

## Chapter 10 : Exposimetry

### I. Introduction

- Ultrasound has become very important in the practice of medicine over the past twenty years. In fact, it has been indispensable in many areas such as cardiology, obstetrics and gynecology. Since ultrasound propagates in the body in a form of mechanical energy, the possibility of producing harm must be of primary concern.
- Since the possibility for adverse bioeffects is of major concern due to the popular and routine use of ultrasound examinations, precise measurements of relevant ultrasound field parameters is critical in determining the relationship between physical parameters and potential bioeffects. In addition, the measurements and potential bioeffects can be weighed against the clinical benefits in developing policies regarding the use of diagnostic ultrasound.
- It is necessary to define the terms *dose* and *exposure*. In general, the term dose refers to the absorption of energy within tissue and dosimetry refers to the measurement of such effects. The absorption of energy is directly related to the bioeffects and typically can be expressed in terms of temperature rise or related to the degree of cell damage. On the other hand, exposure specifically relates to characteristics of the ultrasonic field and it can be expressed in terms of acoustic pressure, intensity and power. The term ultrasonic exposimetry refers to the quantitative study of the spatial and temporal characteristics of medical ultrasonic fields.

### II. Relevant Field Parameters

- Acoustic power: It is the acoustic energy emitted by the source and transmitted along the ultrasound beam per second. The instantaneous value of acoustic power varies but it is the averaged value which is of primary interest. Moreover, the average may be done in time or in space (e.g., over a pulse). Commercial diagnostic ultrasonic imaging systems typically generate average acoustic power less than a few hundred mW, depending on the situations. The acoustic power can be measured by hydrophones, force balances or other thermal techniques.

- Pulse repetition frequency: The repetition frequency of a pulsed waveform. Its inverse is the pulse repetition interval which represents the time interval between the same points on the waveform of two successive pulses.
- Scan repetition frequency: the repetition frequency of a complete scan in angle or position, depending on the scan format.
- Duty factor: The product of the pulse duration and the pulse repetition frequency for a pulsed waveform.
- Beam cross-sectional area ( $A_{cs}$ ): The area on the surface of a plane perpendicular to the beam axis consisting of all points where the pulse intensity integral is greater than 50 percent of the maximum acoustic pressure in the plane (i.e., 6dB criterion).
- Intensity ( $I(t, x, y)$ ): The instantaneous acoustic power (i.e., at time  $t$ ) transmitted in the direction of acoustic wave propagation, per unit area normal to this direction at the point considered (i.e., at point  $(x, y)$ ). As with power, the instantaneous intensity varies with time and the average is often of interest.
- Temporal average intensity ( $I_{TA}(x, y)$ ): It is the time-average of intensity at a point in space. It is also equal to the mean value of the intensity at the point considered. Let  $T_{rep}$  be the repetition period of the pulse waveform, we have

$$I_{TA}(x, y) = \frac{1}{T_{rep}} \int_{T_{rep}} I(t, x, y) dt .$$

- Spatial peak-temporal average intensity ( $I_{SPTA}$ ): It is the value of the temporal average intensity at the point in the acoustic field where the temporal average intensity is a maximum, or is a local maximum within a specified region.

$$I_{SPTA} = \max_{x, y} |I_{TA}(x, y)| .$$

The  $I_{SPTA}$  intensity has been used as an indicator of conditions under which biological effects have been observed in experiments with mice, rats and other laboratory mammals. Moreover, from theoretical considerations it appears that  $I_{SPTA}$  has significance in situations where biological cells aggregate in the

presence of an ultrasonic field..

- Spatial average-temporal average intensity ( $I_{SATA}$ ): It is the temporal average intensity averaged over the beam cross-sectional area in a specified plane.

$$I_{SATA} = \frac{1}{A_{cs}} \int_{A_{cs}} I_{TA}(x, y) dA.$$

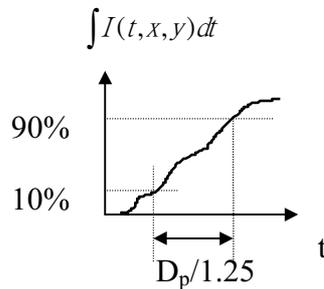
Note that the total output power  $W$  is approximately equal to  $\int_{A_{cs}} I_{TA}(x, y) dA$ .

Therefore,  $I_{SATA} \approx \frac{W}{A_{cs}}$ .

- Spatial peak-temporal peak intensity ( $I_{SPTP}$ ): It is the value of the temporal peak intensity at the point in the acoustic field where the temporal peak intensity is a maximum, or is a local maximum within a specified region.

$$I_{SPTP} = \max_{t, x, y} |I(t, x, y)|.$$

- Spatial peak-pulse average intensity ( $I_{SPPA}$ ): It is the value of the pulse average intensity at the point in the acoustic field where the pulse average intensity is a maximum, or is a local maximum within a specified region. Note that the intensity is averaged over a time duration defined by the interval between 10% and 90% of the temporal integral of the intensity  $I(t, x, y)$ . Let  $D_p$  denote the pulse duration, this can be illustrated in the following.



$$I_{SPPA} = \max_{x, y} \left( \frac{1.25}{D_p} \int_{t_{10\%}}^{t_{90\%}} I(t, x, y) dt \right).$$

Note that  $I_{SPPA}$  and  $I_{SPTA}$  can be related by the following approximation

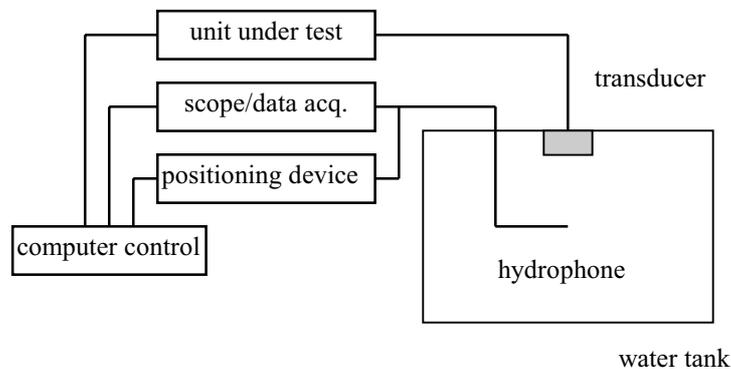
$$I_{SPTA} \approx \frac{D_p}{T_{rep}} I_{SPPA}.$$

### III. Intensity Measurements

- Since intensity is directly related to tissue damaging mechanisms such as heating and cavitation, it has to be managed and to comply with regulations. To measure the intensities that we previously defined, a hydrophone is typically used to measure the pressure at various locations. A hydrophone transforms the received pressure waves into voltage waveforms and then the waveforms are used to derive the intensities. There are other devices that can be used to measure the intensities. They include radiation force devices and thermal devices. Our discussion in this section will limit to piezoelectric hydrophone devices.
- PVDF (polyvinylidene difluoride) hydrophones are the most commonly used hydrophones for intensity measurements. This is because PVDF material provides very wide uniform frequency response and is extremely flexible. In general, the hydrophone should be made as small as possible such that the sound field being measured is not disturbed.
- One challenge of intensity measurement is that the sensitivity can drift unexpectedly and that the frequency response is not perfectly flat and can vary with time. Therefore, hydrophone calibration must be done as an integral part of intensity measurement. To calibrate, a hydrophone needs to be positioned in a known pressure field and the hydrophone output voltage needs to be read out. In other words, let  $p(x, y)$  be the known pressure and  $v$  be the corresponding voltage reading, the ratio  $v/p(x, y)$  is the calibration coefficient of the hydrophone.
- For broadband operations, the calibration process needs to be repeated for all required frequencies. This is particularly important when the system frequency response is not flat. In this case, the calibration coefficient becomes a function of the frequency, i.e.,  $v(f)/p(x, y, f)$ .
- Another important aspect of hydrophone calibration is linearity. In order words, it is necessary to ensure that the intensity level received by the hydrophone varies **linearly** with the driving intensity level. Additionally, it is critical to account for any non-linear effects associated with the propagation medium (i.e., water). Since

water starts to generate non-linear effects at relatively low intensity levels, the calibration process needs to be carried out without being too sensitive to non-linear effects. Therefore, temporal average intensity, instead of peak intensity, is often preferred for linearity calibration since it is less influenced by the harmonic components associated with non-linear propagation.

- After calibration is complete, the intensity measurement can be performed in a water tank where both the transducer under test and the hydrophone are immersed. The intensity values are derived by taking the square of the measured acoustic pressure (linearly proportional to the measured voltage) and divided by the acoustic impedance. A block diagram of the measurement system is illustrated in the following figure.



#### IV. Bioeffects

- The acoustic power output of diagnostic ultrasonic imaging systems sold in the U.S. is limited by **derated** values of  $I_{SPTA}$  and  $I_{SPPA}$  established by FDA. The derating mentioned above refers to the attempt to simulate *in vivo* conditions by multiplying the measured values, which are obtained in water, by an attenuation factor of 0.3dB/cm/MHz. Note that this attenuation value is a rather conservative one. It is intended to account for variations among different imaging conditions and it is intended to be lower than typical values for the sake of safety.
- In all conditions, current FDA regulations limit the derated  $I_{SPTA}$  to be under  $720\text{mW}/\text{cm}^2$  and the derated  $I_{SPPA}$  to be under  $190\text{W}/\text{cm}^2$ . The  $I_{SPTA}$  is intended to be a measure of the potential *in vivo* temperature rise while the  $I_{SPPA}$  is intended to measure the potential for cavitation. These limits are also known as the pre-amendments acoustic output intensity levels since they were chosen based on the

fact that imaging systems available at that time had acoustic power output lower than these values. These output levels are presumably safe.

- During a clinical examination, the **ALARA** (as low as reasonably achievable) principle is strongly recommended. In other words, to minimize the risk, the acoustic output power should be reduced so long as the diagnostic information is achievable. This is particularly important for applications such as fetal and neonatal head imaging.
- There has been increasing interest in the bioeffects associated with diagnostic ultrasound and work has been done in the development of quantitative exposure criteria. In general, the motivation behind all these efforts is the need to determine objective measures by which to assess the potential thermal and mechanical forms of danger resulting from the use of ultrasound. Although  $I_{SPTA}$  and  $I_{SPPA}$  have been widely used for this purpose, new indicators are being explored and proposed in order to better represent the potential bioeffects.
- It has been shown that a temperature increase is more closely related to the spatial integral of the intensity waveform than a point measure. In other words, the  $I_{SPTA}$  may be a poor indicator of the temperature bioeffects. As an alternative, a thermal index ( $TI$ ) has been defined as the following:

$$TI \equiv \frac{W_o}{W_{deg}},$$

where  $W_o$  is the total acoustic output power and  $W_{deg}$  is the total acoustic power needed to achieve a 1° temperature rise. Note that  $W_o$  is a measured value and  $W_{deg}$  can be derived analytically. Using this definition, it can be shown that the temperature rise is more related to  $I_{SATA}$  than  $I_{SPTA}$ .

- Generally speaking, a diagnostic exposure that produces a maximum temperature rise of 1°C above normal physiological levels may be used in clinical examinations without reservation. In addition, an *in vivo* temperature rise to or above 41°C is considered hazardous in fetal exposures. The longer this temperature rise is maintained, the greater the likelihood for damage to occur is.
- Since absorption coefficients are higher in bone than they are in soft tissues, bone heating should receive special attention. This is particularly important in the fetus.

- The output display standard proposed by AIUM/NEMA/FDA requires the display of the following three thermal indices : soft tissue thermal index (TIS), bone thermal index (TIB) and cranial bone thermal index (TIC). TIS is the thermal index related to soft tissue in general, TIB is the thermal index for applications such as fetal or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and the focal region is close to bone. TIC is the thermal index for applications such as adult cranial imaging, in which the ultrasound beam passes through bone which is near the transducer. It is required that the display of the indices should be made clearly visible from the operator's position.
- There exists several non-thermal mechanisms which may produce a bioeffect in response to ultrasound exposure. The most important one of the non-thermal bioeffects is cavitation. Cavitation is defined as the acoustically induced inception of bubbles from microscopic pockets of un-dissolved gas. The formation and growth of these bubbles occurs during the negative (i.e., rarefactional) displacement of the pressure wave. After sufficient growth, the collapse of these bubbles during the positive (i.e., compressional) half of a cycle may be very rapid and mechanical damage may occur. Therefore, to identify the minimum value of rarefactional pressure capable of inducing mechanical damages is of great importance.
- The output display standard proposed by AIUM/NEMA/FDA requires the display of a mechanical index (MI), which is defined as the following.

$$MI \equiv \frac{P_{0.3}}{\sqrt{f_c}},$$

where  $P_{0.3}$  is the peak rarefactional pressure derated by 0.3dB/cm/MHz and  $f_c$  is the center frequency. Similar to the thermal indices, the display of the mechanical index should be clearly visible from the operator's position.

- The mechanical index is inversely proportional to the square root of the frequency. This is because the time period of the negative half cycle of the pressure waveform is critical in determining the extent of bubble growth. The shorter the interval is, the less likely extensive bubble growth and cavitation will occur. Therefore, it becomes straightforward to conclude that cavitation is less likely to

occur at higher frequencies.

- It is important to recognize that the existence of free bubbles is inherently assumed in the modeling. However, the existence in an *in vivo* setting depends on the situations. For example, transient cavitation may present itself as a bigger problem in lung than in other tissues. Therefore, additional experimentation for a clearer picture of cavitation needs to be pursued.
- The bioeffects induced by ultrasonic exposure are clearly a complicated subject. To ensure the effectiveness and safety of diagnostic ultrasound, more accurate measurement techniques need to be developed and the fundamentals of mechanisms of bioeffects need to be better understood. Although information from experimental studies has yielded no known risks in the use of diagnostic ultrasound at current power levels, a conservative approach to the medical use of ultrasound (including both the exposure intensity and the exposure time) is still recommended. In particular, the ALARA principle should be appreciated and implemented to guide the user toward minimization of acoustic emissions.