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Determination of the acoustic outputs of an ultrasound probe with an oblique beam-axis according to the new JIS (or IEC Standards)

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1. Introduction

Transcranial Doppler (TCD) ultrasound is a useful tool for monitoring cerebral blood flows and evaluating stroke associated risks.[1)] However, it is often difficult to get echo signal of enough intensity required for blood flow display from cerebral arteries due to the barrier of cranium, especially in the elderly female people.[2)] To overcome this problem, a blood flow monitor for carotid artery (FURUHATA device, HDK BM001, Hashimoto Electronics Co., Ltd, Mie, Japan) has been developed with a paste type probe (PTP), which can be set on the neck easily with a surgical tape and can automatically emit an obliquely incident ultrasound beam to irradiate the carotid artery and acquire therefrom blood flow signals efficiently in almost all of the examinees. [3)]

On the other hand, with the implement of the JIS T 0601-2-37: 2018 (IEC 60601-2-37: 2007, Amd.1: 2015), the formulae about thermal index (TI) have been changed significantly, based on the revised normative reference IEC 62359: 2010. Especially, a major change is that a bounded-square output power (P_{1x1}) was newly introduced for determination of soft tissue thermal index (TIS) for both scanning and non-scanning modes. However, it has not be reported about how to measure P_{1x1} for an ultrasound probe with an oblique beam-axis, like the PTP.

Therefore, the first purpose of this study was to establish a method to measure P_{1x1} of an ultrasound probe with an inclined beam-axis, according to the requirement of the new IEC standard. The second purpose was to determine if the new Doppler device with a PTP has admittable TI and mechanical index (MI) at FURUHATA's all of the selectable presetting.

2. Test Method

2.1 Measurement of the beam inclination angle

The PTP was fixed into the water tank of an acoustic intensity measurement system (AIMS) with an inclination-correction jig, and the ultrasound field in the azimuth plane including the central beam-axis was raster scanned with a hydrophone and the beam-axis was determined as the straight line that passes through the point of maximum pulse-intensity-integral (PII) and a deeper centrepoint of the beam. The inclination angle (θ) was defined as the angle between the beam-axis and the normal line of the output surface of the probe.

2.2 Measurement of the output power P and P_{1x1}

The PTP was set in center of the water tank of an ultrasound power meter (UPM-DT-1AV) with a jig keeping the beam-axis vertical, and the output power (P) at each condition was measured with an absorbent target, made of an echoless acoustic absorber material (HAM A, NPL, UK) [4)].

For P_{1x1}, a specially made bounded-square output mask, which has an 1 cm×1 cm slit with the same inclination angle as the PTP, was fixed above the absorbent target with the slit`s walls kept vertical. The PTP was set on the mask with a slidable fixer. At first the position with a maximum output through the slit was determined. Then P_{1x1} were measured at the determined position for all setups of FURUHATA.

2.3 Measurement of output beam area and calculation of break-point depth

The PTP was fixed to the AIMS with its emitting face set horizontally, and the ultrasound field at a distance of about 0.5 mm from the emitting face was raster scanned with a hydrophone. At first the -12 dB area at the emitting plane ($A_{aprt,\ o}$) was measured, then the corresponding value (A_{aprt}) of an imaginary emitting aperture that is perpendicular to the beam-axis was calculated as:

$$\mathrm{A_{aprt}} = \mathrm{A_{aprt,o}} \times \cos(\theta),$$

And break-point depth (Z_{bp}) was calculated as:

$$z_{bp} = 1.69 \times \sqrt{\mathrm{A_{aprt}}}$$

2.4 Measurement and calculation of MI and TIS

The PTP was fixed in the water tank of the AIMS with an inclination-correction jig to keep its beam-axis vertically. The PII, peak-rarefactional acoustic pressure (P_r) and f_{awf} were measured along the beam-axis from 1 mm to 100 mm. MI and TIS were calculated as follow,

$$MI = P_{r,\alpha}(z_{MI}) \times {f_{awf}}^{-0.5} \div C_{MI},$$

$$\mathrm{TIS_{as}} = \frac{P_{1x1}\, f_{awf}}{C_{TIS,1}},$$

$$\mathrm{TIS_{bs}} = min\left[\frac{P_{\alpha}(z_{s,ns})\, f_{awf}}{C_{TIS,1}}, \frac{I_{ta,\alpha}\,(z_{s,ns})\, f_{awf}}{C_{TIS,2}}\right]$$

where, TIS_{as} and TIS_{bs} are soft tissue thermal index at surface and below surface, respectively; Z_{MI}, the depth for mechanical index, was the depth on the beam axis from the emitting aperture of the PTP to the point of maximum attenuated pulse-intensity integral (PII_{α}); $Z_{s,ns}$, depth for TIS for non-scanning modes, was the distance along the beam axis from the emitting aperture of the PTP to the point at which the lower value of the attenuated output power (P_{α}) and the product of the attenuated temporal-average intensity ($I_{ta,\ \alpha}$) and 1 cm^2 is maximized over the distance range equal to, or greater than, the break-point depth, Z_{bp}; fawf, acoustic working frequency; C_{MI} = 1 MPa $MHz^{-1/2}$, $C_{TIS,1}$ = 210 mW MHz and $C_{TIS,2}$ = 210 mW cm^{-2} MHz.

3. Results and Discussion

3.1 The inclination angle of the beam-axis

The inclination angle of the beam-axis was found to be about 31°, larger than supposed 25° (Fig.1). Therefore, the angle correction was adjusted to 31° to provide more precise MI and TIS.

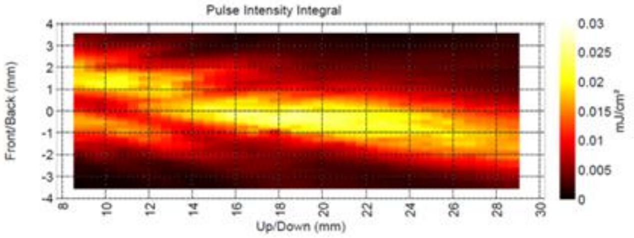

Fig. 1 The ultrasound field in the azimuth plane after a primary inclination angle correction of 25°.

3.2 The output power P and $P_{1\times1}$

Both P and P_{1x1} were found to be linearly dependent on the product of the selected amplitude (Amp) and sample volume (SV) (Fig. 2).

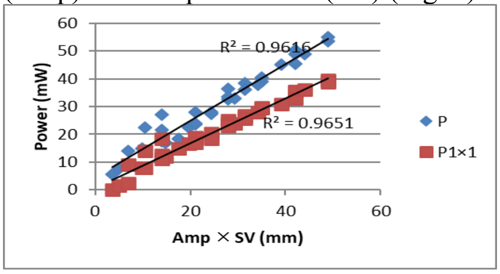

Fig.2 Dependence of P and $P_{1\times1}$ on Amp × SV.

3.3 The output beam area and break-point depth

The output beam area (A_{aprt}) was measured to be ~92 mm^2, and the break-point depth (Z_{bp}) was calculated to be ~16.3 mm, approximated to 1.65 cm.

3.4 MI and TIS of the PTP

Ultrasound fields measured on the beam-axis for all of the selectable conditions have a similar pattern as those shown in Fig. 3. Both of the maximum PII_{α} (not shown) and Pr_{α} were found at a depth of about 12.1 mm; therefore, Z_{MI} was determined as 1.2 cm. And the attenuated output power was found lower than the product of the attenuated spatial-peak temporal-average intensity and 1 cm^2 for all depths; therefore, $Z_{s,ns}$ was determined simply as: $Z_{s,ns} = Z_{bp}$=1.65 cm.

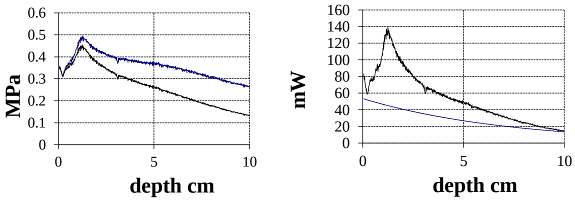

Fig. 3 A typical measurement of ultrasound field along the beam-axis. (A) Negative Pressure (Pr): in water (blue) and in assumed human body (black). (B) attenuated output power P.3 (blue) and Ita.3 * 1cm² (black).

Both the maximum MI and the maximum TIS were found at the maximum output settings, with a value of 0.39 and 0.42, respectively. Both MI and TIS were far less than 1.0, suggesting a very good safety level even at the strongest output of the equipment.

4. Conclusion

We have established a method to measure and calculate TIS and MI for an ultrasound probe with an oblique beam-axis according to the new JIS (IEC standards), and we found that both TIS and MI of the newly developed blood flow Doppler device with a paste type probe were much lower than 1.0, suggesting that it can be applied not only very conveniently and efficiently, but also as safely as conventional TCD devices.

Acknowledgment

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References

1. R. Belvís, RG. Leta, J. Martí-Fàbregas, D. Cocho, F. Carreras, G. Pons-Lladó, and J.L. Martí-Vilalta. J Neuroimaging. 16(2006) 133.
2. G. Seidel, M. Kaps, and T. Gerriets. Stroke. 26(1995) 2061.
3. H. Mitsumura, A. Arai, T. Sato, T. Komatsu, K. Sakuta, K. Sakai, Y. Terasawa, J. Kubota, and Y. Iguchi. J Neurol Sci. 392(2018) 122.
4. B. Zeqiri and C.J. Bickley. Ultrasound in Med. & Biol. 26(2000) 481.

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