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
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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

\[
TI = \frac{P \cdot f_{awt}}{C_{TI}} \quad (1)
\]

\[
MI = \frac{P \cdot f_{awt}^{1/2}}{C_{MI}} \quad (2)
\]

Here, \( P \) [W] is ultrasonic power as measured by radiation force balance or other methods, \( p \) [Pa] is peak-rarefactual acoustic pressure as measured by a hydrophone, and \( f_{awt} \) [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-rarefactual acoustic pressure, \( u_p \) of NMIJ (National Metrology Institute of Japan) are around \( \pm 10 \% \). The acoustic working frequency, \( f_{awt} \), 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 \( f_{awt} \) 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 \( f_{awt} \)
To estimate the uncertainties of \( f_{awt} \), 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, \( f_{awt} \) 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 \( f_{awt} \). 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 \( \pm 50 \% \) of the TI as calculated by using \( f_{awt} \).

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 \( f_{awt} \).

4. Expanded uncertainties of TI and MI
The expanded uncertainties of the TI and MI are calculated by Eqs. (3) and (4). These
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 $u_{TI_{awf}} = \pm 50\%$ for $TI$. The distribution of normalized $MI$, however, is not symmetrical, but approximately $u_{MI_{awf}} = \pm 30\%$.

\[ U_{TI} = k \sqrt{u_p^2 + u_{TI_{awf}}^2} \]  \hspace{1cm} (3)

\[ U_{MI} = k \sqrt{u_p^2 + u_{MI_{awf}}^2} \]  \hspace{1cm} (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 $TI$ 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