Ultrasound Safety

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Reference literature:

Diagnostic ultrasound, physics and equipment, chapter 12
(edited by Peter Hoskins, 2010)
The safe use of ultrasound in medical diagnosis,
(edited by Gail ter Haar, nov 2012)
Medical Ultrasound safety, (AIUM 2009)
Policies, Statements & Guidelines, (BMUS 2009-2012)

Are there any risks with ultrasound scanning?

- ”Ultrasound is widely used because it provides many clinical benefits to the patient and has an outstanding safety record. No patient injury has ever been reported from diagnostic ultrasound”
- Clinicians are performing over 1 miljon examinations worldwide every year in cardiology, radiology, obstetrics, gynecology, vascular ultrasound among others and the number continues to grow
- Hundreds of thousends ultrasound scanners are in use every day
- Only in England are 2,5 milj obstetric scans performed every year without any reports of injuries, many of them were performed with new generations of scanners with potential of significantly higher outputs than earlier

(AIUM 2009 and Dept of Health in England 2012)

Despite the safety record there are some potential risks!

- ***"It must be remembered that the absense of evidence of harm is not the same as absence of harm"*** (Salvesen *et al.,* 2011)
- There are some potential risks in some situations under special circumstances where radiation of ultrasound can create harmful effects in the human body
- For that reason we must be aware of them and learn from education and training
- We must also remember that we always have electrical safety risks with equipment connected to mains, for example leakage currents from an ultrasound transducer in contact with the body
- Artefacts and lost image information due to defect ultrasound transducers can also be a risk because of missed or wrong diagnosis

(from The safe use of ultrasound in medical diagnosis, nov 2012)

Education and training of users are very important

- Ultrasound examinations shall only be performed by competent medical staff who have deep knowledge of those specific risk situations. There is a strong need for continuing education to ensure that appropriate risk/benefit assessments are made. The ultrasound safety record depend on that

- This is particularly important these days since more responsibility for the safe management is passed over to the user by the standard societies

- Several societies and organisations around the world, so called ”bodies”, have given ultrasound safety special attention and education and training is one very important part of it

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Standards and specifications regarding diagnostic ultrasound

- Standard institutes as IEC (International Electrotechnical Commision) is the main body all over the world regarding definition of measurement standards for all electrically connected equipment. For diagnostic ultrasound they have published IEC60601 Part 2-37 (2001) ”to define display of safety indices and to limit transducer surface temperature” and IEC62359 (2006) ”to define safety indices”

- Another important standard institute, especially in Europé, is MDD, Medical Device Directive.
  MDD is intended to harmonise the laws relating to medical devices within the European Union, Counsil Directive 93/42 EEC 1993

- FDA (Food and Drugs Administration) an American body which is responsible for compliance documents in the American ultrasound industrial sector detailing permitted description of an ultrasound machine, testing methods and limits to acoustic outputs. An important document is 510(k), FDA 2008. FDA has a great influence over the whole world.

- AIUM/NEMA (American Institute of Ultrasound in Medicine / National Electrical Manufacturers Association), has defined methods for calculation and display of safety indices

(From British Medical Ultrasound Society, BMUS, nov 2010 and Diagnostic Ultrasound, physics and equipment, Hoskins 2010)

Policies, statements and guidelines regarding diagnostic ultrasound

- AIUM (American Institute of Ultrasound in Medicine) in US, their role is to be a learned society who is defining policies, guidelines and statements for end-users about safety. They have also education programs for its members

- BMUS (Brittish Medical Ultrasound Society) has the same role in UK as AIUM

- WFUMB (World Federation of Ultrasound in Medicine and Biology) The umbrella group for regional ultrasound societies. They produces safety statements and recommendations

- EFSUMB (European Federation of Ultrasound in Medicine and Biology) has the same role as WFUMB but nationally. The umbrella group for regional ultrasound societies. They produces safety statements and recommendations

(From British Medical Ultrasound Society, BMUS, nov 2010)

Example of guidelines for the safe use of diagnostic ultrasound equipment, BMUS 2010

- ”Medical ultrasound imaging should only be used for medical diagnosis”
- ”Ultrasound equipment should only be used by people who are fully trained in its safe and proper operation. This requires:
  - -an appreciation of the potential thermal and mechanical bio-effects of ultrasound
  - -a full awareness of equipment settings
  - -an understanding of the effects of machine settings on power levels”
- ”Examination times should be kept as short as is necessery to produce a useful diagnostic result”
- ”Output levels should be kept as low as is reasonably achivable whilst producing a useful diagnostic result”
- ”The operator should aim to stay within the BMUS recommended scan times (especially for obstetric examinations)”
- ”Scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs”

(From British Medical Ultrasound Society, BMUS, nov 2010)

Statement about prudent use from AIUM 2009

- ” The AIUM advocates the responsible use of diagnostic ultrasound and strongly discourages the nonmedical use of ultrasound for entertainment purposes”
- ”The use of ultrasound without a medical indication to view the fetus, obtain a picture of the fetus or determine the fetal gender is inappropriate and contrary to responsible medical practice”
- ”Ultrasound should be used by qualified health professionals to provide medical benefit to the patient”

How You can minimize any eventual risk?

- Apply a simple principle, ALARA!
- ALARA stand for *”As Low As Reasonably Achievable” and* means that always perform an examination with as low ultrasound exposition as possible without to loose diagnostic information
- Always think of prudent use when examing a patient with ultrasound!

(From Medical Ultrasound Safety, AIUM 2009)

Which adjustments can users do?

- The most important parameter to minimize is the Intensity or Power because with that one You can directly make adjustments on the output power from the ultrasound transmitter (page 41)

- By choosing an application you will automatically influence output power since it is connected to chosen application, f ex *”peripherial vessel, cardiac, carotid, fetal scanning etc”*

- Thereafter you can change adjustments on those functions that indirectly influence output power, f ex system mode as 2D, M-mode and Doppler. Think also of pulse repetition frequency (depth), focus, puls length, sample volume and choice of transducer (see also page 40)

- A basic rule is always to adjust ”receiver gain” or TGC to begin with, thereafter make adjustments according to the rules above.

Scanned och unscanned modes

- In unscanned modes, as PW-doppler, CW-doppler och M-mode are the energy concentrated along a thin layer in the patient which means over a much smaller volume compared with 2D. In those modes are the highest temperatures to be found between the body surface and focus

- When scanned modes are used f ex 2D and color doppler is the ultrasound field spred out over a large volume why the highest temperatures is to be found at the body surface

(Medical ultrasound safety, AIUM 2009)

Acoustic power and intensity

- Acoustic power from the transmitter in the scanner is measured in Watts (W) and can be seen on the screen as a certain value in - dB or % in dB of full power

- Intensity(I) = Power / Area, I = W/m^2, W/cm^2 or mW/cm^2 where the area is the transducer head area

Measurement of intensity

Intensity is a measure of energy flow through an area and is calculated from measurements of pressure using a hydrophone. The basic assumption that is called the ”plane-wave assumption” says that the instantaneous intensity, I (t), is related to the instantaneous pressure, P (t), by the relationship:

$$I(t) = P^2(t) / \rho c$$

where ρ is the density of water and c is the speed of sound in water. The product ”ρ c” is the acoustic impedance z (kg m^{-2} s^{-1} = rayl).

Although this relationship is not strictly true everywhere, it is a good approximation throughout most diagnostic fields and is used in international standards (IEC 62127-1, 2007; (Ultrasonics – Hydrophones - part 1: *Measurements and characterization of medical ultrasonic fields up to 40 MHz)*

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Risks for high intensity in the ultrasound field

- There is a potential risk for too high energy radiation from the ultrasound equipment via the transducers to the patient

- The risks can be of two kind :

  - **Thermal**, risk for heating of soft tissue or bone

  - **Non thermal**, for example mechanical phenomena like cavitation

Thermal risks in general

- Temperature increase is caused by absorption of acoustic energy in tissue
- Since absorption coefficient is high in bone tissue, temperature can increase very fast there and in the surrounding tissue
- Frequency has an influence of absorption so that higher frequency gives higher absorption and accordingly higher temperature, which is true specially in superficial tissues
- The highest temperatures will otherwise arise in the focus area when the wave front are passing by the tissue
- The examination time has a critical roll since temperature will increase with the scanning time

(from The safe use of ultrasound in medical diagnosis, nov 2012)

Particularly thermal sensitive tissues

- Reproductive cells
- Embryo and fetus
- The central nervous system
- The eyes

(AIUM 2007 and BMUS 2009)

Special risks during embryo and fetus examinations

- **A very sensitive situation is when you are performing an ultrasound examination on a fetus during the pregnancy month 4th and 6th, when the bone growing process is taking place (2nd trimester), especially if the mothers belly wall is thin. Energy absorption in amniotic is very small why almost all absorption take place in the bone tissue of the fetus**

- **You must be aware of where you have focus so you can avoid exposures over long time near bone areas**

- **”It seems most likely that the greatest potential risk in ultrasound diagnosis is with fetal spectral doppler studies during first trimester. These studies involve potentially high-output intensities with stationary geometry and a presumably more temperature sensitive fetus. Pulsed wave doppler or colour flow imaging should not be used routinely”**

- Developing tissues of the embryo and fetus are particularly susceptible to damage by heating and the effects can have serious consequences

- The developing fetus is especially sensitive to hyperthermia during the period of neural tube closure

- The induction of teratogenic effects (production of malformed fetus) depends on a combination of the elevation above normal physiological temperature and the duration for which the increased temperature is maintained

(from BMUS Safety Group 2010 and EFSUMB/AIUM 2011)

Temperature limits and other guidelines

- An increase of 4°C above normal body temperature in 0,5 minutes may be hazardous to embryonic and fetal development. Exposures longer than 5 min involve significant risk of harm
- A temperature increase in fetal tissue to 41ºC and more is considered as dangerous while temperature increases < 1ºC in general is considered not to be any biological risk
- 1,5°C above normal physiological temperature (37°C) does not appear to present a risk from thermal effects in humans for an imaging session of less than 30 min
- Ultrasound scanning of febrile obstetric patients requires particular care
- A 30-fold increase in absorption coefficient has been reported as the fetal bone matures and have become ossified, important to think of when scanning a fetus during 2nd and 3rd trimester
- Simple 2D greyscale exposures are not capable of producing harmful temperature increases in tissue

(from The safe use of ultrasound in medical diagnosis, nov 2012)

Animal studies in laboratory

- Lung haemorrhage in animal models has been observed as a result of ultrasound exposure (rat, rabbit, mouse and pig)
- Diagnostic frequencies used, about 3-5 MHz and exposure times from 10 seconds to 3 minutes
- Other organs in which effects in small animals have been seen:
  - Bone; ”vascular damage near developing bone”
  - Intestine; ”activation from ultrasound”
  - Heart; ” radiation force can reduce the strength of contraction”

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Selfheating of the transducer

- During use of endocavity transducers f ex vaginal transducers, rectal transducers and esophagus transducers must attention be taken to the selfheating of the transducer. The temperature indices system can therefore underestimate the temperature rise within about 5 mm of the transducer
- Esofagus (TEE) transducers have f ex always a temperature sensing device at the tip
- Temperature can together with the patients body temperature (37 ºC or more at fever) rise to more than 40 ºC. In this situation there is no possibility for the heat energy in an endocavity transducer to reach the surroundings, so the transducer can not be cooled down properly.
- The problem can arise f ex with use of vaginal transducers during checks of pregnancy

Limits on surface temperatures and temperature rise for ultrasound transducers specified by IEC 60601-2-37 (2001)

	In air	On tissue (external use)	On tissue (internal use)
Maximum temperature (ºC)	50	43	43
Maximum temperature rise (ºC)	27	10	6

Heating spots at the transducer surface

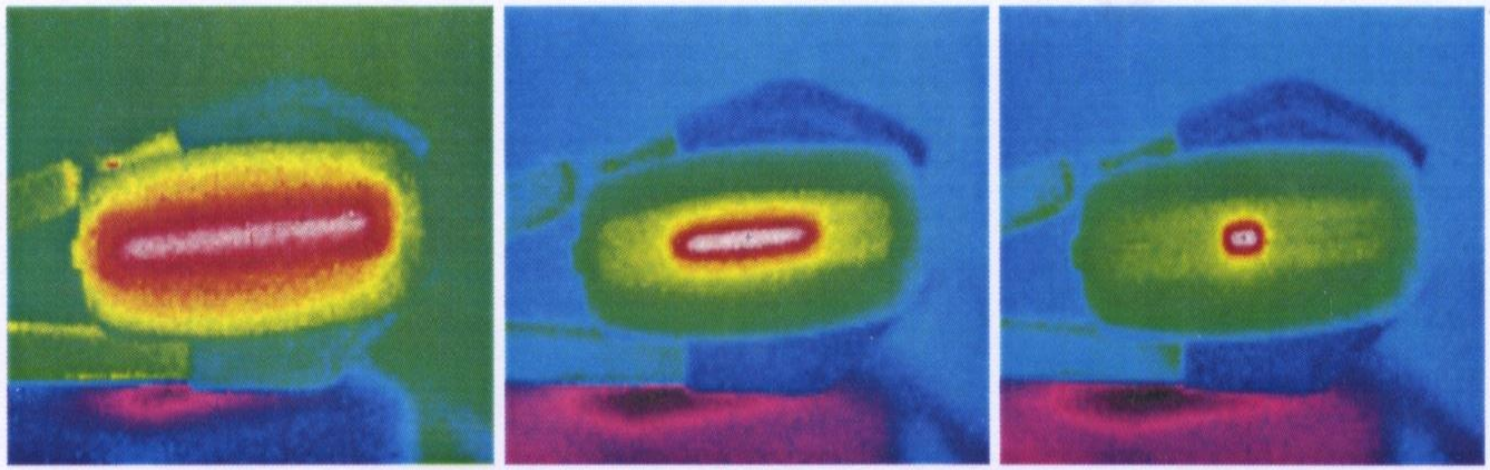


Figure 3.9. Infra-red images of a linear array transducer operating in B-mode (left—maximum =27.7 °C), colour-flow (centre—maximum=31.5 °C) and PW Doppler mode (right—maximum =31.6 °C).

(From The safe use of ultrasound in medical diagnosis, nov 2012)

The fraction of acoustic power absorbed in soft tissue up to a particular depth with different frequencies

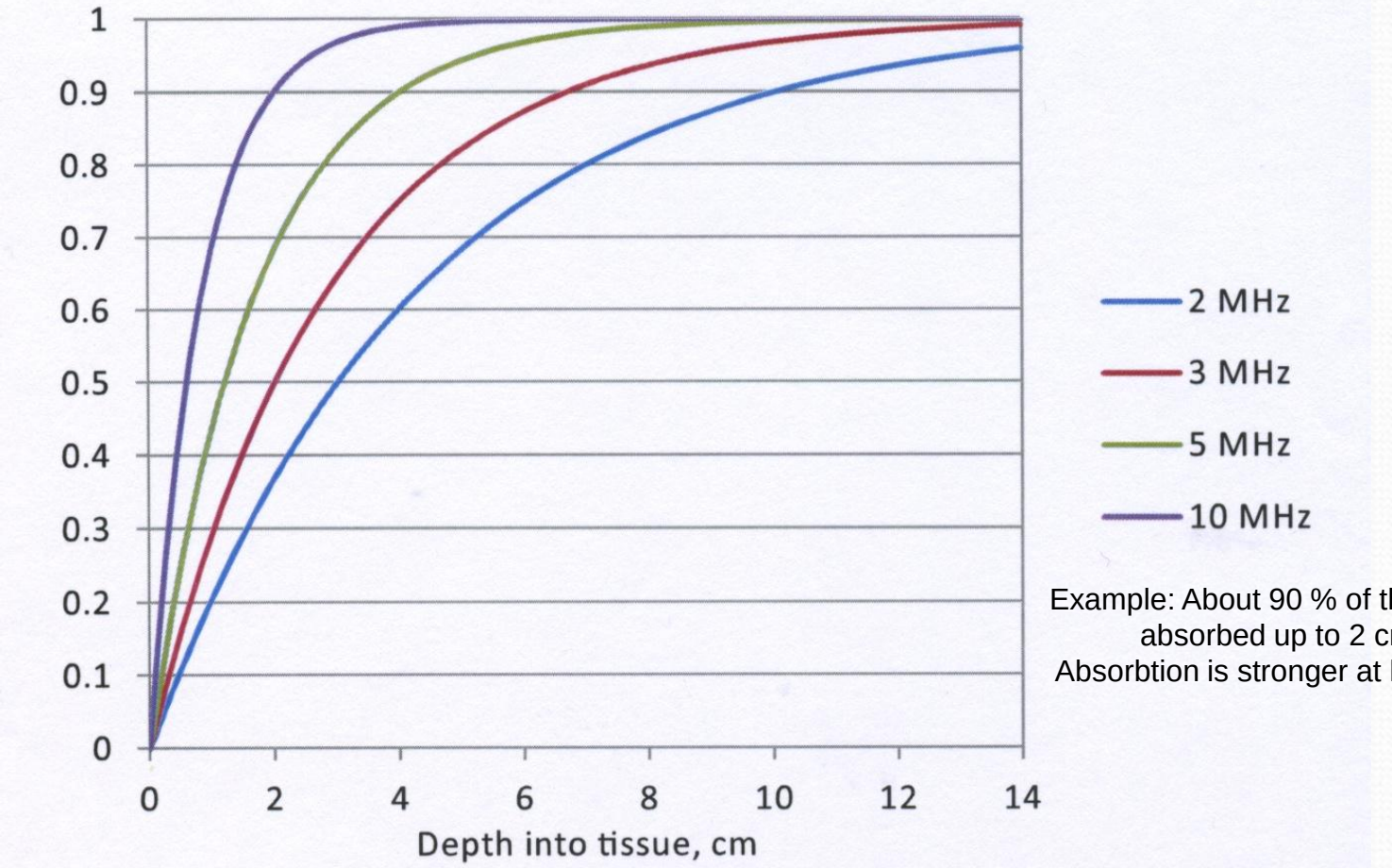


Figure 2.3. The fraction of the acoustic power leaving the transducer which is deposited in soft tissue up to a particular depth, depending on frequency. An absorption coefficient of 0.5 dB cm^{-1} MHz^{-1} has been assumed.

Example: About 90 % of the energy is already absorbed up to 2 cm at 10 MHz!
Absorbtion is stronger at higher frequencies !

(From The safe use of ultrasound in medical diagnosis, nov 2012)

The Ultrasound pulse in 2D

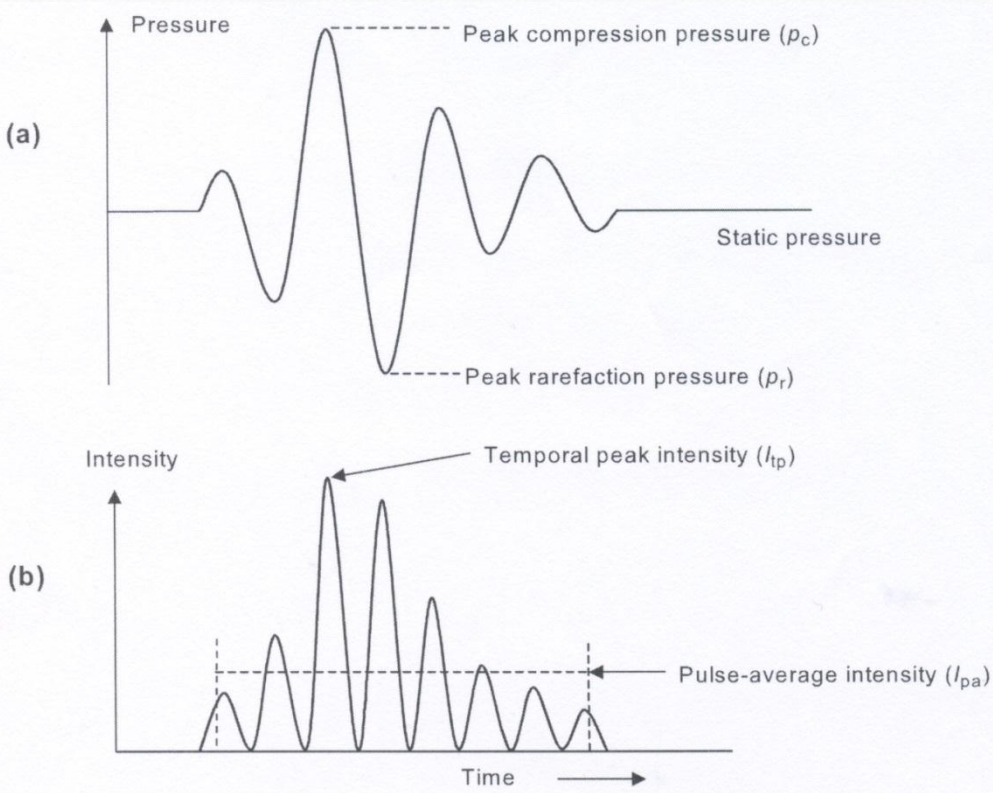


Figure 3.1 (a) The peak compression and rarefaction pressures are the maximum and minimum values of pressure in the medium during the passage of an ultrasound pulse. (b) The intensity is related to the pressure squared and is always positive. The temporal-peak intensity is the maximum value during the pulse. The pulse-average intensity is the average value over the duration of the pulse.

The pressures are normally measured in MPa

Intensity is related to pressure squared

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Quantities often used by FDA among others

I-spta

(mW/cm²)

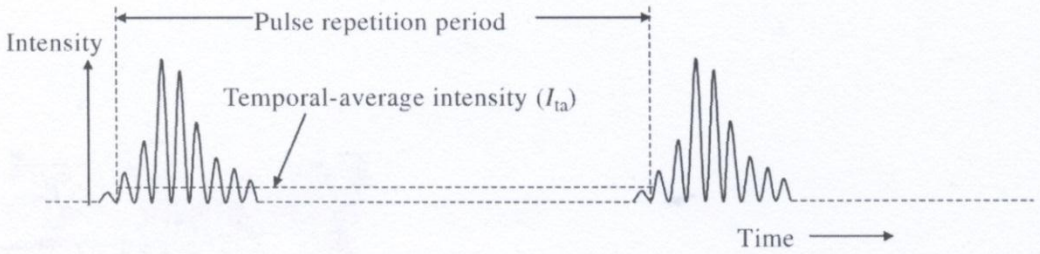


Figure 3.3. The intensity waveform is repeated with every pulse-echo cycle. The temporal-average intensity is the average value over a complete pulse-echo cycle and is much lower than the pulse-average intensity.

I-sppa

(W/cm²)

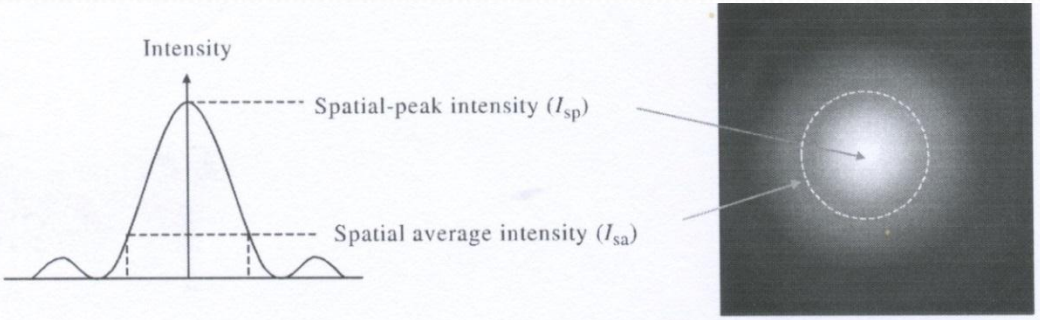


Figure 3.4. The values of the various intensity parameters change with position in the beam also. The highest value in the beam is the spatial-peak intensity. The average value over the area of the beam is the spatial average intensity.

Important intensities measure for temperature increases

- **I-SPTA** stand for **I**ntensity at **S**patial-**P**eak-**T**emporal-**A**verage and means the intensity at that spatial position which have the highest ultrasound intensity, averaged over time, normaly Prp. Common measuring unit is mW/cm^2
- I-SPTA is one of the most important quantities regarding possible biological risks from temperature increases in tissue, it is often refered to in standards. Manufacturers must declare that value in their technical specifications
- **I-SPPA** stand for **I**ntensity at **S**patial-**P**eak-**P**ulse-**A**verage and means the intensity at that spatial position which have the highest ultrasound intensity, average over the pulse time. Common measuring unit is W/cm^2

Transportable hydrophone for measurment of ultrasound intensity

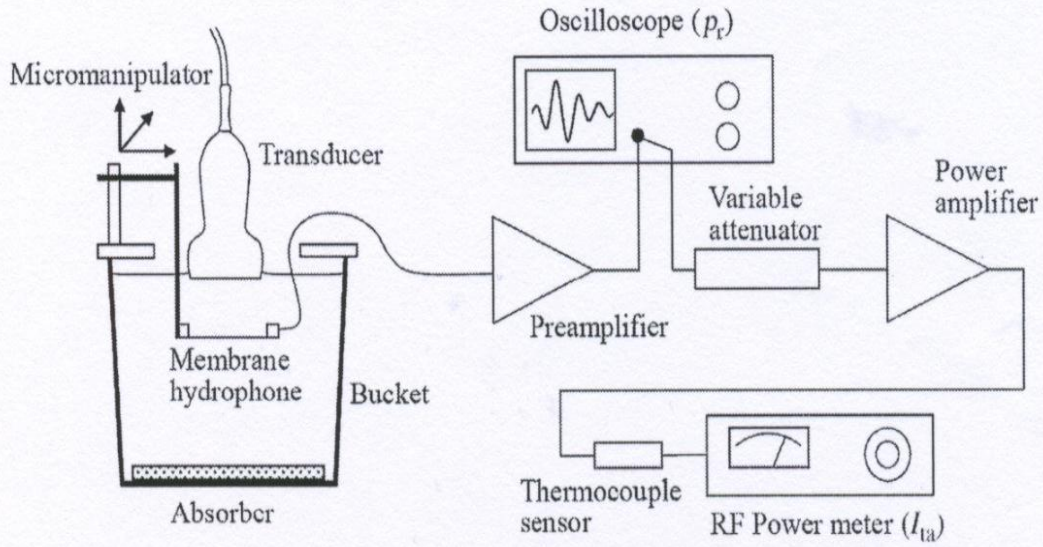
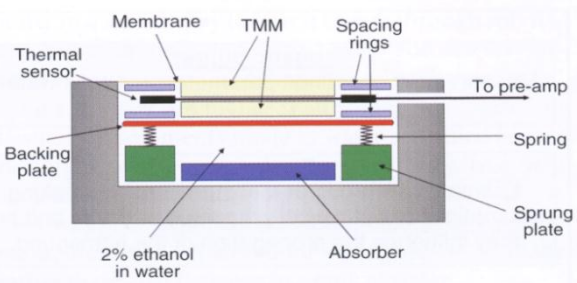


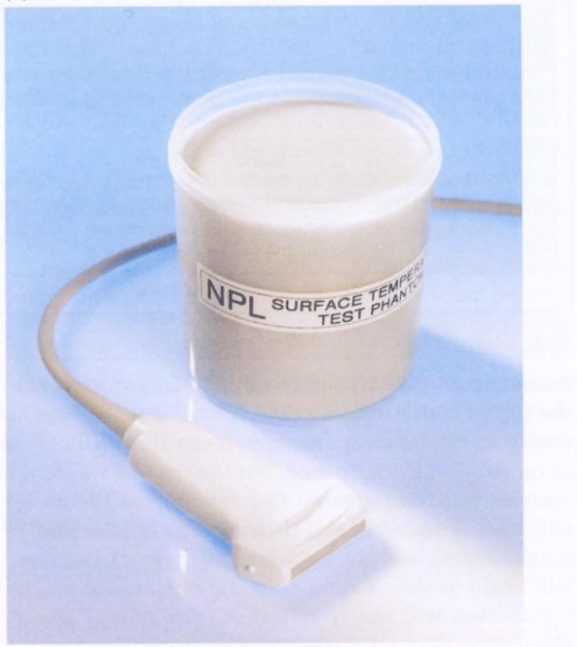
Figure 3.7 Principle features of the portable "hydrophone in a bucket" system developed in Newcastle.

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Temperature measuring devices (left) and a radiation force balance, RFB, for measurment of acoustic power (below)



(a)



(b)

Fig. 12.3 (a) Diagram of a thermal test object. The temperature rise in the middle of the tissue-mimicking material (TMM) is measured with a small thermocouple of less than 0.5 mm in diameter. (b) Photograph of a commercial thermal test object for testing surface temperature rise against the limits specified by the IEC.

(From Hoskins 2010)

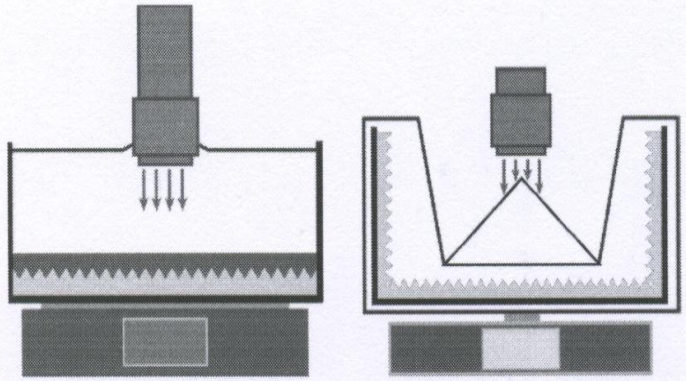


Figure 3.8. Two schematic RFB configurations showing the absorbing well (left) and suspended target (right) types.

The force on an absorbing target is approximately 68 µg/mW of incident power

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Acoustic Intensity Measurement System

Acoustid ntensity Measurement System

AIMS III with Soniq Software

AIMS III is the latest generation hydrophone scanning system that enhances acoustic measurement productivity to map acoustic fields in liquids. User workflow is improved by productivity enhancements that save time in the measurement set-up, scanning, and reporting. These enhancements are based on decades of scanning technology development. Combined with *Soniq* software, the user benefits from real-time plotting, automated FDA reporting, and improved positioning performance. AIMS III continues to be the de facto standard scanning tank for hydrophone-based measurements.

Features:

- Productivity enhancements to measurement set-up, scanning, and reporting
- Compatible with Windows 7 (in addition to Windows XP and 2000)
- Real-time plotting to confirm optimal measurement set-up early
- Automated diagnostic and physiotherapy reporting tables compliant with the latest IEC standards and FDA guidance documents
- Mechanical improvements to advance the positioning accuracy and reliability
- .dll interface for external software control
- SmartSCAN to enable forward and reverse scanning to reduce scanning time
- Angular positioner to accommodate various orientations including "shoot down"
- Over 100 measurement parameters available

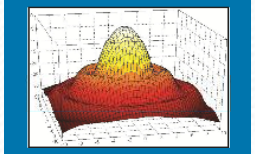
Applications:

The AIMS III offers the right balance between versatility and easy-to-use operations to meet the most advanced requirements in R&D characterization, regulatory testing, and production QC.

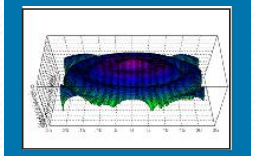
The system is commonly used to characterize and validate transducer designs. Features such as the 5 axis motion, various firing/measuring orientations, and real-time plotting make it the tool of choice to meet the most stringent environments.

The AIMS platform has also established itself as the premier instrument in the regulatory community. The system allows for automatic reporting compliant with standards for diagnostic equipment (AIUM-NEMA UD-2/UD-3 and IEC 60601-2-37, 61217-1, and 62359) as well as for physiotherapy (US 21 CFR 1050.10 and IEC 60601-2-5 and 61689).

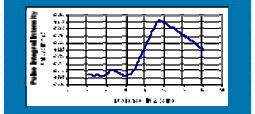
AIMS III System



2D Beam Intensity Plot



2D transaxial planar scan of a 1 MHz physiotherapy probe



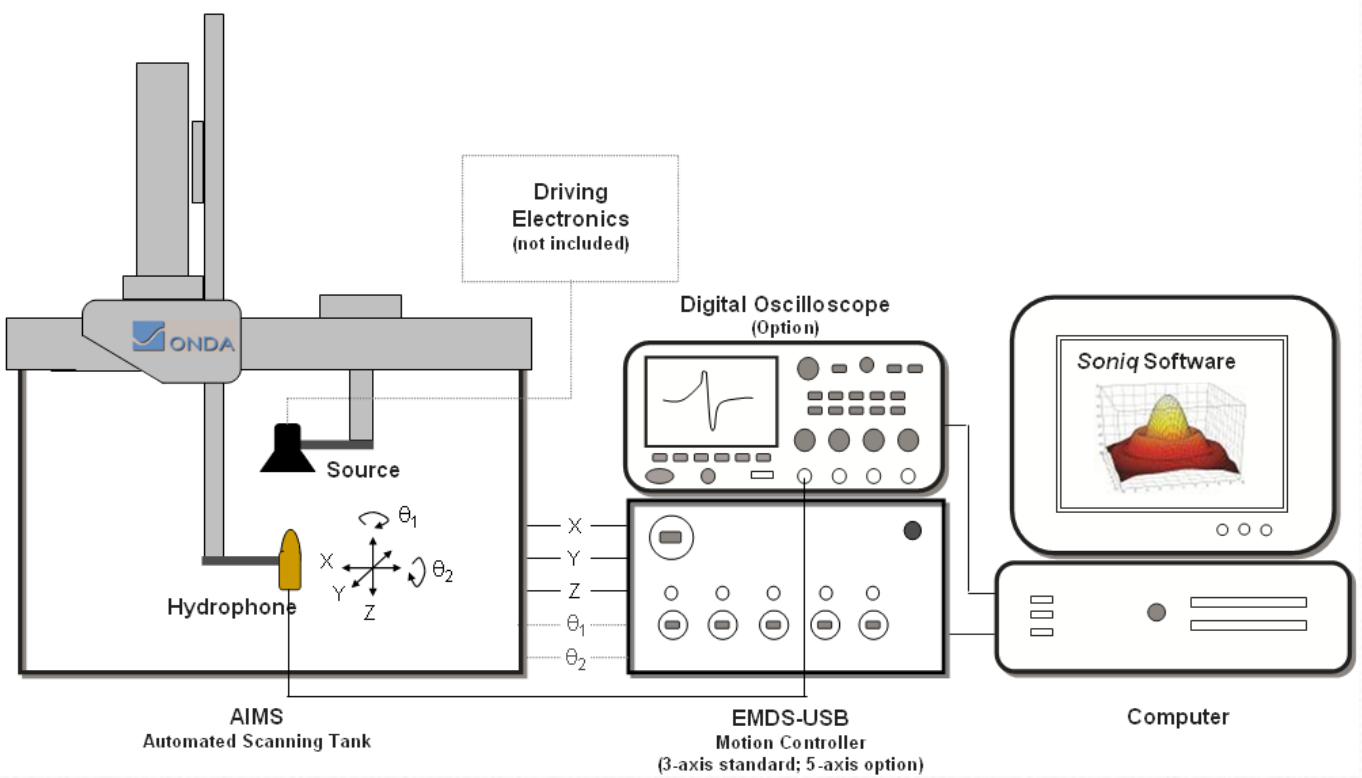
1D Intensity Z-Plot

Onda_AIMSIII_DataSheet_101103

AIMS III acoustic intensity measurement system, ONDA corp

Simple Measurement Set-up

[Not to scale]



Membrane and needle hydrophones

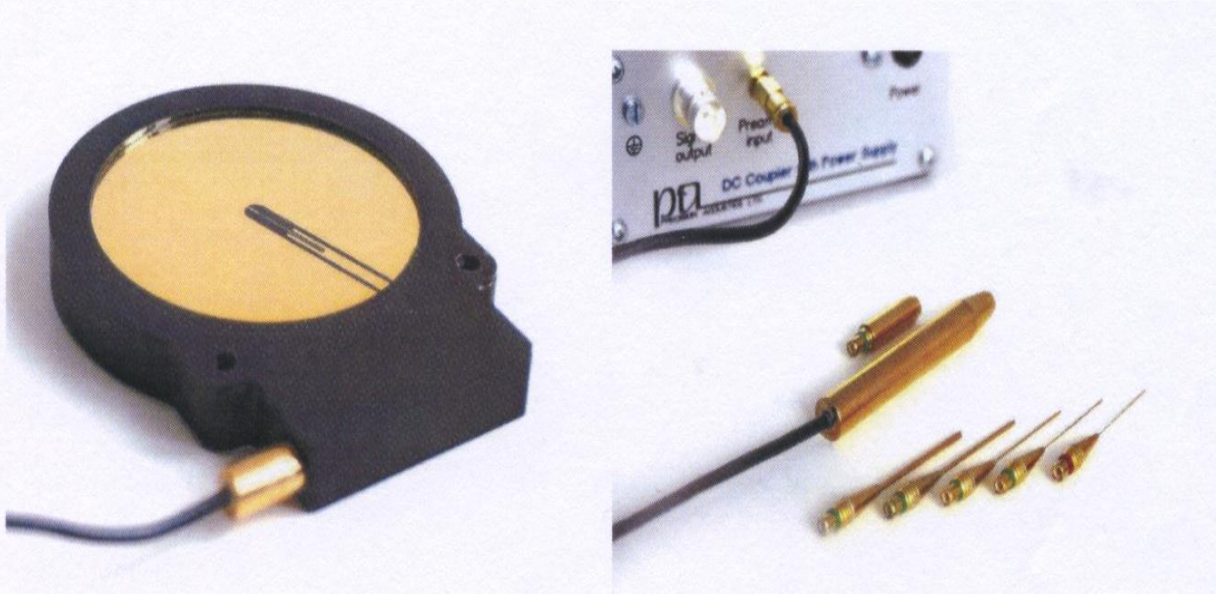


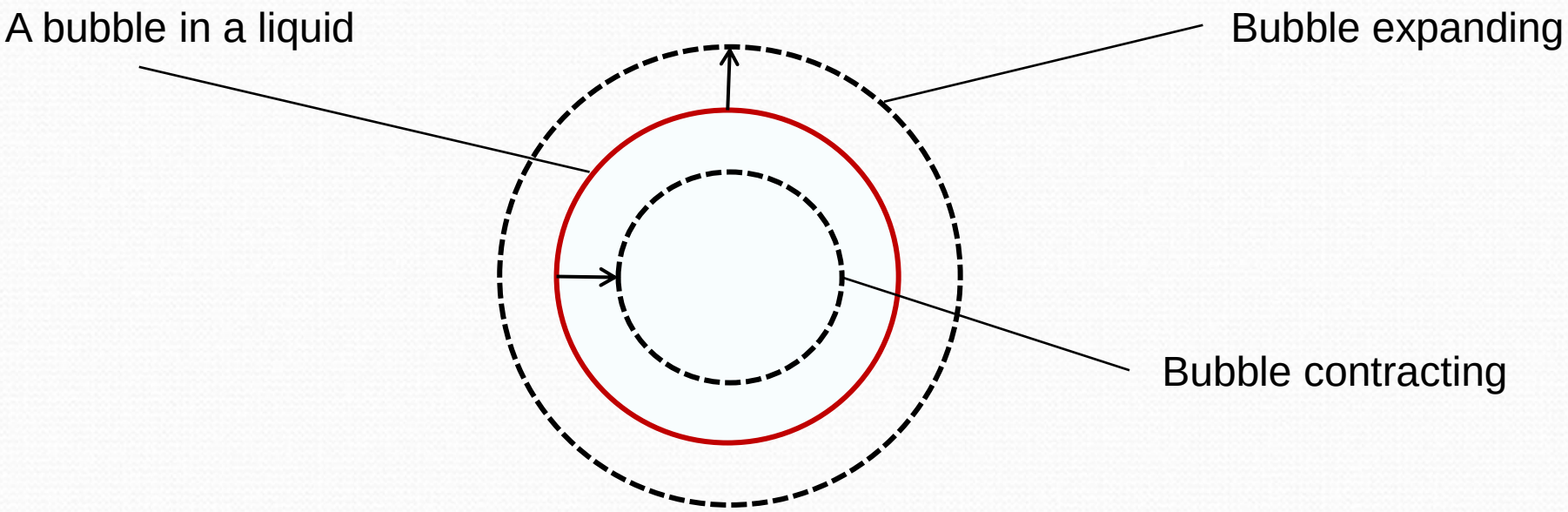
Figure 3.5. Membrane hydrophone (left) and needle hydrophones (right). Photographs courtesy of Precision Acoustics Ltd.

Non-thermal risks

- Ultrasound pulses consists of both positive and negative pressures
- The largest negative pressure, s c peak rarefactional pressure, ($p_{r.3}$), together with the center frequency may influence certain gas microbubbles in the tissue
- This behavior is called acoustic cavitation and can be stable or unstable
- Stable or non-inertial cavitation can arise at low pressures and refers to a pulsating or breathing motion of gas bubbles which can exist in some tissues. The diameter follows the pressure variation in the ultrasonic wave (next page)
- If the rarefactional pressure rise too high, there is a risk for unstable inertial cavitation which occurs at higher and short peakpressure pulses where small bubbles undergoes very large size variations and can be brought to burst and cause damage in the surrounding tissue

(From Hoskins 2010)

A gasbubble under pressure



A gasbubble in a liquid with variation in pressure, expanding during periods of decreased pressure and contracting during the compression half period of the wave.

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Mechanical Index

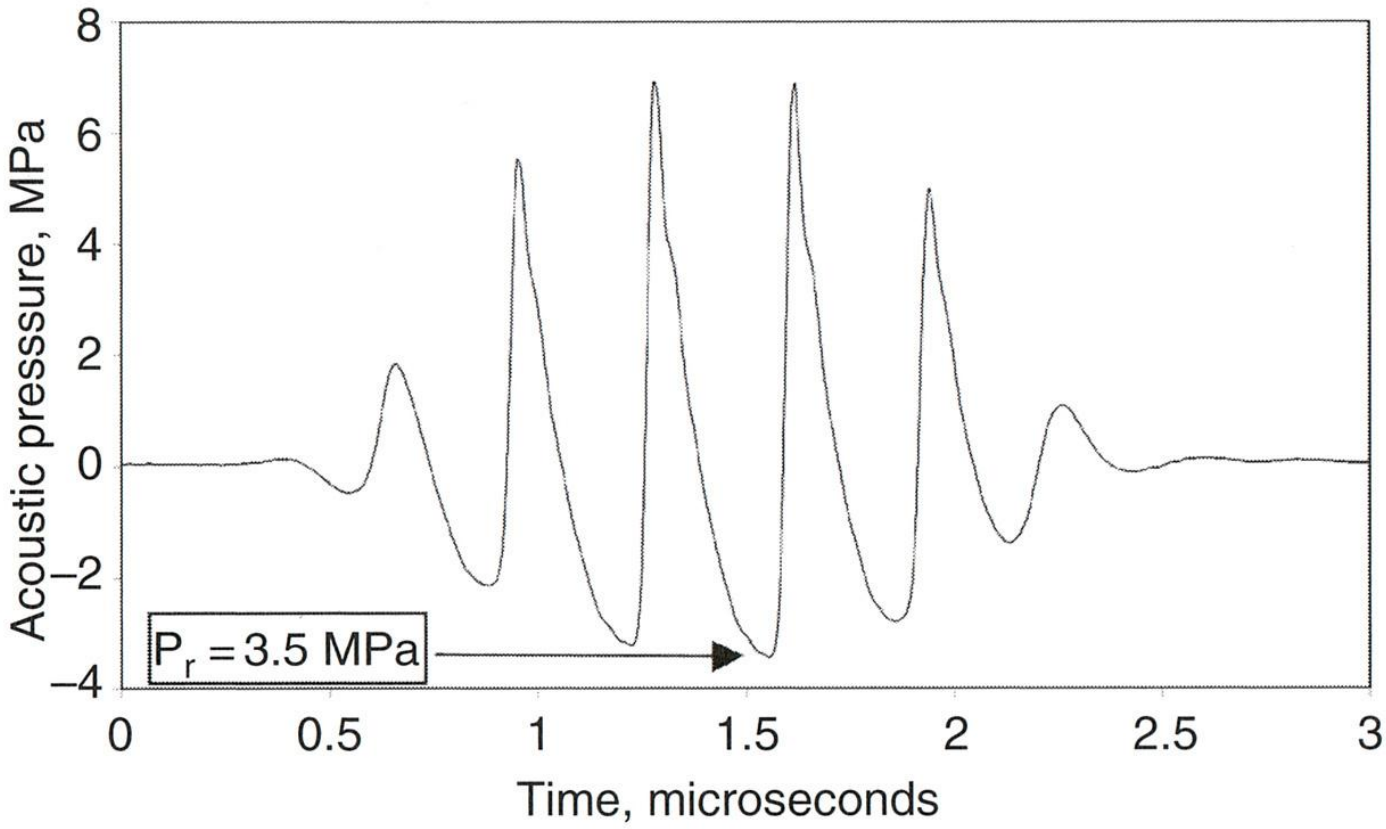
- The risk of acoustic cavitation depends primarily on the ultrasound pulse itself, peak rarefactional pressure, $p_{r.3}$, and transducer frequency. f_c. Also grade of focusing of the ultrasound field, pulsed or continues wave, standing waves etc is of importance. The Mechanical index, MI, may be used as a risk indicator for cavitation and is written as;

$$MI = p_{r.3} / \sqrt{f_c} \text{ with no units}$$

- Cavitation is a threshold phenomena which means that it can only happen above a certain MI value

- The highest risk for cavitation is during use of ultrasound together with contrast agents but can also happen in other gasfilled tissues , f ex at the surface of lung tissues or in gasfilled intestine tissues

A pulse from a pulsed doppler system



(From Hoskins 2010)

Fig. 12.1 Variation of acoustic pressure with time in a pulsed Doppler ultrasound pulse near the focus in water.

Output Display Standard

- Authorities, organisations such as AIUM/NEMA and IEC have agreed about an Output Display Standard, ODS, (1998, 2001 and 2006) which mean that ultrasound scanners must have a built-in display system so the ultrasound users can see what parameters are active in a certain examination

- From that display shall two types of s c *index* be shown, which have strong connection to *output power, frequency and tissue pressure*

- Those are:
  - ***Thermal Index or TI***, which is related to temperature increase and
  - ***Mechanical Index or MI,*** which has connection to non-thermal biological effects f ex cavitation

The higher index figure on TI och MI the higher is the potential risk

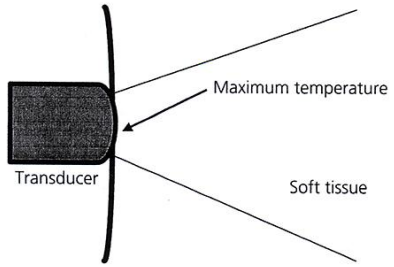
- Thermal index can further be devided into three or four sub groups

Shortening	Measure	Description
MI	Mechanical index	To be used only in 2D-scanning
TIS	Thermal index, soft tissue	Is recommended for soft tissue scanning and fetus scanning during 1st trimester
TISF	Thermal index, soft tissue in focus	Show TIS for focus region in M-, PW- and CW-modes
TIB	Thermal index, skeleton bone in focus	Recommended for fetus scanning during 2nd and 3rd trimester
TIC	Thermal index, skeleton bone at surface, skull	Recommended for head scanning on adults or newborns

(after user manual Siemens/Acuson Sequoia)

Thermal conditions at TIS, TIB and TIC

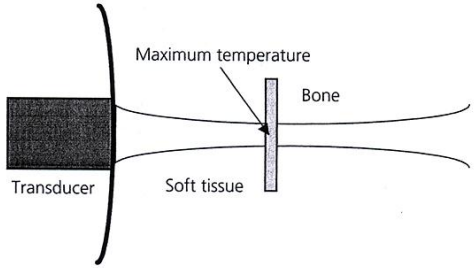
(scanned)



TIS

Fig. 13.4 Diagram showing conditions for TIS for scanning (these conditions are also assumed to apply for the calculation of TIB for scanning).

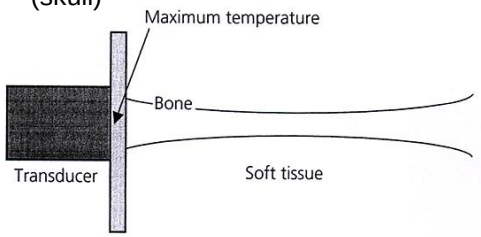
(unscanned)



TIB

Fig. 13.5 Diagram showing the conditions for TIB.

(skull)



TIC

Fig. 13.6 Diagram showing the conditions for the TIC.

(from Hoskins et al 2010)

Simple models used for calculation of soft-tissue thermal index (TIS) and bone-at-focus thermal index, TIB. Soft tissue is modelled as a homogeneous material with an attenuation of 0,3 dB/cm MHz.

Temperature measurements on transducer surface when changing settings

(Opportunity for useful staff training of awareness)

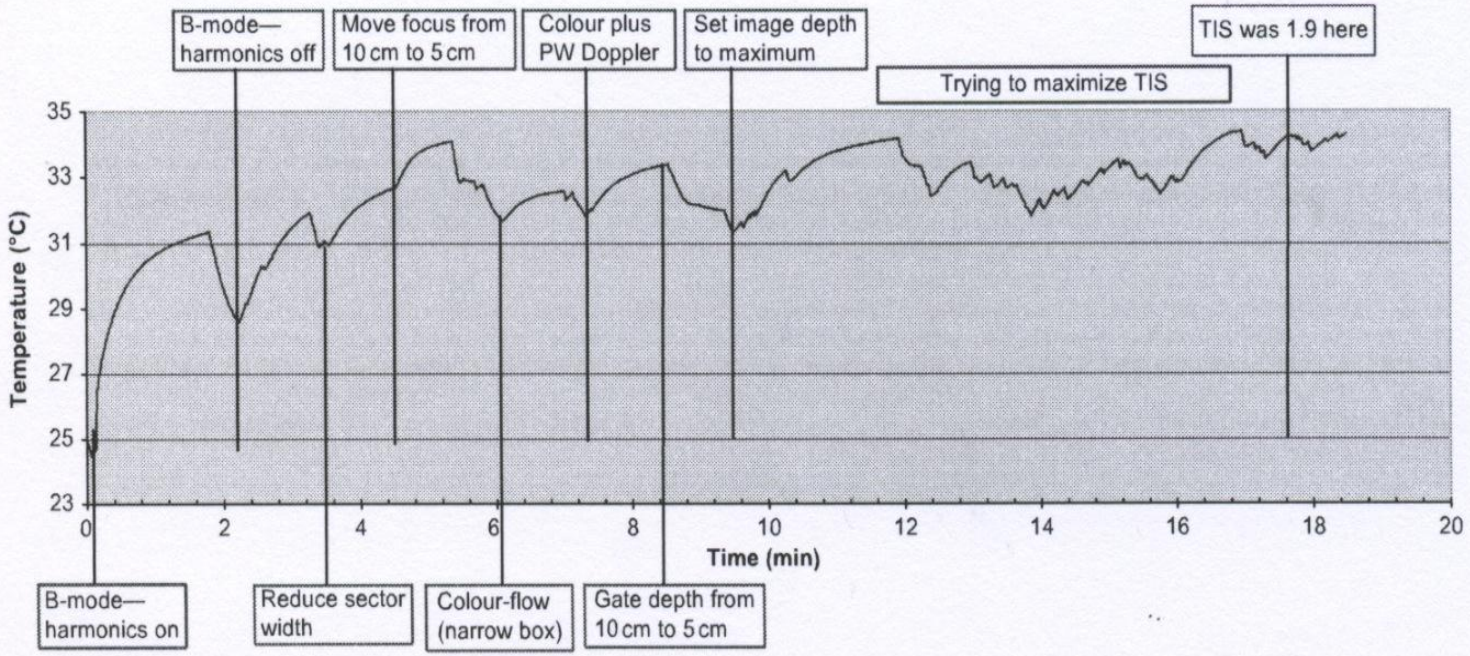


Figure 3.10. Example showing the variation in the surface temperature of a 3 MHz linear array transducer as scanner settings are adjusted.

(From The safe use of ultrasound in medical diagnosis, nov 2012)

Output display

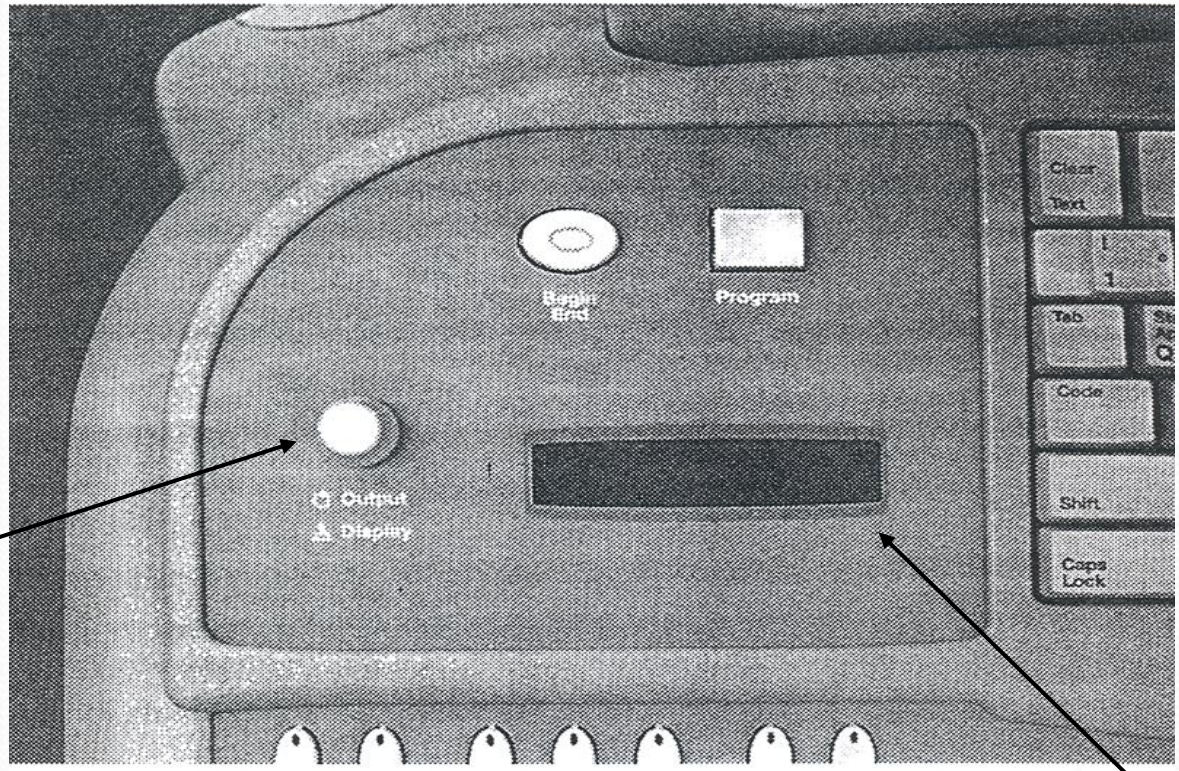


Figure 4-1 Output Display

Adjustment of output power

Powerdisplay for MI ond TI

The Sequoia ultrasound system has a built-in power display which make it possible to follow the acoustic power parameter levels for the active transducer in the actual mode during an examination

(From user manual Siemens/Acuson Sequoia)

Acoustic Power Indication

Acoustic output and display on the Vivid 7/Vivid 7 PRO

In the title bar, two fields are allocated for the display of power values as shown in Figure 14-1.

1. Title bar
2. MI
3. TI

Figure 14-1: The display of MI and TI on the screen

The Vivid 7/Vivid 7 PRO chooses the correct category based on mode of operation and chosen application, and presents only one TI to the operator. It is therefore important that the operator chooses the right application.

The Vivid 7/Vivid 7 PRO has an internal limit of 4.0 on TI. IEC87 has suggested some time dependent thresholds that are partly implemented on the Vivid 7/Vivid 7 PRO as color-coding of the thermal index. The color-coding scheme together with the thermal exposure times in the table below are not meant as limits on TI or exposure time, but as an aid for the operator. Note that the Vivid 7/Vivid 7 PRO does not monitor the thermal exposure time. The displayed TI is coded as follow:

TI	Color	Recommended thermal exposure time
0.0 – 0.4	Dimmed	-
0.4 – 1.5	White	-
1.5 – 2.0	White	< 12 h
2.0 – 3.0	White	< 1 h
3.0 – 4.0	Red	< 15 min.

MI and TIS

(From user manual GE Healthcare Vivid 7)

Color-coded TI levels and recommended exposure times

Vivid 7 has an internal limit of 4.0 on TI

Formula for calculation of Thermal Index,TI

- The basic definition of Thermal index is: $TI = W_0 / W_{deg}$
- Where W_0 is the source power of the ultrasound system and W_{deg} is the source power required to increase the temperature of a specific tissue model by 1 °C
- Thermal index has also a simple form which is valid for soft tissue
- $TIS = (W \times f \times k_1)$, where W is the acustic power in mW, f is the transducer frequency in MHz. The constant, k_1, is a factor which include all other detailed constant values and is in this formula, 1 / 210
- For heating at a bone surface is the formula slightly changed:
- $TIB = (W \times k_2)$ without depending of frequency and where k_2 always is larger than k_1

Manufacturers are forced by authorities to declare those specifications for every transducer type in every mode (2D, M-mode, PW-doppler etc)

(Specified by GE in user manual for System 5)

Transducer Model: 2.5 MHz FPA, KG100001

Operating Mode: M-Mode

Index Label				MI	TIS			TIB	TIC
					scan	non-scan			
						$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value				1.33	-	-	0.54	-	< 0.4
Assoc.	$P_{r.3}$		(MPa)	-1.69					
	W_0		(mW)		-	-		-	#
Acoustic	min of ($W_{.3}(z_1)$, $I_{TA.3}(z_1)$)		(mW)				67		
	z_1		(cm)				2.52		
Param.	z_{bp}		(cm)				2.52		
	z_{sp}		(cm)	3.57				-	
	$d_{eq}(z_{sp})$		(cm)					-	
	f_c		(MHz)	1.61	-	-	1.69	-	#
	Dim of	X	(cm)		-	-	1.86	-	#
	A_{aprt}	Y	(cm)		-	-	1.3	-	#
Other	PD		(μs)	1.53					
	PRF		(Hz)	1000					
Info	P_r @ PII_{max}		(MPa)	-2.07					
	d_{eq} @ PII_{max}		(cm)					-	
	Focal	FL_x	(cm)		-	-	1.61		#
	Length	FL_y	(cm)		-	-	0.64		#
	$I_{pa.3}$ @ MI_{max}		(W/cm^2)	123.5					
Operator	Depth		(cm)	30			30		
	Frequency			Min			Min+1		
	Focus		(mm)	115			300		
Controls	Power		(dB)	0			0		
	Beam Angle (TB)		(deg)	0			0		

TIS = W • f • k1

where k1 = 0.00476, W power in mW and f frequency i MHz

Ex TIS = 67 • 1.69 • 0.00476

TIS = 0.538

Formula for calulation of Mechanical Index, MI (repetition)

- Mechanical Index,MI, is calculated from a measured maximum negative peak pressure, $p_{r.3}$(”peak rarefactional pressure”) in MPa divided by the square rote of the center frequency, f_c , in MHz according to :

- $MI = p_{r.3} / \sqrt{f_c}$ with no unit

- The ”$p_{r.3}$” rarefactional pressure of the acoustic field derated at 0,3 dB/cm MHz, which is a value between water (0,02) and soft tissue (0,5) attenuating factors

- The MI-value tells the user how large the negative pulse is in use at the time. If you increase the output power or lower the frequency the MI value will increase proportionally

Acoustic Output Reporting Tables, Track 3

Transducer Model: 2.5 MHz FPA, KG100001

Operating Mode: 2D

Index Label				MI	TIS			TIB	TIC
					scan	non-scan			
						$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Index Value				1.28	2.16	-	-	-	2.01
Assoc. Acoustic Param.	$P_{r,3}$		(MPa)	-1.70					
	W_0		(mW)		264	-		-	141
	min of ($W_{.3}(z_1)$, $I_{TA.3}(z_1)$)		(mW)				-		
	z_1		(cm)				-		
	z_{bp}		(cm)				-		
	z_{sp}		(cm)	2.82				-	
	$d_{eq}(z_{sp})$		(cm)					-	
	f_c		(MHz)	1.76	2.86	-	-	-	1.71
	Dim of A_{aprt}	X	(cm)		1.85	-	-	-	1.86
		Y	(cm)		1.30	-	-	-	1.30
Other Info	PD		(μs)	1.08					
	PRF		(Hz)	71					
	P_r @PII_{max}		(MPa)	-2.02					
	d_{eq} @PII_{max}		(cm)					-	
	Focal Length	FL_x	(cm)		1.42	-	-		1.64
		FL_y	(cm)		0.42	-	-		0.64
	$I_{pa.3}$ @MI_{max}		(W/cm^2)	103					
Operator Controls	Depth		(cm)	30	14				30
	Framerate		(fps)	71	117				42
	Angle		(deg)	30	30				30
	Frequency			Min+2	Max				Min+2
	Tilt		(deg)	0	0				0
	Focus		(mm)	30	150				300
	Power		(dB)	0	0				0
Notes	Zone for max. MI[1]			1	1				1
	Number of transmit zones[a]			1	1				1

a. See explanation of measurements with several focal zones on page I-4.

MI = 1.7 / √ 1.76 = 1.28

(Specified by GE in user.manual for System 5)

Maximum exposure

The upper limits of exposure specified by FDA in USA (2003).The upper limit of 6.0 for thermal index is advisory. At least one of the quantities MI and I-SPPA must be less than the specified limit. A TI value of 2.0 correspond to a temperature elevation of about 2 °C. SPPA stand for **S**patial **P**eak **P**ulse **A**verage and take also the pulselength into consideration

Application	Derated I-SPTA (mW/cm2)	Derated I-SPPA (W/cm2)	Mechanical index (MI)	Thermal index (TI)
All applications except ophtalmology	720	190	1.9	(6.0)
Ophtalmology	50	Not specified	0.23	1.0

(After FDA)

Comparism with older values

Table 12.3 Maximum ultrasound exposure measured in water, from B-mode and M-mode operation.

Application	Range	Median
B-mode imaging and M-mode		
Peak rarefaction pressure, p_r (MPa)	0.45–5.54	2.4
Spatial peak pulse average intensity, I_{sppa} (W cm^{-2})	14–933	230
M-mode only		
Spatial peak temporal average intensity, I_{spta} (mW cm^{-2})	11.2–430	106
Total acoustic power (mW)	1–68	9
B-mode only		
Spatial peak temporal average intensity, I_{spta} (mW cm^{-2})	0.3–991	34
Total acoustic power (mW)	0.3–285	75

$P_{r.3}$ are 50-75% higher 2010 than 1998 regarding 2D, PW- and Colour doppler

Table 12.4 Maximum ultrasound exposure measured in water for pulsed Doppler and Doppler imaging modes.

	Range	Median
Spectral pulsed Doppler		
Peak rarefaction pressure, p_r (MPa)	0.67–5.32	2.1
Spatial peak pulse average intensity, I_{sppa} (W cm^{-2})	1.1–771	144
Spatial peak temporal average intensity, I_{spta} (mW cm^{-2})	173–9080	1180
Acoustic power (mW)	10–440	100
Doppler imaging		
Peak rarefaction pressure, p_r (MPa)	0.46–4.25	2.38
Spatial peak pulse average intensity, I_{sppa} (W cm^{-2})	60–670	275
Spatial peak temporal average intensity, I_{spta} (mW cm^{-2})	21–2050	290
Acoustic power (mW)	15–440	90

(From, Hoskins 2010)

BMUS Guidelines (for obstetric and neonatal ultrasound)

Table 1. Recommended exposure time and index values for obstetric and neonatal ultrasound.

Application	Values to monitor (A)	Thermal Index value			Mechanical Index value		
		0 - 0.7	0.7 - 3.0	>3.0	0 - 0.3	>0.3	>0.7
Obstetrics up 10 weeks after LMP (and gynaecology when pregnancy is possible)	TIS and MI	✓	(B) restrict time to 0.7<TIS≤1.0 : 60 min 1.0<TIS≤1.5 : 30 min 1.5<TIS≤2.0 : 15 min 2.0<TIS≤2.5 : 4 min 2.5<TIS≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Obstetrics more than 10 weeks after LMP	TIB and MI	✓	(B) restrict time to 0.7<TIB≤1.0 : 60 min 1.0<TIB≤1.5 : 30 min 1.5<TIB≤2.0 : 15 min 2.0<TIB≤2.5 : 4 min 2.5<TIB≤3.0 : 1 min	Scanning of an embryo or fetus is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Neonatal – transcranial and spinal	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min	Scanning of the central nervous system is not recommended, however briefly	✓	✓	(E) risk of cavitation with contrast agents
Neonatal - general and cardiac imaging	TIB and MI recommended	✓	(C) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min 3.0<TIB≤4.0 : 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: not recommended.		✓	(D) Possibility of minor damage to lung or intestine. Minimise exposure time.	(E) risk of cavitation with contrast agents
Fetal Doppler heart monitoring	TI or MI are not usually available for dedicated fetal heart monitors.	The power levels used by dedicated fetal heart monitors are sufficiently low that the use of this modality is not contra-indicated, on safety grounds, even when it is to be used for extended periods.					

✓: There is no known reason to restrict scanning times in this region.
A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.
B: TI > 0.7 - the overall exposure time (including pauses) of an embryo or fetus or of the neonatal central nervous system should be restricted.
C: TI > 1.0 - the overall exposure time (including pauses) of other parts of the neonate should be restricted.
D: MI > 0.3 - there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, try to reduce the exposure time as much as possible.
E: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.

(from Safety guidelines BMUS nov 2010)

BMUS Guidelines (for non-obstetric and non-neonatal ultrasound)

Table 2. Recommended exposure time and index values for non-obstetric and non-neonatal ultrasound.

Application	Values to monitor (A)	Thermal Index value		Mechanical Index value	
		0 – 1.0	> 1.0	0 - 0.3	> 0.7
General abdominal Peripheral vascular Unlisted applications	Usually TIB and MI. [use TIC and MI if bone closer than 1 cm; TIS and MI only if bone does not come into the image]	✓	(B) restrict time to 1.0<TIB≤1.5 : 120 min 1.5<TIB≤2.0 : 60 min 2.0<TIB≤2.5 : 15 min 2.5<TIB≤3.0 : 4 min 3.0<TIB≤4.0 : 1 min 4.0<TIB≤5.0 : 15 sec 5.0<TIB≤6.0 : 5 sec TIB>6: not recommended	✓	(C) risk of cavitation with contrast agents
Eye	TIS and MI recommended	✓	Scanning of the eye is not recommended	✓	(C) risk of cavitation with contrast agents
Adult transcranial (imaging and stand-alone) (D)	TIC and MI	✓	(B) restrict time to 0.7<TIC≤1.0 : 60 min 1.0<TIC≤1.5 : 30 min 1.5<TIC≤2.0 : 15 min 2.0<TIC≤2.5 : 4 min 2.5<TIC≤3.0 : 1 min TIC>3: not recommended	✓	(C) risk of cavitation with contrast agents
Peripheral pulse monitoring	TI or MI are not usually available for dedicated peripheral pulse monitors.	The output from CW Doppler devices intended for monitoring peripheral pulses is sufficiently low that their use is not contra-indicated, on safety grounds			

✓: There is no known reason to restrict scanning times in this region.
A: Many scanners allow MI and one of the TI values to be displayed simultaneously: the most appropriate TI value depends on the clinical application.
B: TI > 1.0 - the overall exposure time (including pauses) should be restricted.
C: MI > 0.7 - there is a risk of cavitation if an ultrasound contrast agent containing gas micro-spheres is being used. There is a theoretical risk of cavitation without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
D: Transcranial ultrasound investigations may require higher acoustic output or longer monitoring times than other applications. When times longer than those recommended here are required, it is recommended that monitoring is paused regularly to minimise exposure.

(from Safety guidelines BMUS nov 2009)

Leakage currents

According to **SS-EN 60601-1**, *Electromedical equipment, general requirements for safety*

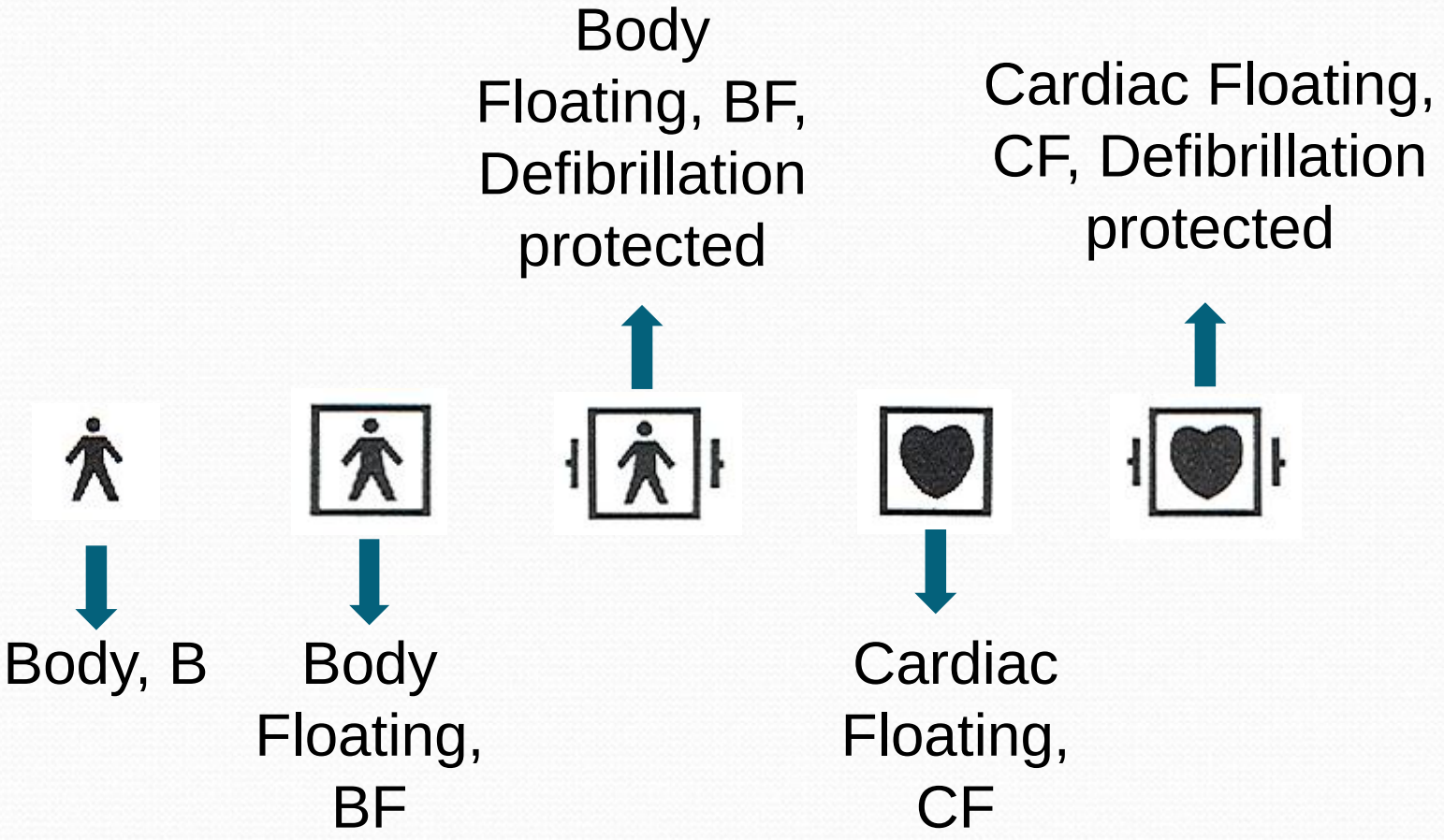
- Following protection grades are used :

- Type B (Body), means low leakage currents but you have no limitation from currents floating from equipment through the patient. This can be a dangerous situation for the patient if he come in contact with mains voltage from a broken equipment near him

- Type BF (Body; Floating), means the same low leakage currents as type B but has also a high resistance against currents from eqiupment to the patient. In this case is it limited to 5 mA which can protect the patient from dangerous currents. Normal protection grade for an ultrasound scanner with probes

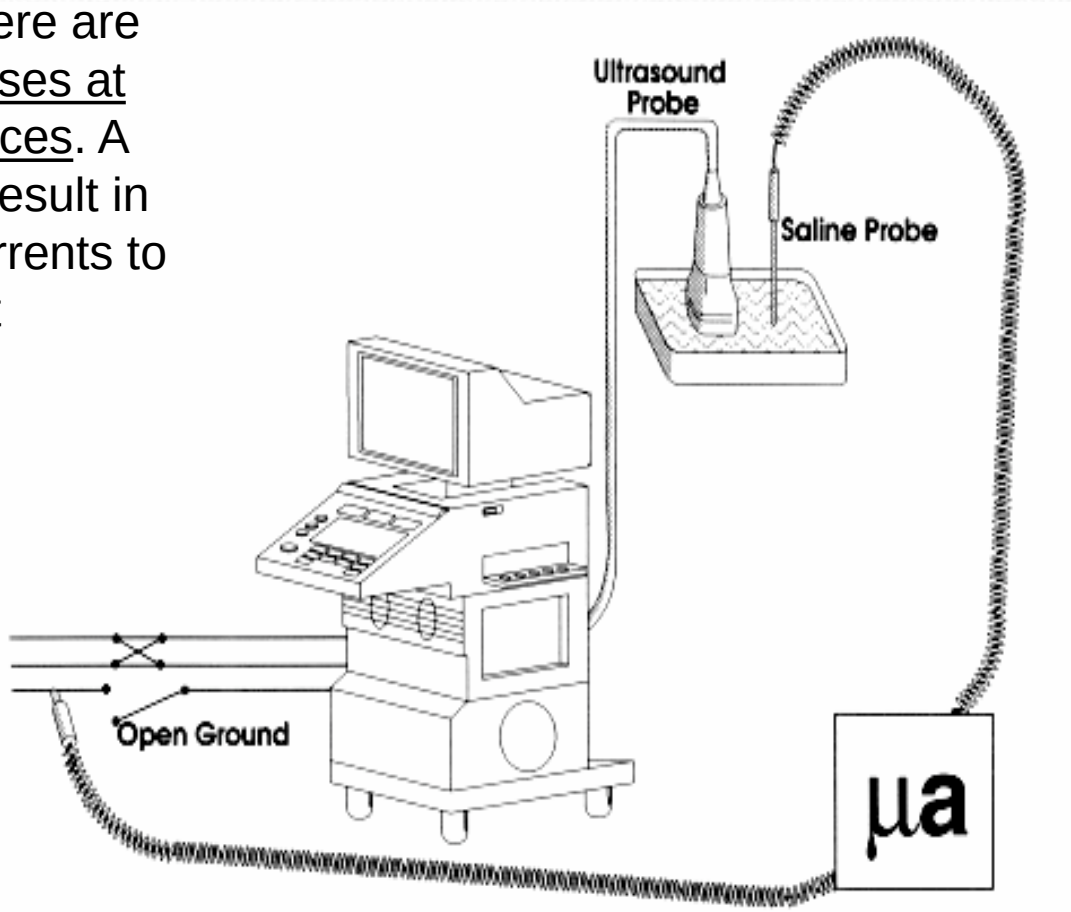
- Type CF (Cardiac; Floating), means better isolation and lower leakage currents than type BF and the maximum leakage current is here limited to 50 µA. Ultrasound transducers for internal use have this protection grade, f ex esofagus transducers

Symbols for protection grades



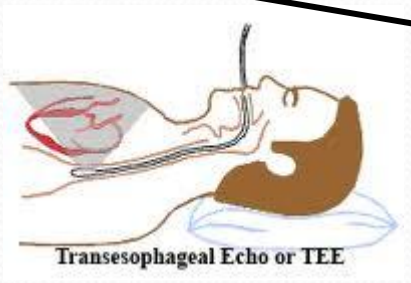
Checking of leakage currents from an ultrasound scanner

Very important to do this tests because there are often broken lenses at transducer surfaces. A broken lens can result in higher leakage currents to the patient



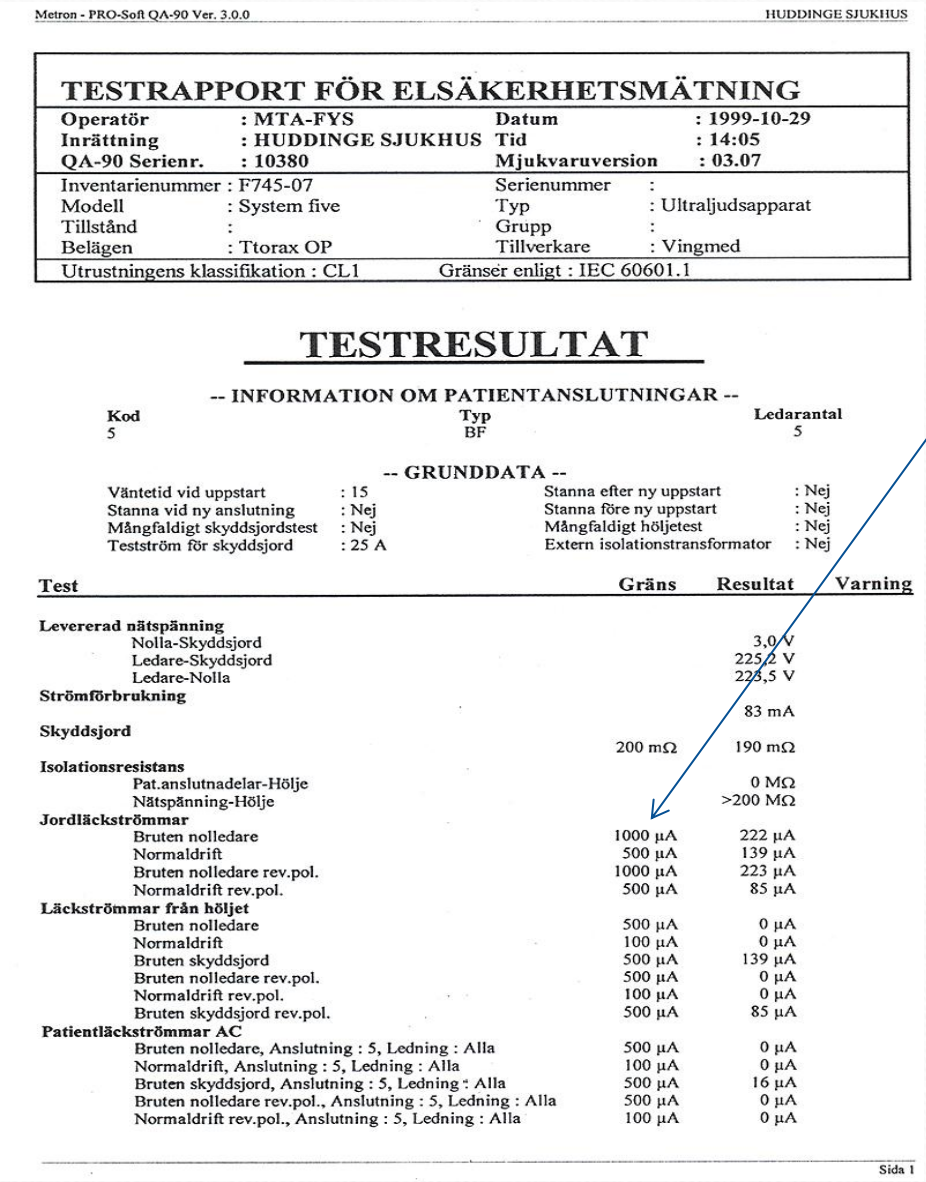
TEE probes must be handled with care

- Trans Esophageal Echocardiography probes are tested for electrical failures before each patient examination because of the sensitive scanning situation. Special bite-guards are used.



Analyzer for checking of electrical safety

Electrical safety protocol



Metron - PRO-Soft QA-90 Ver. 3.0.0 HUDDINGE SJUKHUS

TESTRAPPORT FÖR ELSÄKERHETSMÄTNING

Operatör	**: MTA-FYS**	**Datum**	**: 1999-10-29**
Inrättning	**: HUDDINGE SJUKHUS**	**Tid**	**: 14:05**
QA-90 Serienr.	**: 10380**	**Mjukvaruversion**	**: 03.07**
Inventarienummer	: F745-07	Serienummer	:
Modell	: System five	Typ	: Ultraljudsapparat
Tillstånd	:	Grupp	:
Belägen	: Ttorax OP	Tillverkare	: Vingmed

Utrustningens klassifikation : CL1 Gränser enligt : IEC 60601.1

TESTRESULTAT

-- INFORMATION OM PATIENTANSLUTNINGAR --

Kod	Typ	Ledarantal
5	BF	5

-- GRUNDDATA --

Väntetid vid uppstart	: 15	Stanna efter ny uppstart	: Nej
Stanna vid ny anslutning	: Nej	Stanna före ny uppstart	: Nej
Mångfaldigt skyddsjordstest	: Nej	Mångfaldigt höljetest	: Nej
Testström för skyddsjord	: 25 A	Extern isolationstransformator	: Nej

Test	Gräns	Resultat	Varning
Levererad nätspänning			
Nolla-Skyddsjord		3,0 V	
Ledare-Skyddsjord		225,2 V	
Ledare-Nolla		228,5 V	
Strömförbrukning		83 mA	
Skyddsjord	200 mΩ	190 mΩ	
Isolationsresistans			
Pat.anslutnadelar-Hölje		0 MΩ	
Nätspänning-Hölje		>200 MΩ	
Jordläckströmmar			
Bruten nolledare	1000 µA	222 µA	
Normaldrift	500 µA	139 µA	
Bruten nolledare rev.pol.	1000 µA	223 µA	
Normaldrift rev.pol.	500 µA	85 µA	
Läckströmmar från höljet			
Bruten nolledare	500 µA	0 µA	
Normaldrift	100 µA	0 µA	
Bruten skyddsjord	500 µA	139 µA	
Bruten nolledare rev.pol.	500 µA	0 µA	
Normaldrift rev.pol.	100 µA	0 µA	
Bruten skyddsjord rev.pol.	500 µA	85 µA	
Patientläckströmmar AC			
Bruten nolledare, Anslutning : 5, Ledning : Alla	500 µA	0 µA	
Normaldrift, Anslutning : 5, Ledning : Alla	100 µA	0 µA	
Bruten skyddsjord, Anslutning : 5, Ledning : Alla	500 µA	16 µA	
Bruten nolledare rev.pol., Anslutning : 5, Ledning : Alla	500 µA	0 µA	
Normaldrift rev.pol., Anslutning : 5, Ledning : Alla	100 µA	0 µA	

Sida 1

Testing of different leakage currents while comparing with approved limit values (left)

Electrical safety protocol /2

Mains on applied part

Unit passed the test

Metron - PRO-Soft QA-90 Ver. 3.0.0 HUDDINGE SJUKHUS

Patientläckströmmar AC (fortsätter)		
Bruten skyddsjord rev.pol., Anslutning : 5, Ledning : Alla	500 µA	19 µA
Nätspänning på patientanslutna delar		
Förstafel tillstånd, Anslutning : 5, Ledning : Alla	5000 µA	1129 µA
Förstafel tillstånd rev.pol., Anslutning : 5, Ledning : Alla	5000 µA	773 µA
Patientmätstömmen AC		
Bruten nolledare, Anslutning : 5, Ledning : 4	500 µA	2 µA
Normaldrift, Anslutning : 5, Ledning : 5	100 µA	0 µA
Bruten skyddsjord, Anslutning : 5, Ledning : 5	500 µA	8 µA
Bruten nolledare rev.pol., Anslutning : 5, Ledning : 4	500 µA	2 µA
Normaldrift rev.pol., Anslutning : 5, Ledning : 5	100 µA	0 µA
Bruten skyddsjord rev.pol., Anslutning : 5, Ledning : 5	500 µA	10 µA
Patientmätströmmen DC		
Bruten nolledare, Anslutning : 5, Ledning : 5	50 µA	0 µA
Normaldrift, Anslutning : 5, Ledning : 5	10 µA	0 µA
Bruten skyddsjord, Anslutning : 5, Ledning : 5	50 µA	0 µA
Bruten nolledare rev.pol., Anslutning : 5, Ledning : 5	50 µA	0 µA
Normaldrift rev.pol., Anslutning : 5, Ledning : 5	10 µA	0 µA
Bruten skyddsjord rev.pol., Anslutning : 5, Ledning : 5	50 µA	0 µA
Patientläckströmmar DC		
Bruten nolledare, Anslutning : 5, Ledning : Alla	50 µA	0 µA
Normaldrift, Anslutning : 5, Ledning : Alla	10 µA	0 µA
Bruten skyddsjord, Anslutning : 5, Ledning : Alla	50 µA	0 µA
Bruten nolledare rev.pol., Anslutning : 5, Ledning : Alla	50 µA	0 µA
Normaldrift rev.pol., Anslutning : 5, Ledning : Alla	10 µA	0 µA
Bruten skyddsjord rev.pol., Anslutning : 5, Ledning : Alla	50 µA	0 µA

***** ENHETEN KLARADE TESTET! *****

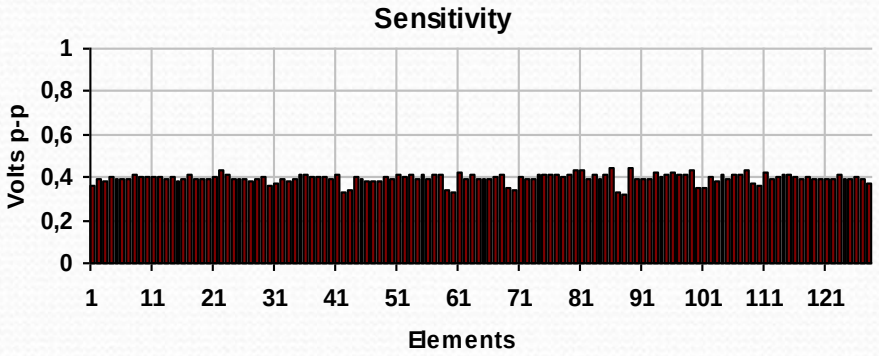
Signatur :

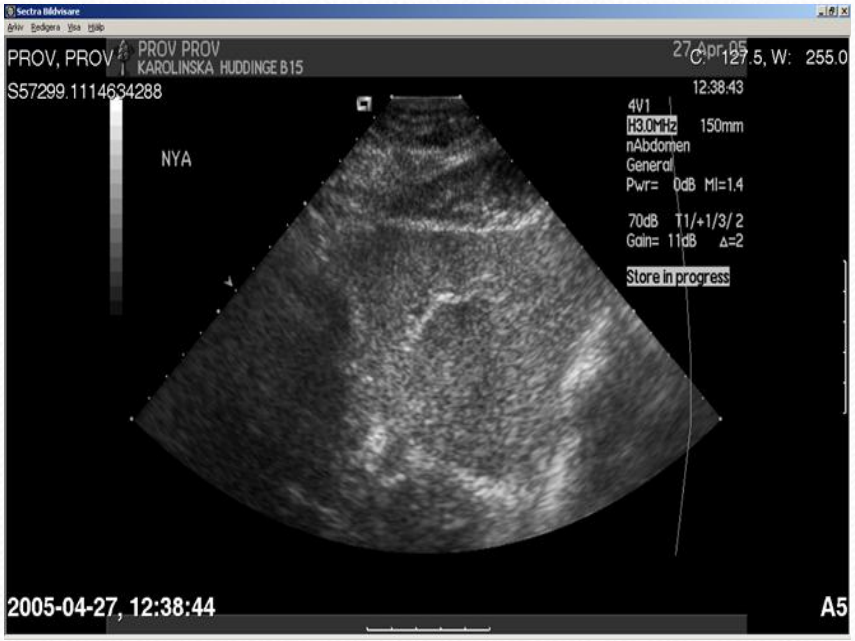
Sida 2

Ultrasound examination radiologi

(Same patient and same settings in the two images)

New transducer





Older transducer with many elements defect