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Measurement uncertainties in thermal and mechanical indices related to medical ultrasonic diagnostics

医用超音波における thermal および mechanical indices 計測の不確かさ

Tsuneo Kikuchi †(National Metrology Institute of Japan (NMIJ)/AIST)
菊池　恒男†(NMIJ/AIST)

1. Introduction

In medical ultrasonic diagnostics, it is important to both achieve the medical aim and to satisfy safety needs. As the ultrasonic power and ultrasonic pressure used in medical fields have increased, finding appropriate ways to control ultrasound has become more important. In particular, the thermal and mechanical effects are important factors in deciding the limits to the human body's exposure to ultrasound. To avoid risks, a thermal index (*TI*) and a mechanical index (*MI*) have been defined in IEC 62359 [1]. These indices are calculated by using measured ultrasonic power and ultrasonic pressure. Measurement uncertainties are very important in evaluating the quality of measurements, and thus these physical measurements are standardized by IEC standards such as IEC 61161 [2] and IEC 62127-1 [3]. Details regarding measurement uncertainties are given in the GUM (Guide to the expression of uncertainty in measurement) [4]. However, uncertainties regarding the *TI* and the *MI* have not been discussed enough, despite the fact that these indices are important in complying with FDA (Food and Drug Administration) documents [5].

In this paper, measurement uncertainties of the *TI* and *MI* are tentatively evaluated, and it is shown that these measurement uncertainties are especially important in the case of wideband ultrasound.

2. Uncertainty factors of *TI* and *MI*

The typical expressions of the *TI* and *MI* given in IEC 62359 are

$$TI = \frac{P \cdot f_{\mathrm{awf}}}{C_{TI}} \qquad (1)$$

$$MI = \frac{p_r \cdot f_{\mathrm{awf}}^{-\frac{1}{2}}}{C_{MI}} \qquad (2)$$

Here, P [W] is ultrasonic power as measured by radiation force balance or other methods, p_r [Pa] is peak-rarefactional acoustic pressure as measured by a hydrophone, and f_{awf} [Hz] is the arithmetic-mean acoustic working frequency as defined in IEC standards, C_{TI} [mW MHz] and C_{MI} [MPa MHz$^{-1/2}$] are constant. In these equations, ultrasonic power, pressure, and frequency are measurement values, the measurement uncertainties of which are also evaluated. Typical measurement uncertainties of ultrasonic power as measured by radiation force balance, u_P, and of peak-rarefactional acoustic pressure, u_{pr}, of NMIJ (National Metrology Institute of Japan) are around ±10 %. The acoustic working frequency, f_{awf}, is defined in IEC 62359 as "an arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude". This means that fawf is an approximated frequency of a wideband ultrasonic signal, and so the uncertainty of an approximation of a wideband frequency should be considered as equivalent to other measured values.

3. Uncertainty estimations of f_{awf}

To estimate the uncertainties of f_{awf}, the frequency characteristics of the ultrasonic pressure are assumed to be expressed by a Gaussian function with a center frequency of 5 MHz. As the Gaussian function is symmetric with this center frequency, f_{awf} is also 5 MHz. Here, the bandwidth is defined by f_2/f_1.

Figures 1 and 2 show the frequency characteristics of a normalized ultrasonic pressure, and normalized *TI* and *MI* when f_2/f_1 equals 3. The *TI* and *MI* are normalized by those calculated at f_{awf}. Here, it is assumed that a frequency range over a -3 dB bandwidth contributes to the determination of the *TI* and *MI*.

In the case of the *TI*, it is proportional to the frequency as shown in eq. (1) and Fig. 1. When f_2/f_1 is 3, the -3 dB frequency range is 2.5-7.5 MHz. This means that the *TI* is distributed between ±50 % of the *TI* as calculated by using f_{awf}.

Figure 2 shows a similar result for the *MI*. In this case, the normalized *MI* is proportional to $f^{-0.5}$. As a result, the *MI* is distributed from -41% to 18% of the *MI*, which is calculated by using f_{awf}.

4. Expanded uncertainties of *TI* and *MI*

The expanded uncertainties of the *TI* and *MI* are calculated by Eqs. (3) and (4). These

tsuneo.kikuchi@aist.go.jp

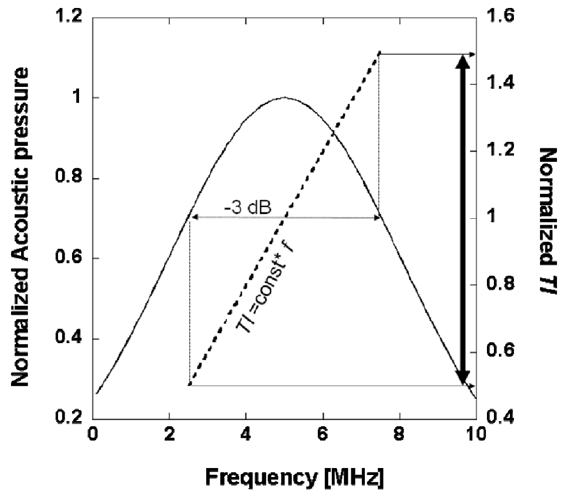

Fig. 1 Frequency characteristics of ultrasonic pressure and normalized *TI*.

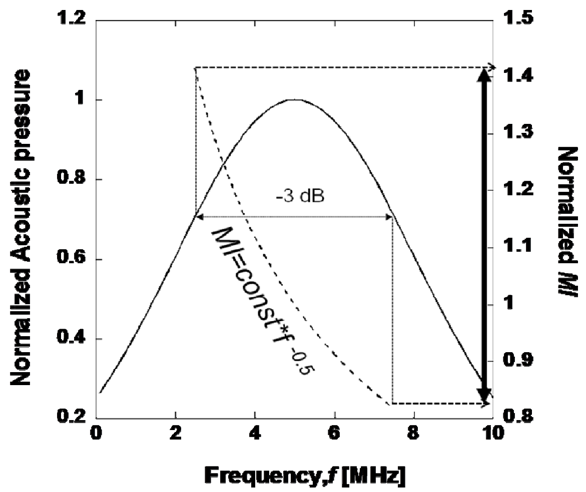

Fig. 2 Frequency characteristics of ultrasonic pressure and normalized *MI*.

distributions of the *TI* and *MI* caused by f_{awf} should be considered as uncertainty factors. From these estimations, in the case of f_2/f_1 equal to 3, the uncertainties caused by f_{awf} can be roughly estimated as $u_{\mathrm{TI\_fawf}} = \pm 50$ % for *TI*. The distribution of normalized *MI*, however, is not symmetrical, but approximately $u_{\mathrm{MI\_fawf}} = \pm 30$ %.

$$U_{\mathrm{TI}} = k\sqrt{{u_{\mathrm{P}}}^2 + {u_{\mathrm{TI\_f_{awf}}}}^2} \qquad (3)$$

$$U_{\mathrm{M}I} = k\sqrt{{u_{\mathrm{p_r}}}^2 + {u_{\mathrm{MI\_f_{awf}}}}^2} \qquad (4)$$

Here, k denotes the coverage factor. In this case, k equals 2 at level of confidence 95 %. The expanded uncertainties calculated as a function of bandwidth f_2/f_1 are shown in **Fig. 3**. From these results, it is found that the magnitudes of uncertainties of both

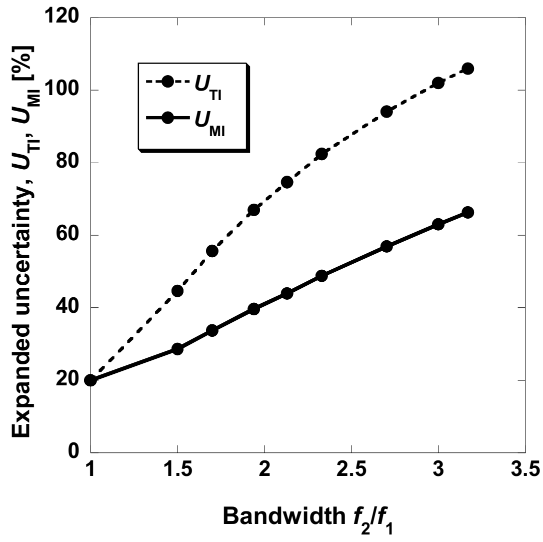

Fig. 3 Relationship among expanded uncertainties of *TI*, *MI* and bandwidth.

the *TI* and *MI* become large when the ultrasound has a wide bandwidth. In the case of continuous wave, namely f_2/f_1 equal to 1, the both uncertainties become 20 % which are caused by measurement uncertainties of ultrasonic power or ultrasonic pressure.

5. Conclusions

The uncertainties of the *TI* and *MI* are so large that they cannot be ignored. The main reason for these large uncertainties is that the magnitude of bandwidth is not taken into consideration when calculating the *TI* and *MI*. These uncertainties should be taken into consideration when complying numerical regulations, such as FDA information [5]. If such uncertainties are taken into account, in some cases it is possible for the *TI* and *MI* to exceed the limit as laid down in guideline. Consequently, it is required to consider new definition of regulations.

References

1. IEC 62359 Ed. 2:2010
2. IEC 61161 Ed. 2:2006
3. IEC 62127-1 Ed. 1:2007
4. *Guide to the expression of uncertainty in measurement,* International Organization for Standardization, 1995.
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