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# Evaluation of Risk on the Excessive Temperature Rise at Acoustic Radiation Surface of Ultrasound Transducers

超音波トランスデューサの音響放射面の過剰温度上昇のリスク評価

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## 1. Introduction

In IEC 60601-2-37 [1] the accepted maximum temperature or maximum temperature rise at acoustic radiation surface of ultrasound transducers are regulated as **Table I** from the point of view of biological safety. The maximum value during the activation period of 30 minutes are measured under each transmission condition of "in still air" and "in contact with Tissue Mimicking Material (TMM)". For example, in case of serial measurements in still air condition the total measurement period of several weeks may be required for the measurement of a transducer with comprehensive transmission conditions. In this case over a year may be required for the whole measurement of an ultrasound system with a complete set of transducers applying a comprehensive transmission conditions. It may take impractical long period for the entire evaluation, although it is one of the approaches on an effective validation in the overall system operation covering hardware and software.

In this study the evaluation of risk on excessive temperature rise was considered experimentally in still air condition only since obtained information was considered as screening check or preliminary check. Additionally, its shorter measurement time than one of TMM combination is convenient to realize the practical measurment period for a huge number of serial measurements in the evaluation. Estimated temperature rise was obtained based on a combination of measured value in two kinds of activation periods, those were extremely shorter activation period of a minute and regulated normal period of 30 minutes. Total evaluation period was approx. a week and it was expected to become a practical method for a complete set of transducers of ultrasound system applying a comprehensive transmission conditions. Expanded uncertainty of the estimated temperature rise was also considered.

## 2. Method

Thermographic camera was prepared for the measurements of temperature [2] and [3]. Spatial resolution of thermal image was approx. 0.5 mm. The maximum expanded uncertainty of ± 0.38 °C @ 50 °C on the commercially available devices in the range of affordable price [4] was conservatively referred for the estimation of uncertainty on this evaluation with coverage factor $k$ of 2 for confidential interval of 95 % in the normal distribution assumed.

Table I　Accepted temperature / temperature rise at acoustic radiation surface regulated in IEC 60601-2-37.

| Transducer type → | | External use | Non-external use |
|---|---|---|---|
| Still air | Temperature rise | $\Delta T_{max} \leq 27$ °C<br>($T_{amb} = 23$ °C ± 3 °C. Initially, $T_{trans} = T_{amb}$) | |
| Simulated use (Combined with TMM) | Temperature | $T_{max} \leq 43$ °C<br>($T_{TMM} \geq 33$ °C. ) | $T_{max} \leq 43$ °C<br>($T_{TMM} \geq 37$ °C. ) |
| | Temperature rise | $\Delta T_{max} \leq 10$ °C | $\Delta T_{max} \leq 6$ °C |
| | | ($T_{amb} = 23$ °C ± 3 °C.<br>Initially, TMM-transducer interface temperature = $T_{amb}$) | |

Note
- $T_{amb}$ : ambient temperature.
- $T_{trans}$ : transducer temperature.
- $T_{max}$ , $\Delta T_{max}$ : maximum of transducer-surface temperature, temperature rise.
- $T_{TMM}$ : TMM temperature, TMM: Tissue Mimicking Material.
- Skin layer at surface of TMM is considered for external-use transducers.

The evaluation consists of measurements and estimation as shown in **Fig. 1**. The temperature measurement took two kinds of activation period of a minute ($\Delta T_{1min}$) and 30 minutes ($\Delta T_{30min}$), where the reference temperature on the temperature rise was $T_{0min}$. The former was performed for a huge number of fast measurements performed with comprehensive transmission conditions. The later was taken for only the condition on the maximum value in $\Delta T_{1min}$ measurement. The estimated temperature rise $\Delta T_{30min\_est}$ was defined as the product of Coeff (average of ratio of $\Delta T_{30min}$ to $\Delta T_{1min}$ which were obtained in the measurement of $\Delta T_{30min}$ under the condition of maximum $\Delta T_{1min}$) and $\Delta T_{1min}$ based on Eq. (1) and Eq. (2).

$$\Delta T_{30min\_est} = \mathrm{Coeff} \times \Delta T_{1min} \tag{1}$$

$$\mathrm{Coeff} = \frac{1}{\mathrm{N}} \sum_{\mathrm{focus(i)}}^{\mathrm{N}} \left[\frac{\Delta T_{30min}}{\Delta T_{1min}}\right]\Bigg|_{\Delta T_{1min\_max}} \tag{2}$$

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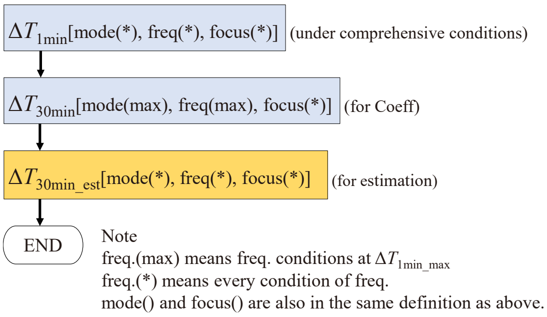


Fig. 1 Flowchart of risk evaluation on excessive temperature rise in still air.

## 3. Result and discussion

Temperature rise for activation period of a minute ($\Delta T_{1\min}$) was shown in Fig. 2 (a) which took approx. 70 hours for entire measurements with a linear transducer for body surface scan. The order of transmission conditions was preliminarily programmed based on combination of scan/non-scan mode, frequency and focus distance etc. The period of over an hour for sufficient rest was given after every serial measurement. The data for activation period of 30 minutes ($\Delta T_{30\min}$) is shown in Fig. 3 (a) and (b) measured with specified transmission conditions for scan mode and non-scan mode, respectively. It took approx. 70 hours and generally took approx. a week for entire measurement of $\Delta T_{1\min}$ and $\Delta T_{30\min}$.

Expanded uncertainty ($U_{\Delta T_{30\min\_est}}$) of ± 2.7 °C was obtained based on Eq. (3) with coverage factor $k$ of 2 for confidence interval of 95 % in assumed normal distribution, where combined standard uncertainty ($u_{\Delta T_{30\min\_est}}$) was obtained based on standard uncertainties $u_{\text{Coeff}}$ and $u_{\Delta T_{1\min}}$ in Eq. (4). Those were considered according to ISO GUM [5]. Since the first term of right side was dominant in Eq. (4), $u_{\Delta T_{30\min\_est}}$ strongly depended on $\Delta T_{1\min}$ and $u_{\text{Coeff}}$. It seemed that $\Delta T_{1\min}$ depended on inverse of effective heat capacity of transducer and $u_{\text{Coeff}}$ tended to be lager in scan modes.

$$U_{\Delta T_{30\min\_est}} = k \times u_{\Delta T_{30\min\_est}} \quad , \quad k : \text{coverage factor} \tag{3}$$

$$u_{\Delta T_{30\min\_est}} = \sqrt{\left(\Delta T_{1\min} \times u_{\text{Coeff}}\right)^2 + \left(\text{Coeff} \times u_{\Delta T_{1\min}}\right)^2} \tag{4}$$

Coeff and $\Delta T_{1\min}$ were 2.27 °C and 5.47 °C for scan mode and 1.72 °C and 7.44 °C for non-scan mode, respectively. Therefore, $\Delta T_{30\min\_est}$ and $\Delta T_{30\min}$ was 12.4 °C and 10.6 °C for scan mode and 12.8 °C and 9.9 °C for non-scan mode, respectively. The difference between $\Delta T_{30\min\_est}$ and $\Delta T_{30\min}$ for scan mode and non-scan mode were approximately in the range of the expanded uncertainty.

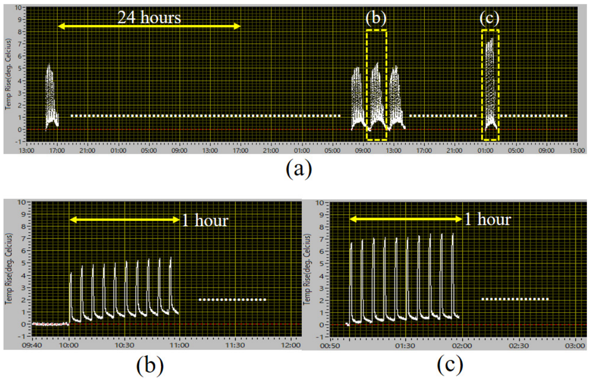


Fig. 2 Temperature rise for activation of a minute on a linear transducer. (a): comprehensive transmission conditions (b): maximum in scan modes. (c): maximum in non-scan modes.

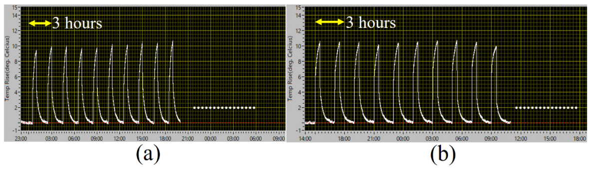


Fig. 3 Temperature rise for activation of 30 minutes on a linear transducer. (a): maximum in scan modes. (b): maximum in non-scan modes.

## 4. Summary

An approach of estimated temperature rise ($\Delta T_{30\min\_est}$) in still air was proposed based on both $\Delta T_{1\min}$[mode(*), freq.(*), focus(*)] (activation of a minute) and $\Delta T_{30\min}$ [mode(max), freq.(max), focus(*)] (activation of 30 minutes) as a screening check for the risk of the excessive temperature rises with practical measurement period.

Expanded uncertainty of ± 2.7 °C was estimated on $\Delta T_{30\min\_est}$ with coverage factor $k$ of 2 for confidential interval of 95 % in the normal distribution assumed. It was considered the uncertainty was acceptable for evaluation of the risk.

Since $\Delta T_{30\min\_est}$ was practically estimated for comprehensive transmission conditions based on the measurement of $\Delta T_{1\min}$ and $\Delta T_{30\min}$ in approx. a week, it was useful as a screening check at a first step in order to detect the temperature rise in still air which may exceed the regulated value. It was expected that this approach would contribute to efficiently reduce the number of conditions on the another evaluation of temperature rise in the simulated use with TMM.

## References

1. IEC 60601-2-37 Ed.2 (2007) + AMD1 (2015).
2. Tech. Rep. AER-6009 JEITA (2005) [in Japanese].
3. IEC TS 63070 Ed.1 (2019).
4. N. Sasajima, S. Yamazaki and M. Yoshioka: Proc. USE (2019) 2P5-10, S2805.
5. ISO/IEC Guide 98-3 (2008) (GUM:1995).