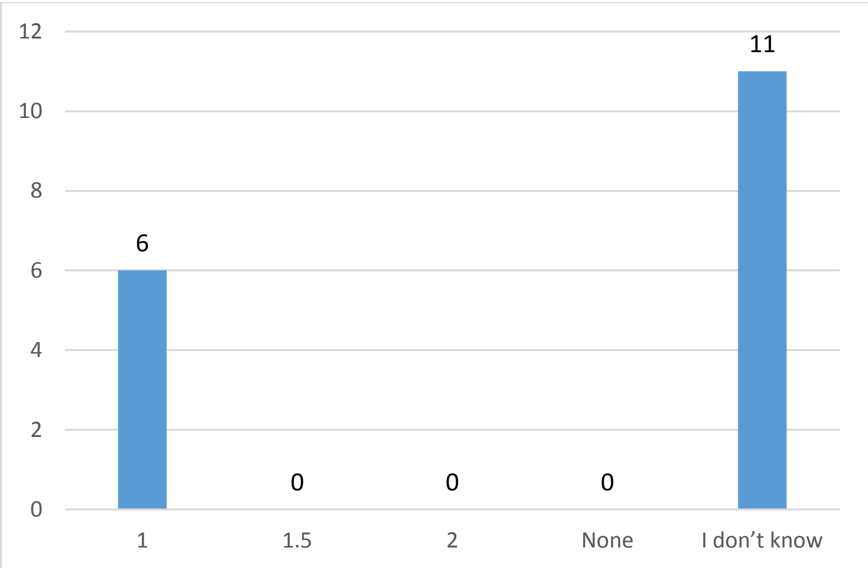


Figure 6.17 Rise in temperature for 1.0 thermal index value by numbers.

5.2.20 Global maximum mechanical index

Seventeen participants responded to the question on the global maximum mechanical index. Thirteen (13) participants indicated that they did not know the global maximum mechanical index and only two (2) provided the correct answer, as illustrated in Figure 6.18.

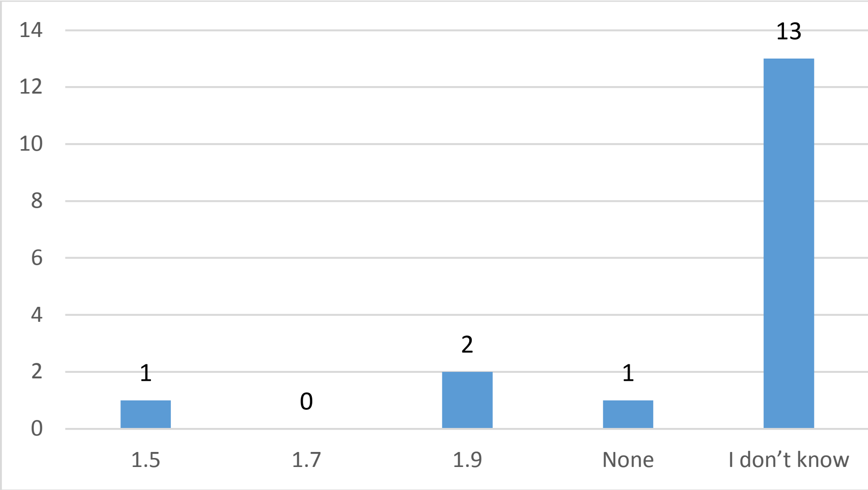


Figure 6.18 Knowledge of the global maximum mechanical index.

6.2.21 Identifying thermal and mechanical indices during examinations

All participants responded to the question on how they could identify the thermal and mechanical indices during examinations. Various options were provided. Six stated that they could look it up in a text book and seven said they could read it off the monitor during the examination. Three indicated that they did not know.

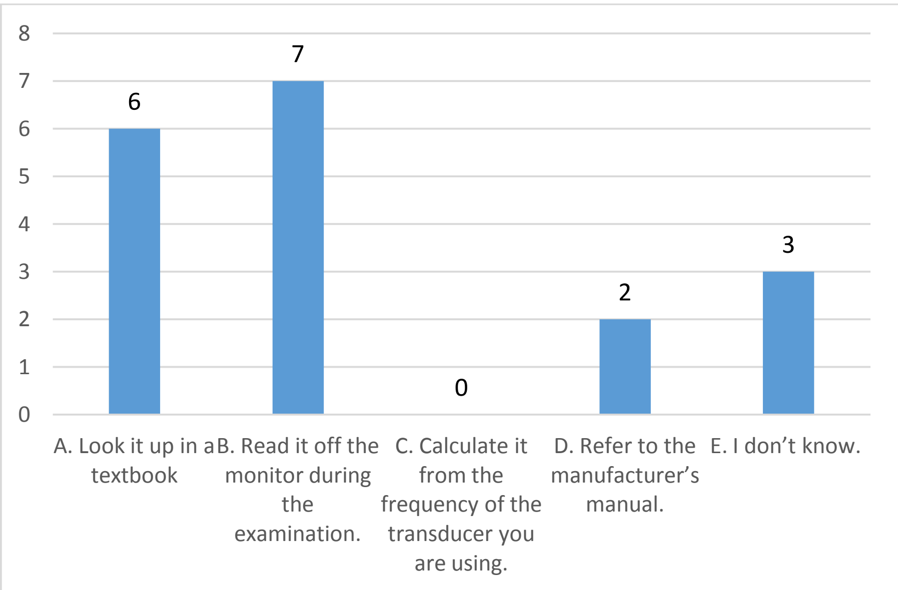


Figure 6.19 Identifying thermal and mechanical indices by numbers.

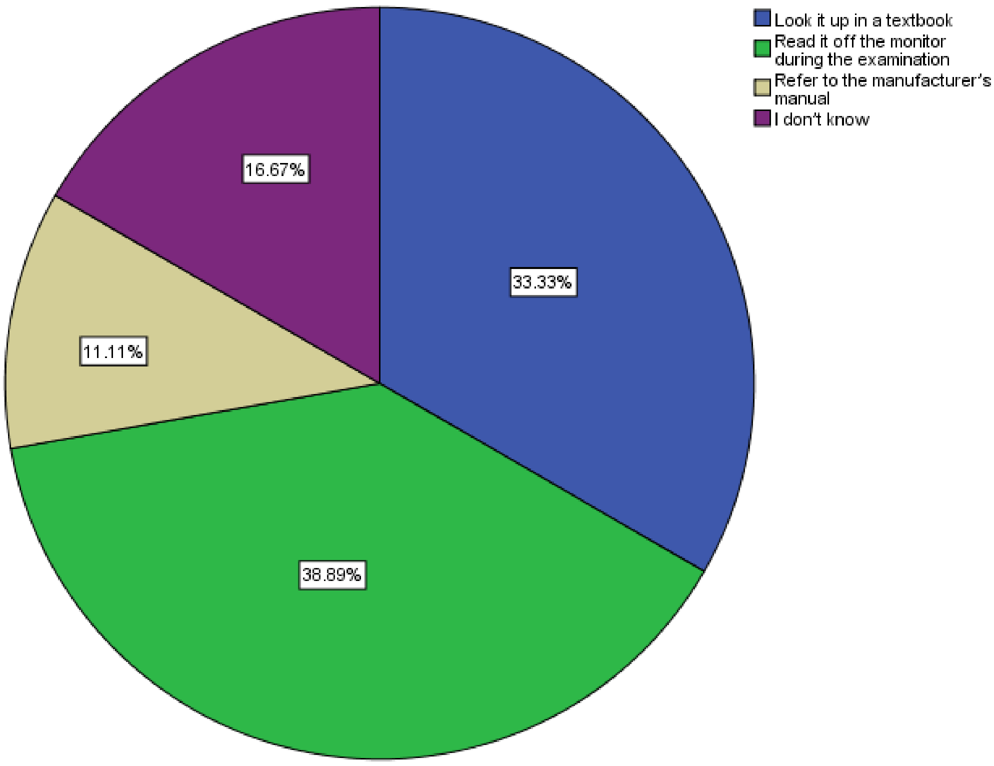


Figure 6.20 Identifying thermal and mechanical indices by percentage.

6.2.22 Use of ultrasound for entertainment

Participants were asked what they thought about using ultrasound for entertainment such as keepsake photos of the unborn child performed in a nonmedical facility. Fifteen (15) stated that it is not right to use it for that. Three (3) of them agreed that ultrasound could be used for entertainment.

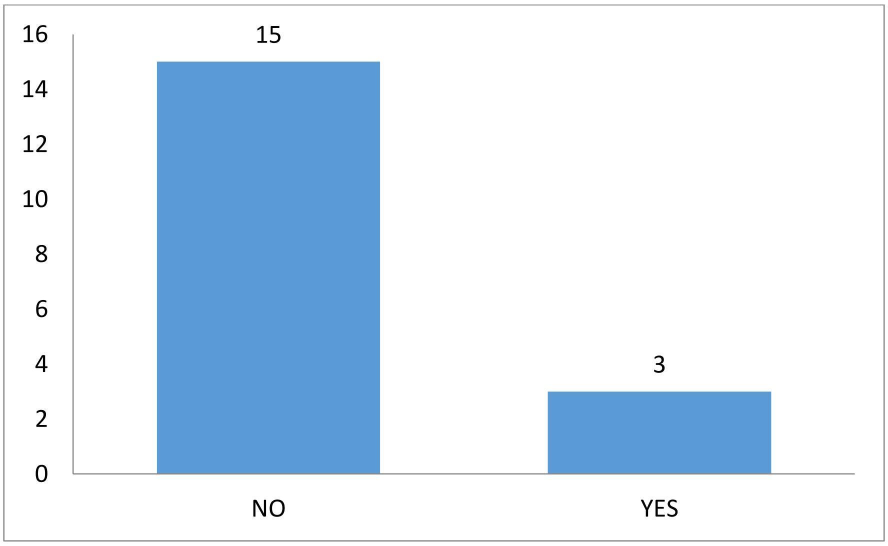


Figure 6.21 Using ultrasound for entertainment, by numbers.

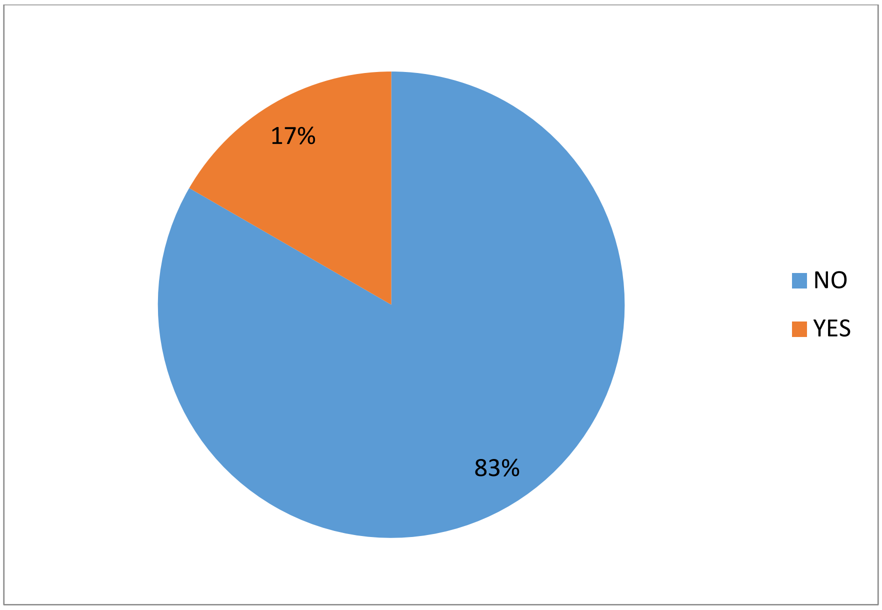


Figure 6.22 Using ultrasound for entertainment, by percentage.

6.3 Summary

This chapter provides a synthesis of the research findings. Data from questionnaires were entered into an Excel spread sheet. The data are then analysed descriptively. The findings are presented in figures, tables and narratively. Statistical analyses are performed using the SPSS package (SPSS Inc., Chicago, IL).

CHAPTER SEVEN

DISCUSSION

7.1 Preface

There is always concern regarding ultrasound end users' knowledge of safety issues. During this study a questionnaire was distributed to professionals using ultrasound for foetal examinations in Cape Town. The study included 18 participants in different professions and from five different hospitals. Half of the participants (50%) were sonographers and nearly twenty-two per cent (22%) were physicians. Fourteen (78%) of the participants were females and the majority (61%) were working in private practice (see Table 7.1).

Table 7.1: Characteristics of the study group

Characteristics	Result
Sex	
Male	4 (22%)
Female	14 (78%)
profession	
Admin Clerk	2 (11.11%)
Gynaecology	2 (11.11%)
Physician	4 (22.22%)
Radiology	1 (5.56%)
Sonographer	9 (50%)
Place of work	
Hospital	7 (39%)
Private practice	11 (61%)
Average examinations/day	18 / day

Almost seventy-two per cent (72%) knew what the meaning of TI is, and just thirty-three per cent (33%) could give a perfect definition. Thirty-nine per cent (39%) knew what the meaning of MI is, but only twenty-two per cent (22%) could give a correct definition of MI. Only twenty per cent (20%) knew the location of the indices on their own machines (see Table 7.2).

Table 7.2: Knowledge of safety issues.

Characteristics	Result
Familiar with the term TI.	13 (72%)
Familiar with the term MI.	7 (39%)
Correct answer of TI definition.	6 (33%)
Correct answer of MI definition.	4 (22%)
Knowledge of location of TI/MI.	3 (20%)

Unfortunately, the study does not show a good background about acoustic output indices. The participants show poor knowledge of safety issues, at least from the gynaecologist and the physician.

Most of the participants did not answer the TI question correctly, and even fewer answered the MI question correctly. The main purpose of the output display standard (ODS) was to provide the capability for end users of diagnostic ultrasound to operate their own devices at higher levels to increase diagnostic capabilities. The ODS did not specify any upper limits with a specific acoustic output under full control of the end users, as was mentioned in Chapter Three, section 2.

Manufacturers have been forced to supply information on safety indices (i.e. the TI and MI values), but the responsibility for the ultrasound output energy is, eventually, the end users'. End users of diagnostic ultrasound should be aware of the output energy, how to control it, and, accordingly, how to use the device safely. However, where the end users are not aware of the acoustic indices or where to find them, one can believe that they will not be able to control them. Almost 83% of the ultrasound professionals actually disapproved of keepsake ultrasound examinations without any clinical indication (see Table 7.3).

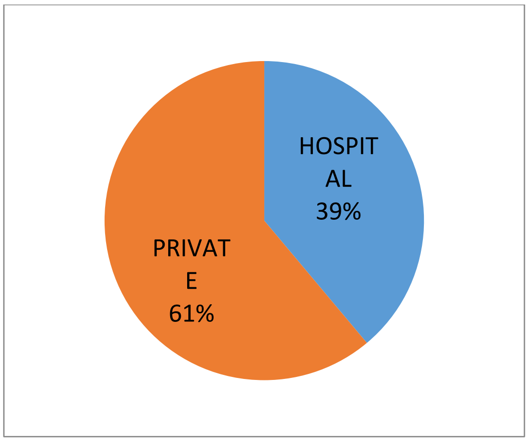
Table 7.3: Personal views of end users of diagnostic US Examinations and Practice

Characteristics	Result
Do you think that ultrasound examinations are safe?	
Yes	17(100%)
No	none
Do you think there should be limitations regarding number of examinations in low-risk pregnancy?	
Yes	11 (61%)
No	6 (33%)
How many ultrasound examinations during low-risk pregnancy?	3 ± 1 (72%)
Are there any adverse effects to the foetus during ultrasound examinations?	
Yes	3 (17%)
No	14 (78%)
Opinion about using ultrasound for entertainment (keepsake ultrasound).	
Agree	15 (17%)
Disagree	3 (83%)

7.2 Socio-demographic information on participants

7.2.1 Workplace

Figure 7.1 shows the places where participants were working. The majority of the participants in this study were from the private sector, about sixty-one per cent (61%). The participants who worked in the private sector had more information than those that worked at a hospital. Generally the end users that work at public places involved a complicated procedural method to collaborate on research.



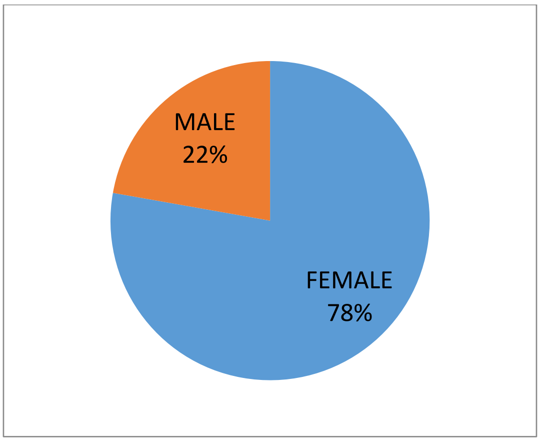


Figure 7.1: Place of work of participants.

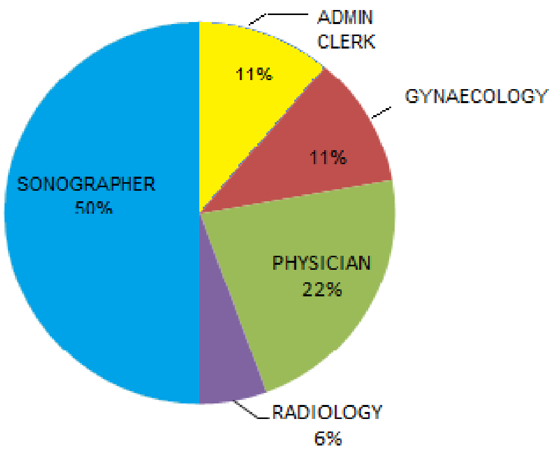
Figure 7.2 Gender of participants.

7.2.2 Gender

The figure above (Figure 7.2) illustrates gender distribution of the participants. Almost seventy-eight per cent of the participants (78%) were female.

7.2.3 Profession

Various professions were represented amongst the participants. These included gynaecologists, physicians, sonographers and radiologists. Fifty per cent (50%) were qualified sonographers and they were in the majority. Twenty-two per cent (22%) were qualified physicians, eleven per cent (11%) were qualified in gynaecology and admin clerk. Figure 7.3 shows the numbers of the professions represented.



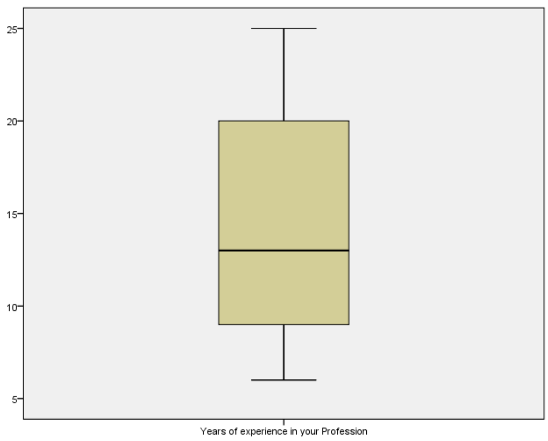


Figure 7.3: Professions of participants.

Figure 7.4: Years of professional experience.

7.2.4 Years of professional experience

The average number of years of professional experience of participants was 14 years (Figure 7.4). The majority (n=8) of the participants had between 6 and 10 years of experience, seven (7) had 13 to 20 years of professional work experience, and none had less than six years of experience, as shown in Chapter Six (Table 6.1).

7.2.5 Average number of ultrasound examinations per day

The average number of ultrasound examinations that participants performed per day was 18. Most of the participants reported that they performed 11 to 20 ultrasounds per day at their institutions. Only two participants stated that there were more than 30 ultrasound examinations per day (see Figure 7.5).

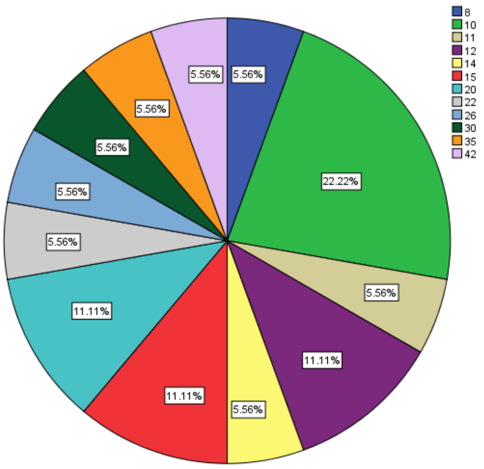


Figure 7.5: US examinations per day.

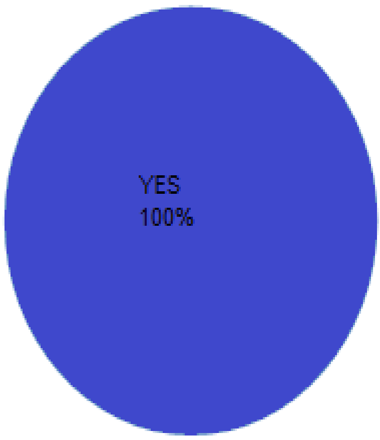


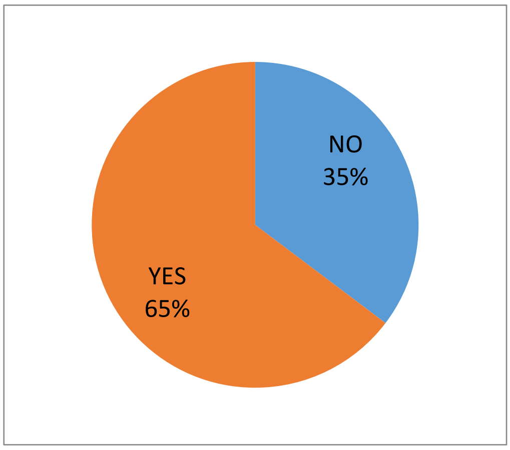
Figure 7.6: Safety of US examinations.

7.2.6 Safety of ultrasound examinations

The participants were asked about whether they thought that ultrasound examinations are safe or not. All of them (100%) responded that ultrasound examinations are safe, as can be observed in Figure 7.6.

7.2.7 Limit of ultrasound examinations

Participants were asked if they thought there should be limitations regarding the number of ultrasound examinations that ‘low-risk’ pregnant women should have during pregnancy. Almost sixty-five per cent (65%) agreed that there should be a limit, as shown in Figure 7.7.



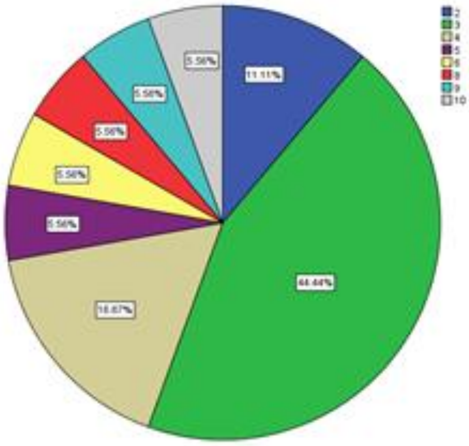


Figure 7.7 Limit of ultrasound examinations.

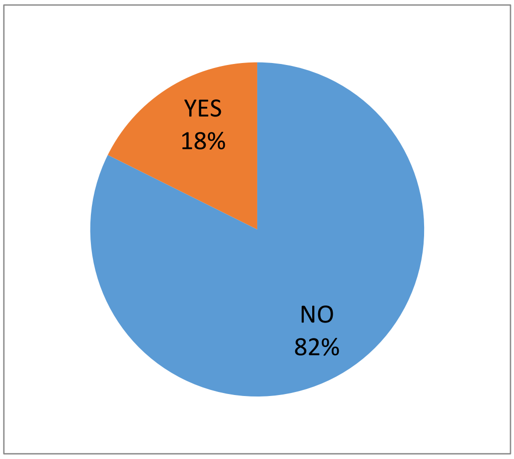
Figure 7.8: Number of US examinations.

7.2.8 Number of ultrasound examinations for women during low-risk pregnancy

Several of the participants indicated that women experiencing 'low-risk' pregnancy should receive less than four ultrasound examinations. Almost forty-four per cent (44%) reported there should be three examinations and about seventeen per cent (17%) stated there should be four or less than four (see Figure 7.8).

7.2.9 Adverse effects of ultrasound

Nearly eighty-eight per cent (82%) of participants responded that there are no adverse effects of ultrasound to the foetus (see Figure 7.9). However, eighteen per cent (18%) believed that there are adverse effects on the foetus and they gave several explanations, as was mentioned in 6.2.10.



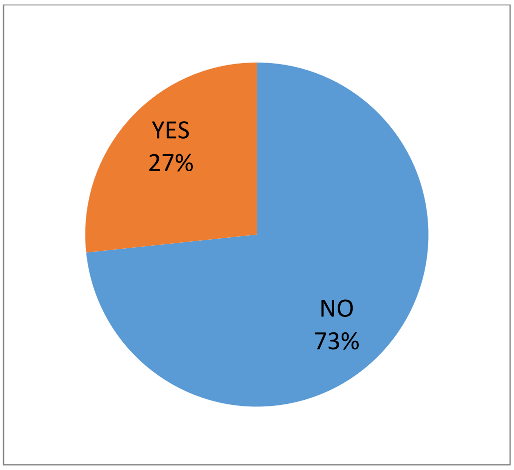


Figure 7.9: Adverse effects of US.

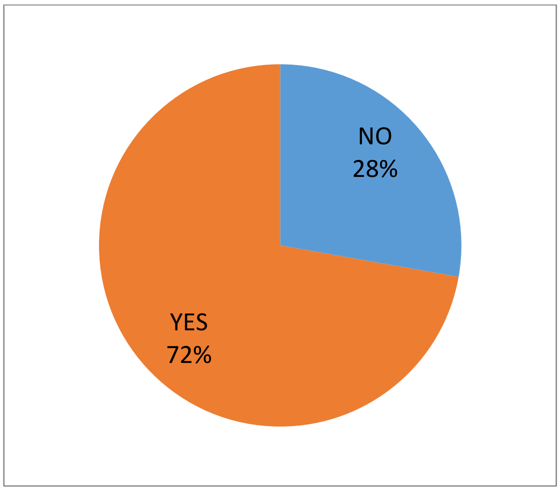
Figure 7.10: Bio-effects of ultrasound.

7.2.10 Bio-effects to the foetus during ultrasound examinations

The majority of the participants (73%) stated that there are no bio-effects to the foetus during ultrasound examinations, and (27%) of the participants stated that there are. See Figure 7.10 above.

7.2.11 Knowledge of thermal index

Participants were asked if they knew what the thermal index was. A large number of participants (72%) stated that they knew what the term thermal index meant, as shown in the above Figure 7.11. Almost 28% did not know what the thermal index was. These included a physician, a gynaecologist and a radiologist.



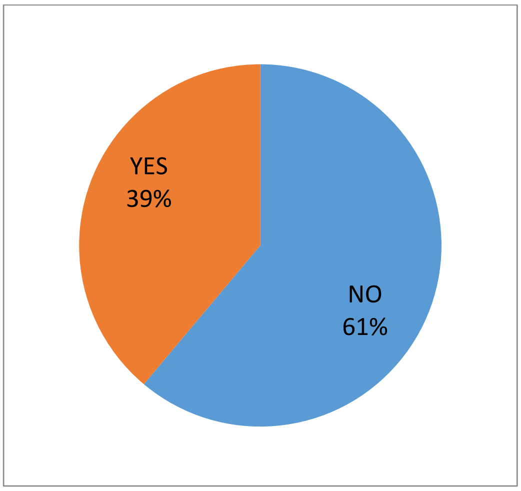


Figure 7.11: Knowledge of the TI.

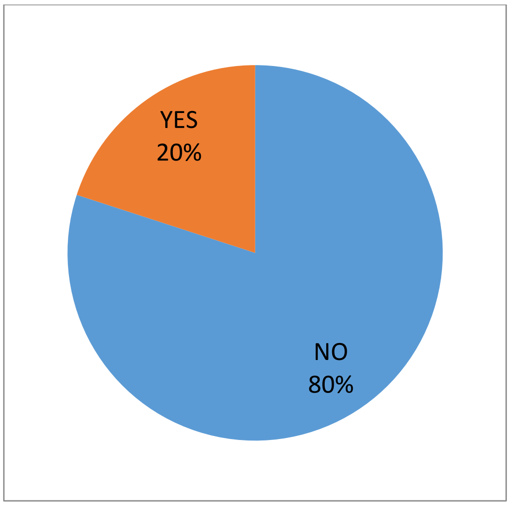
Figure 7.12: Knowledge of the MI.

7.2.12 Knowledge of mechanical index

Participants were requested to respond whether they knew what the mechanical index was. About 39% of the participants knew what mechanical index was, and 61% stated that they did not know what it was. See Figure 7.12.

7.2.13 Location of MI and TI

Participants were asked if they knew the location of the thermal index (TI) and the mechanical index (MI). The majority, eighty per cent (80%) did not know the location of the indices. The twenty per cent (20%) that indicated that they knew the location did give the correct location of the indices (see Figure7.13).



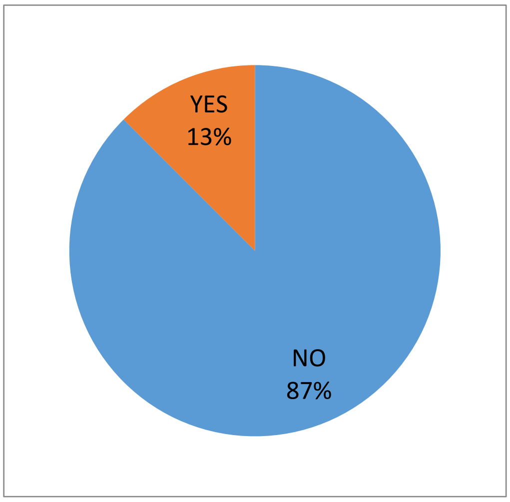


Figure 7.13: Location of TI and MI indices.

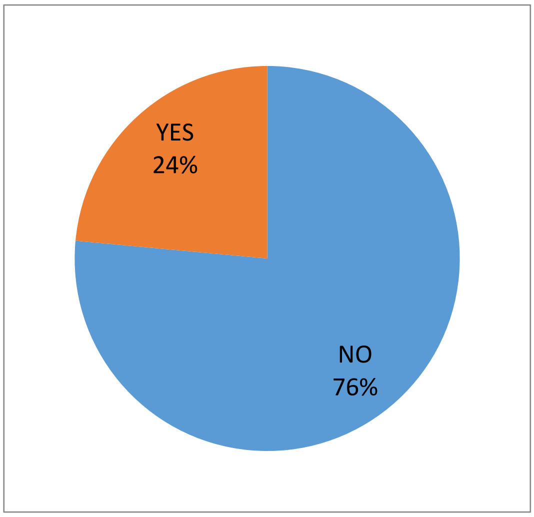
Figure 7.14: Observation of indicators.

7.2.14 Observation of indicators during ultrasound examinations

The figure above (7.14) shows that most of participants (87%) indicated that they did not observe indicators during ultrasound examinations, and just thirteen per cent (13%) said they did.

7.2.15 Rise in thermal and mechanical index

Respondents were asked to indicate if they knew what can cause the rise in the value of TI and MI. Most of the participants (76%) did not know what can cause a rise in thermal and mechanical index values and (24%) did know, as shown in Figure 7.15. Specific information provided by participants as to what they believed can make the values of thermal and mechanical indices rise have been mentioned in Chapter Six (Table 6.4).



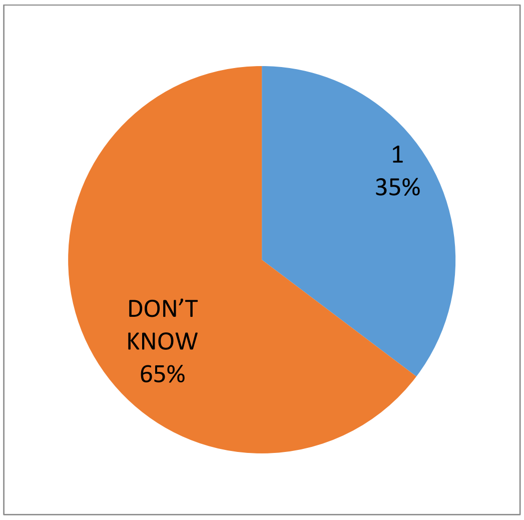


Figure 7.15: Rise in TI and MI index values.

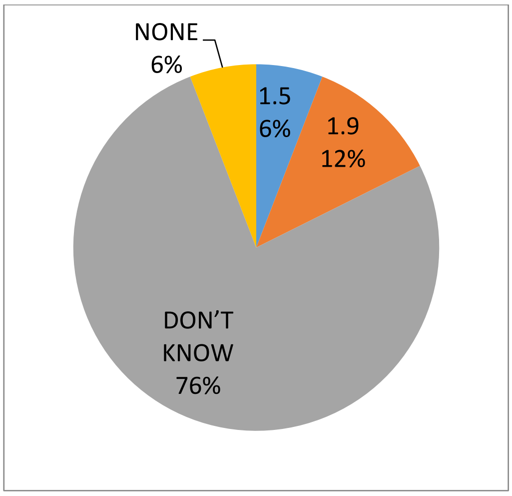
Figure 7.16: Rise in ^{0}C for 1.0 TI value.

7.2.16 Rise in temperature for specific rise in thermal index values

For any particular value of thermal index, there is a specific rise in temperature. Participants were asked by how much the temperature would rise for a thermal index value of 1.0. None of the participants provided the correct answer. Sixty-five per cent (65%) stated that they did not know, as shown in the above Figure 7.16.

7.2.17 Global maximum mechanical index

Seventeen participants responded to the question on the global maximum mechanical index. Seventy-six per cent (76%) of the participants indicated that they did not know the global maximum mechanical index and only (12%) provided the correct answer, as illustrated in Figure 7.17.



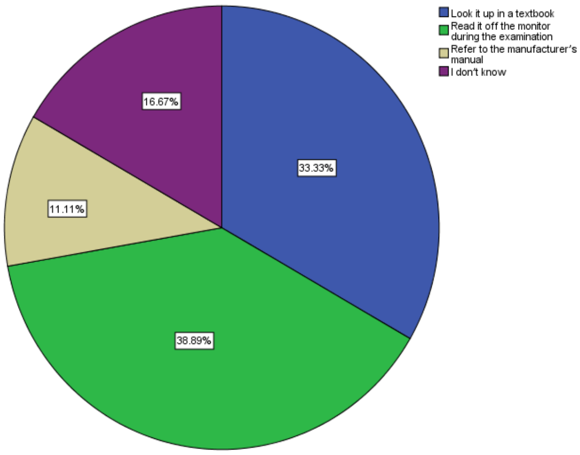


Figure 7.17: The global maximum of MI.

Figure 7.18: Identifying TI and MI indices.

7.2.18 Identifying thermal and mechanical indices during examinations

All participants responded to the question on how they can identify the thermal and mechanical indices during examinations. Various options were provided. Almost thirty-nine per cent (39%) stated that they could read it off the monitor during the examination. Thirty-three per cent (33%) they could look it up in a textbook. About seventeen per cent (17%) indicated that they did not know (see Figure 7.18).

7.2.19 Using ultrasound for entertainment (keepsake photo of unborn child).

Participants were asked what they thought about using ultrasound for entertainment, such as keepsake photos of the unborn child performed in a nonmedical facility. Eighty-three per cent (83%) of them stated that it is not acceptable to use it for this.

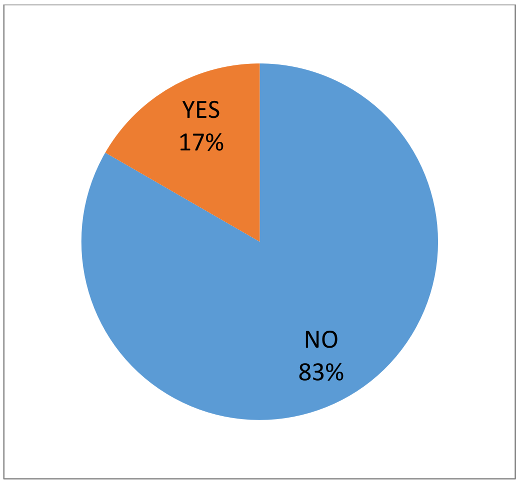


Figure 7.19: using ultrasound for entertainment by numbers.

7.3 Values of TI & MI during routine obstetric ultrasound examinations

Ultrasound has been considered as a form of energy that may have the potential to cause bio-effects. However, epidemiological studies have failed to confirm harmful effects of ultrasound in humans (Lyons et al., 1988). As a result, ultrasound imaging has been considered to be generally safe if used correctly and monitoring of values of acoustic outputs that display on screen by two indices called TI and MI as described previously is performed.

Acoustic outputs of ultrasound devices can be described by special indices. Intensity can be described in duration of its value in relation to time of the cycle. For example, the most commonly used spatial-peak temporal-average intensity (I_{SPTA}) (milliwatts per square centimetre) (mW/cm^2) or spatial-peak pulse-average intensity (I_{SPPA}) (mW/cm^2) describes the intensity of each pulse. But these are not useful during a clinical study (Sheiner et al., 2007, 1665-1670). For this reason and other different reasons, the Output Display Standard (ODS) was conducted in 1992 (AIUM/NEMA, 1992).

After that, the ODS has become an important factor to display on-screen by manufacturers. The objective of the output display standard was to provide the end-users of diagnostic ultrasound (DUS) the ability to operate their devices at higher levels, with a view to increasing diagnostic abilities. The ODS did not allocate any upper limits. The manufacturers were forced to provide all information on-screen by safety indices (i.e. the TI/MI values). Nevertheless, the full responsibility for ultrasound output energy is on the end-users. Hence ultrasound end-users must be aware of the output energy, how to control it and how to use the machine in a safe way. In case the end-users are not aware of acoustic indices or where to find them, they will not be able to control them.

When the previous values that were obtained from different examinations were compared to each other, acoustic output as measured by TI and MI during routine obstetrics ultrasound examinations were very close and comparable with each, as shown in Figure 7.20. With the importance of knowing that, the calculated values of the indicators might vary from one manufacturer to another and fluctuate with changes in the settings of equipment, except the pulse wave Doppler (PWD), which recorded values are slightly higher, relative to the other values. Thermal (TI) can be recorded higher than 1.5 during PWD. Mean TI during all of the last examinations was approximately 0.46. That indicates that exposure to Doppler ultrasound can heat biological tissue by a large proportion due to relatively high intensities used, and the need to keep a transducer motionless during the examination for a period of time. All these values of TI that were conducted by different examinations in different devices were compared with the lower and higher of the benchmark that was conducted by BMUS. The lower benchmark of TI which was measured by BMUS is 0.1 while the higher benchmark is 2.5, as shown below in Figure 7.20.

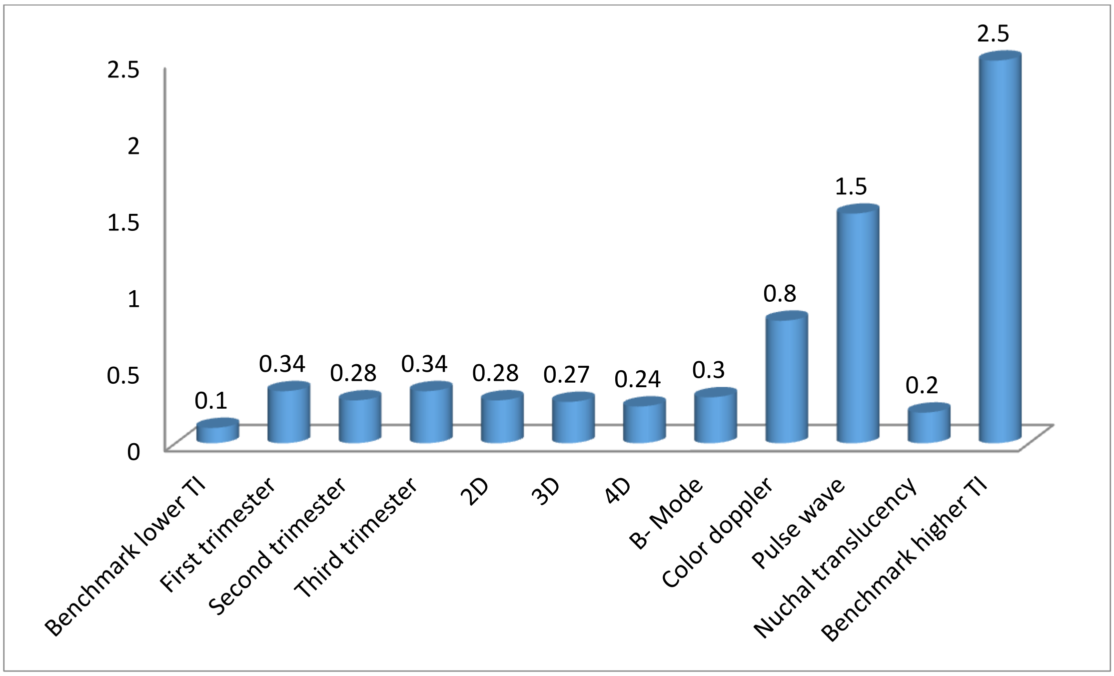


Figure 7.20: Values of TI in different examinations from different studies.

Mechanical index (MI) values were also almost convergent together in various examinations. There is no record height in these examinations as shown in Figure 7.21. Mean MI during all of the last three examinations was approximately 1.0. This is low particularly in routine obstetrics ultrasound scanning when compared to the standard level set by the Ultrasound Food and Drug Administration (FDA), which is a maximum of 1.9. All these values of MI when different examinations were conducted in different devices also compared with the lower and higher of the benchmark measurement that was conducted by BMUS. The lower benchmark of MI which was measured by BMUS is 0.2 while the higher benchmark is 1.6, as shown below in Figure 7.21.

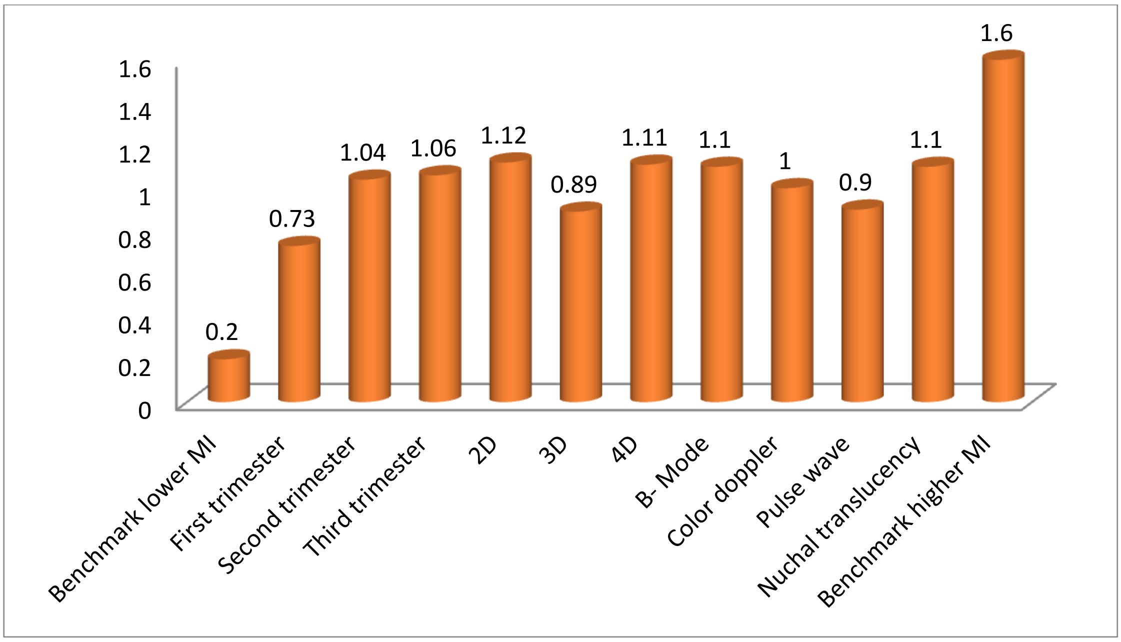


Figure 7.21: Values of MI in different examinations from different studies.

The figure below (7.22) shows the comparison between acoustic output indices in different devices of ultrasound during pregnancy as measured by TI and MI.

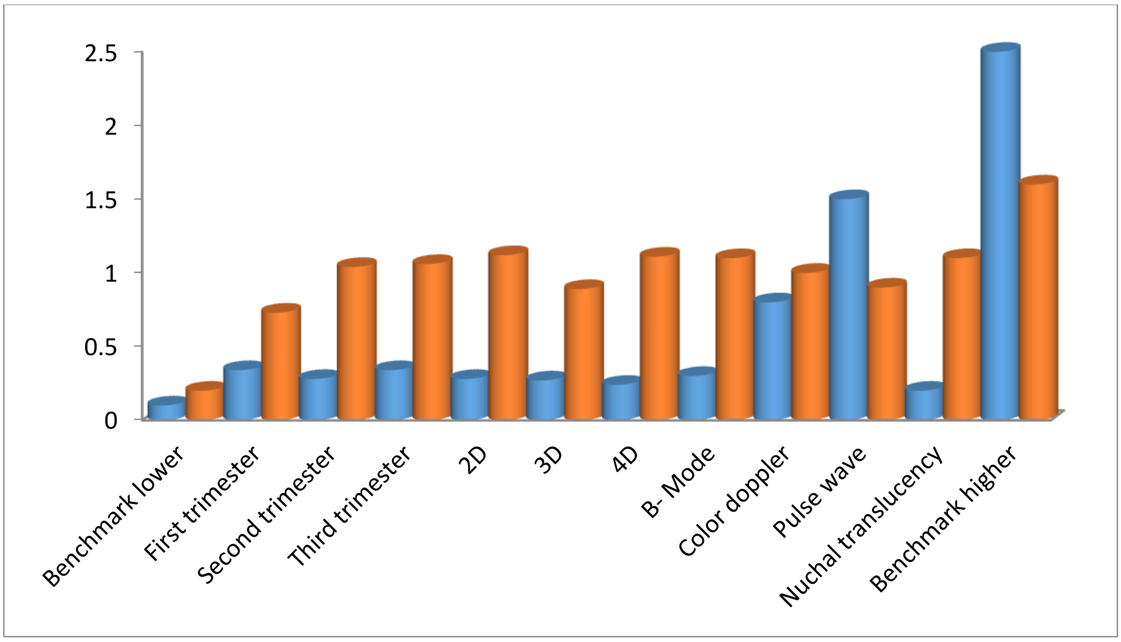


Figure 7.22: Comparison of TI and MI in different devices during each pregnancy.

7.4 Summary

The questionnaire investigating end-users' knowledge regarding the safety of ultrasound is discussed and presented in this chapter by figures and tables. Acoustic output indices in different ultrasound examinations as measured by TI and MI are investigated and compared with each (focusing on 2D and 3D). Those values are compared with the lower and higher benchmark that was established by BMUS.

CHAPTER EIGHT

CONCLUSION AND RECOMMENDATION

8.1 Conclusion

Ultrasound practitioners are often asked the question of whether the technology is safe for the foetus. The answer generally given is “Of course. Ultrasound is not x-rays; it is not invasive, has been used for close to 50 years and is perfectly safe.” While this answer contains some correct facts (ultrasound is not x-rays and it has been used for a long time), the concept of absolute safety is not scientifically valid, and furthermore, the level of knowledge regarding potential bio effects of ultrasound in tissues is, by and large, very low among clinicians.

Ultrasonic imaging has been used for more than 5 decades and its use as a means of diagnosis is becoming more popular. It has become an important diagnostic tool used for obtaining information about function or structure in human beings. It is widely used in healthcare institutions, especially obstetrical clinics. Epidemiological studies have missed in the past to identify the adverse effects of ultrasound in human bodies, which is considered a form of energy that causes bio-effects. The two mechanisms of ultrasound are heating and cavitation. These mechanisms are referred to on the screen of the device by two of the indicators: the thermal index (TI) and the non-thermal index called also the mechanical index (MI).

It is necessary to know and observe those indicators during ultrasound examinations. Therefore the researcher determined end-users’ knowledge regarding safety aspects of diagnostic ultrasound during pregnancy. A questionnaire was distributed to ultrasound end users working at five different hospitals in Cape Town, and he noted that the majority of participants do not have enough information about those indicators. The participants did not even know where to find those indictors despite their appearing on screen in their machines. Most of the participants also were not familiar with the terms TI and MI and what can cause a rise in the value of these measurements.

Acoustic output indices (AOI) in different ultrasound examinations as measured by TI and MI are investigated in this study and compared with each other (focusing on 2D and 3D). Those values have been compared with the lower and higher of the benchmark that was conducted by BMUS, and the researcher noted the pulse wave Doppler (PWD) which recorded values slightly more relative to other values. Thermal (TI) can be recorded higher than 1.5 during PWD. All these values of TI that were noted in different examinations conducted in different devices compared with the lower and higher benchmark when conducted by BMUS. The lower benchmark of TI which was measured by BMUS is 0.1 while the higher benchmark is 2.5.

Mechanical index (MI) values were also almost convergent together in various examinations. There is no record height in these examinations, as shown in Figure 7.21. Mean MI during all of the last three examinations was approximately 1.0. This is low particularly in routine obstetrics ultrasound scanning when compared to the standard level set by the Ultrasound Food and Drug Administration (FDA), which is a maximum of 1.9. All these values of MI that were conducted by different examinations in different devices also compared with the lower and higher benchmark when conducted by BMUS. The lower benchmark of MI which was measured by BMUS is 0.2 while the higher benchmark is 1.6.

The co-array (spatial convolution of the transmit-and-receive arrays) can be used to find effective array designs that catch all of the spatial frequency content (a transmit–receive element combination corresponds to a spatial frequency) with a reduced number of active channels and firing events. The research reviews four reduced redundancy 2D array configurations (XT-FR, XT-PR, XT-BR and BRT-BCR) for miniature 3D ultrasonic imaging systems, and the researcher recorded that the XT-FR creates the best image quality when compared to XT-BR, XT-PR and BRT-BCR. The front face complications of the XT-BR, XT-PR and BRT-BCR are very comparable, while the image quality of the XT-BR is better than the other two.

8.2 Recommendation and Future work

In this thesis, the researcher examines the 2D and 3D ultrasound systems in the development of medical imaging technology. In future work it should be interesting to investigate and evaluate the values of acoustic output indices as measured by MI and TI in devices used at Cape Town hospitals.

The end user of clinical ultrasound is interested in knowing how to keep the examination safe. One needs to provide recommendations based on scientific evidence. As should be apparent from the above, this is a difficult task. In terms of clinical exposure, a general recommendation is that DUS should be used only when indicated and exposure should be kept as low as possible to obtain diagnostic images. Furthermore, exposure time should be kept as short as possible. These are, of course, the components of the As Low As Reasonably Achievable (ALARA) principle. The most rigorous recommendations are from the British Medical Ultrasound Society (BMUS). Their 1999 Statement reaffirmed in 2009 declares, “For equipment for which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. When the safety indices are not displayed, TI max should be less than 1 °C and MI max should be less than 0.3. Frequent exposure of the same subject is to be avoided." They have very strict recommendations for maximum allowed exposure time, depending on the TI. In addition, in febrile patients, extra precaution may be needed to avoid unnecessary additional embryonic and foetal risk from ultrasound examinations. Precautions are much softer regarding mechanical phenomena, which, in the absence of gas nuclei (as is the case in foetal lungs and bowels and assuming no use of contrast agents) are probably negligible. Pulsed Doppler is an area where particular precaution is warranted, specifically in early gestation.

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APPENDICES

APPENDIX A: Questionnaire Investigating End User Knowledge Regarding the Safety of Ultrasound.

Survey on ultrasound safety at Cape Town's hospitals (public & private)

<u>**Appendix 1:** Questionnaire Investigating End User Knowledge Regarding the Safety of Ultrasound.</u>

DEAR PARTICIPATN:

We would like to take a few minutes of your time for a survey Investigating End User Knowledge Regarding the Safety of Ultrasound. It shouldn't take more than 10 minutes to complete. Thank you for your time.

1. Place of work: ◯ Hospital ◯ Private practice
2. Sex: ◯ Male ◯ Female
3. Profession: ◯ Physician ◯ Nurse ◯ sonographer ◯ Radiology ◯ other (………).
4. Years of experience in your Profession …………………, in sonography ……………..…
5. Average number of ultrasound examinations you perform per day ……………………...
6. Do you think that ultrasound examinations are safe? ◯ Yes◯ No
7. Do you think there should be limitations regarding the number of ultrasound examinations a "low-risk" pregnant woman should have during her pregnancy? ◯ Yes ◯ No
8. How many ultrasound examinations should a woman undergo during "low-risk" pregnancy? (………………………..)
9. Are there any adverse effects to the fetus during ultrasound examinations? ◯ Yes◯ No
   If the answer was (Yes) please specify (…………………………..…...).
10. Are there any bio-effects to the fetus during ultrasound examinations? ◯ Yes ◯ No
11. Do you know what is meaning of Thermal Index (TI)?
    ◯ Yes ◯ No (please specify: …………………………………).
12. Do you know what is meaning of Mechanical Index (MI)?
    ◯ Yes ◯ No (please specify: ………………………………………).
13. Do you know exactly where these indicators are? ◯ Yes ◯ No (please specify: ………..).
14. Are you observing these indicators during ultrasound examinations? ◯ Yes ◯ No
15. Do you know what caused that, if there is a rise in the value of Thermal TI & MI?
    ◯ Yes ◯ No (please specify: ……………………………………………………).
16. To the best of your knowledge:
    - A Thermal Index (TI) of 1.0 means that there is a potential of rise of temperature of……degrees Celsius.
      ◯ 1.0 ◯ 1.5 ◯ 2.0◯ None ◯ I don't know
    - The global maximum Mechanical Index (MI) must be or less than ………….
      ◯ 1.5 ◯ 1.7 ◯ 1.9◯ None ◯ I don't know
17. If you want to know what are the TI & MI during a particular examination, you will:
    A. ◯ Look it up in a textbook.
    B. ◯ Read it off the monitor during the examination.
    C. ◯ Calculate it from the frequency of the transducer you are using.
    D. ◯ Refer to the manufacturer's manual.
    E. ◯ I don't know.

    What do you think about using ultrasound for entertainment (keepsake photos of the unborn child performed in a nonmedical facility)? ◯ Agree ◯ Disagree

APPENDIX B: COVER LETTER AND CONSENT FORM

COVER LETTER AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: 2D and 3D ultrasound systems in development of medical imaging technology

PRINCIPAL INVESTIGATOR: Abdalla Agila Eljaaidi

ADDRESS: Cape Peninsula University of Technology, Faculty of Engineering.

CONTACT NUMBER: 076 588 5820

Dear Participant,

Your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the ethics committee at Cape Peninsula University of Technology and will be conducted according to ethical guidelines for Research.

What is this research study all about?

- The study is being conducted at your hospital investigating end user knowledge regarding the safety of ultrasound.

Why have you been invited to participate?

- I have invited you because you use ultrasound.

What will your responsibilities be?

- Your responsibility will be to answer questions truthfully.

Are there any risks involved in your taking part in this research?

- There are no risks to you in taking part in this study.

Who will have access to your medical records?

- The information collected will be treated as confidential and protected. If it is used in a publication or thesis, your identity will remain anonymous. I am the only one who will have access to the information.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

- There is no harm in taking part in this study.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

You will receive a copy of this cover letter for your own records.

Declaration by participant

By signing below, I …………………………………..…………. agree to take part in a research study entitled *2D and 3D ultrasound systems in development of medical imaging technology*.

I declare that:

- I have read this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ....…........……… On (*date*) …………...……….. 2014.

…………………………………….. **……………………………….**

Signature of participant Signature of witness

Declaration by investigator

I **Abdalla Agila Eljaaidi** declare that:

- I explained the information in this document to …………………………………..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above

Signed at (*place*) ....……………….. On (*date*) …………...……….. 2014.

…………………………………………   …..………………………………

Signature of investigator   Signature of witness

Acoustic Output as Measured by Thermal and Mechanical Indices and its Bio-effect During Ultrasound Scanning in Obstetrics

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Abstract

While ultrasound (US) is supposed to be totally safe, it is a form of energy. Diagnostic ultrasound (DUS) has the prospect to have effects on living tissues it crosses, such as bio-effects. The two most important mechanisms for effects are thermal and non-thermal, also called mechanical. These two main mechanisms are indicated on screen by two indices: the thermal index (TI) and the mechanical index (MI), to express the potential for rise in temperature at the ultrasound's focal point and the probability of harm from the mechanical effects such as cavitation. It is important to understand bio-effects of acoustic output during ultrasound scanning in obstetrics. This paper identifies the need for users of ultrasound to understand thermal and mechanical indices appearing on ultra-sound screens. Some users do not use the indices and others do not know or are unaware of their importance.

Keywords: ultrasound, acoustic output, bio-effects, thermal index, mechanical index, safety, fetus, diagnostic ultrasound.

1. Introduction

Physicians have used ultrasound (US) to make images of the inside of the human body for nearly half a century *(NCRP, 2002)*. Ultrasound imaging has been used for more than 4 decades for fetal imaging ***(NCRP, 1983)***. It has become the most commonly used diagnostic imaging modality in obstetrics and gynecology ***(Jacques S.A, 2008)***. It has become available in every academic department, private offices, emergency departments, and even, recently, the shopping malls ***(Jacques S.A, 2008) (Abramowicz, 2002)***. Most pregnant women have at least 1 ultrasound scan during pregnancy, and almost 40% of all ultrasound scans performed are for obstetric use ***(Hershkovitz et al., 2002; Duck, 1999)***. To date, there is no confirmation that diagnostic ultrasound (DUS) causes harm in human tissues or the developing fetus when used correctly ***(Thomas et al., 2009)***.

2. Significance of the study:

The majority of physicians depend on ultrasound diagnoses in their clinics. Although, there are no studies concerning of safely of ultrasound, long-term epidemiological studies have failed to show harmful effects of ultrasound on human ***(Lyons et al., 1988)*** as a form of energy it might cause bioeffects.

This paper will be reviewed the former studies to evaluate the acoustic outputs (AOP) of ultrasound devices as measured by TI and MI, those appear on the screen. However, most of sonographers are not aware of the significance of those indices, which might affect harmfully on the patient. The study can also explain if the

THE KNOWLEDGE OF USERS REGARDING SAFETY OF ULTRASOUND DURING PREGNANCY

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ABSTRACT

Ultrasound (US) is widely used in most medical clinics, especially obstetrical clinics. It is a way of imaging methods that has important diagnostic value. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. The use of two-dimensional ultrasound (2DUS) in obstetrics has been established. However, there are many disadvantages of 2DUS imaging. Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three- and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound, has boomed, particularly in the United States. However, long-term epidemiological studies have failed to show the adverse effects of ultrasound in human tissues. Until now, there is no proof that diagnostic ultrasound causes harm in a human body or the developing foetus when used correctly. While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses (bio-effects). The two most important mechanisms for effects are thermal and non-thermal. These two mechanisms are indicated on the screen of ultrasound devices by two indices: The thermal index (TI) and the mechanical index (MI).

Keywords: Acoustic output, foetus, thermal index, mechanical index, questionnaire survey.

INTRODUCTION

Ultrasound (US) has become an important diagnostic tool used for obtaining information about function or structure in human beings (Minister of Public Works and Government Services, Canada, 2001). It is widely used in healthcare institutions, especially obstetrical clinics. The World Health Organization manual of diagnostic ultrasound (WHO, 2013) states that during the last decades, the use of ultrasonography increased in health care practice globally, and the benefits have been widely reported. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. Malhotra, Shah, Kumar, Acharya, Panchal and Malhotra (2014) state that the use of two-dimensional ultrasound (2DUS) in obstetrics is well established. But there are many disadvantages of 2D-US imaging.

Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound has boomed, particularly in the United States, even though long-term epidemiological studies have never succeeded in showing the adverse effects of ultrasound on human bodies (Hershkovitz et al., 2002; Newnham et al., 2004). Until now, there is no proof that diagnostic ultrasound causes harm in humans or the developing foetus when used correctly (Chan & Perlas, 2011). While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses. From the early days of ultrasound, researchers have been aware of the potential bio-effects of ultrasound. After World War I, Chilowsky and Langevin took advantage of the enabling technology of