Uncertainty evaluation of dead zone of diagnostic ultrasound equipment

R M Souza[1], A V Alvarenga[1], D S Braz[1], L I Petrella[2], R P B Costa-Felix[1]

[1] Laboratory of Ultrasound (Labus), Directory of Scientific and Industrial Metrology (Dimci), National Institute of Metrology, Quality and Technology (Inmetro); [2] Institute of Nuclear Sciences Applied to Health, University of Coimbra, Portugal

E-mail: raquel.ms.eng@gmail.com

Abstract: This paper presents a model for evaluating measurement uncertainty of a feature used in the assessment of ultrasound images: dead zone. The dead zone was measured by two technicians of the INMETRO's Laboratory of Ultrasound using a phantom and following the standard IEC/TS 61390. The uncertainty model was proposed based on the Guide to the Expression of Uncertainty in Measurement. For the tested equipment, results indicate a dead zone of 1.01 mm, and based on the proposed model, the expanded uncertainty was 0.17 mm. The proposed uncertainty model contributes as a novel way for metrological evaluation of diagnostic imaging by ultrasound.

Keywords: Dead zone, Diagnostic ultrasound, Uncertainty, Metrology.

1. INTRODUCTION

Medical ultrasound imaging equipments (USIE) are widely used in the most of Brazilian health centers. Although the emergence of new medical equipment with increasingly sophisticated technologies provides more confidence in medical activities, there is still need for quality control of such equipment [1].

It is worth pointing out that measurement procedures for evaluating USIE images are often subject of research, but, typically, no proper uncertainty evaluation is undertaken. These measurement procedures are based on standards and documents published by international organizations, such as the American Association of Physicists in Medicine (AAPM) [2] and the International Electrotechnical Commission (IEC) [3]. Specific indicators as contrast, axial and lateral resolutions, and dead zone, among others are quantified using phantoms and used to evaluate the ultrasound imaging quality [2][3].

Measurement uncertainty is a non-negative parameter that characterizes the dispersion of the quantity values being attributed to a measurand [4][5]. Considering the expression of uncertainty of the indicators used in assessing the quality of medical images, the literature does not present conclusive works. It is noteworthy that estimating the measurement uncertainty is essential to evaluate variations in the measurand, providing a metrological approach on quality control.

The dead zone occurs because the ultrasound system cannot send and receive data simultaneously [2]. A change in the system's dead zone is indicative of a problem with the transducer, the pulsing system or both. The IEC/TS 61390 defines the dead zone as the

distance from the phantom surface to the nearest target that can be unequivocally imaged [3]. This standard also states that an estimate of the dead zone can be obtained by noting the most superficial target that can be imaged on a phantom having a set of targets at the top surface. Hence, if the first target observed is located at 1 mm away from the phantom top surface, the dead zone will be considered 1 mm.

In this paper, we propose also measuring the distance between the first target imaged and the top of the image, using the USIE caliper. This procedure gives a measured value of the dead zone, and allows expressing the measurement uncertainty.

2. MATERIALS AND METHODS

2.1. Phantom

The phantom adopted for the tests is the Multi-purpouse, Multi-tissue, Ultrasound Phantom 040GSE (CIRS, Virginia, USA). Within the phantom, the targets group used to determine the dead zone consists of nylon monofilament wires (100 μm diameter), horizontally spaced 6 mm apart from center to center (figure 1).
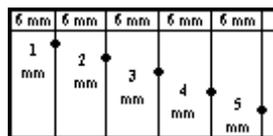

Figure 1. Near field target. (Wire diameter: 0.1 mm).

Vertical distance from the center of each wire to the top edge of the scanning surface ranges from 5 mm down to 1 mm in 1 mm increments. These targets allow assessing the distance from the front face of the transducer to the closest distinguishable echo.

2.2. Ultrasound Equipment

The USIE used for this evaluation was the CTS-5500V with a transducer C5F20, presenting convex shape, and operating at 5 MHz (SIUI, Guangdong, China).

2.3. Positioning system

To carry out the measurements, a positioning system was used to allow the stable position of the transducer on the phantom scanning surface. Pressure on the phantom surface was avoided to prevent any distortions in the image.

2.4. Equipment Environmental conditions

The environmental conditions were monitored and were always within the limits established in [3], namely: room temperature between 21°C and 25°C and relative humidity from 45% to 75%.

2.5. Instrument Settings

The instrument settings were performed in two steps. The first one, called "basic instrument setting" was carried out scanning the phantom as if it were a patient and the controls were adjusted to produce the best possible clinical image. Care was taken to not emphasize or exaggerate a particular image attribute [2]. The "specific instrument setting" was carried out for better viewing the targets. The focal zone was defined closest to scanning window and the gain was adjusted to reduce the background echoes [2].

2.6. Dead Zone Testing Procedure

The measurement procedure was defined based on references [2][3] and it is described as follows:

- Fill the water on top of the phantom as the transducer coupling medium;

- Adjust the basic instrument setting;

- Position the transducer in a vertical plane;

- Apply the specific instrument setting;

- Scan the region in the phantom containing the dead zone test targets (figure 1);

- Freeze the image and determine the closest target that can be imaged;

- Use the electronic caliper of the ultrasound imaging equipment to measure the depth of this target and record dead zone.

2.7. Technicians

The inter-observer variability in assessing US images is well documented. In order to include the inter-observer variability in the uncertainty assessment, two trained technicians assessed the dead zone. Both technicians repeated the measurements thrice, under the same environmental conditions, using the same instrument settings and testing procedures.

2.8. Expression of uncertainty

To express the uncertainty of measurement, it was used the method described in the Guide to the Expression of Uncertainty in Measurement [4]. The mentioned method for evaluating and expressing the uncertainty of the result measurement starts by defining the measurand.

Here, the measurand is the distance between the target and the top of the image, which is the particular quantity itself. Two sources of uncertainties are considered: (i) the number of independent observations obtained under the same conditions of measurement, and (ii) the resolution (R) in millimeters of caliper.

For the estimate obtained from the statistical analysis of series of observations, it is carried out the Type A evaluation of standard uncertainty (u_s), which is calculated by (1).

$$u_s = \frac{s}{\sqrt{n}} \tag{1}$$

Where s is the experimental standard deviation and n is the number of independent observations obtained under the same conditions of measurement.

The resolution of the diagnostic equipment caliper ($R = 0.18$ mm) was used to calculate the Type B standard uncertainty (u_R). Assuming a rectangular distribution, all values have equal probability of occurring. Therefore, u_R is given by (2).

$$u_R = \frac{R}{\sqrt{12}} \tag{2}$$

Thus, $u_R = 0.052$ mm.

The combined standard uncertainty (u_C) can be obtained by combining the uncertainty components that characterize the dead zone.

$$u_C = \sqrt{(u_R{}^2 + u_s{}^2)} \tag{3}$$

Finally, the expanded uncertainty (U) is calculated by (4):

$$U = k \times u_C \tag{4}$$

Where k is the coverage factor determined by considering the effective degrees of freedom and the level of confidence of 95%.

2.9. Difference test between means

The difference test between means is applied in order to verify if the measurements carried out by two technicians can be considered statistically equal for a given coverage probability. If there is not enough statistical evidence to reject the equal variances hypothesis, the combined standard uncertainty (u_{cP}) can be determined according to (6).

$$u_{cP} = \sqrt{\frac{(n_1 - 1)u_{c1}{}^2 + (n_2 - 1)u_{c2}{}^2}{n_1 + n_2 - 2}} \tag{6}$$

Where u_{c1} and u_{c2} are the combined uncertainty from technicians 1 and 2, while n_1 and n_2 are the respective number of measurements.

Subsequently, it is considered the null hypothesis of equality between means and the alternative hypothesis of differences between means; thus, the statistical t_{calc} test is being given by (7).

$$t_{calc} = \frac{X_{tec.1} - X_{tec.2}}{u_{cP}\sqrt{\left(\frac{n_1 + n_2}{n_1 \times n_2}\right)}} \tag{7}$$

Where $X_{tec.}$ is the mean value of the measurements of each technician.

The value obtained for t_{calc} is compared with t_{tab}, which is extracted from Student's *t-*

distribution table, on the basis of the degrees of freedom $(v \mid v = n_1 + n_2 - 2)$. If t_{calc} is less than t_{tab}, the null hypothesis cannot be rejected, thus the result of each technician can be combined to determine the final result of the measurement. Finally, the expanded uncertainty arising from the measurement combination of both technicians is given by:

$$U = t_{tab.} \times u_{cP} \sqrt{\left(\frac{n_1 + n_2}{n_1 \times n_2}\right)} \qquad (8)$$

3. RESULTS

Table 1 provides results obtained by technician 1, as well the coverage factor, expanded uncertainty and absolute error (E_{abs}). Similarly, Table 2 provides results obtained by technician 2.

Table 1. Result of measurements carried out by technician 1.

Reference value (mm)	X (mm)	s (mm)	u_s (mm)	u_R (mm)	k	U (mm)	E_{abs} (mm)
1.0	0.92	0.065	0.038	0.052	2.12	0.13	0.08

Table 2. Result of measurements carried out by technician 2.

Reference value (mm)	X (mm)	s (mm)	u_s (mm)	u_R (mm)	k	U (mm)	E_{abs} (mm)
1.0	1.09	0.035	0.020	0.052	1.98	0.11	0.09

The figure 2 presents the region in the phantom containing the dead zone test targets imaged by the USIE.

Figure 2. Image of dead zone.

The dead zone measured by the technician 1 resulted in 0.92 mm ± 0.13 mm, whereas for the technician 2, the result was 1.09 mm ± 0.11 mm. Applying the difference test between means for a coverage probability of 95 %, it was observed

that the null hypothesis cannot be rejected. Thus, the results from both technicians may be combined by providing a dead zone of 1.01 mm ± 0.17 mm.

4. DISCUSSIONS AND CONCLUSION

The result suggests that the dead zone of the equipment tested is 1.01 mm, with an expanded uncertainty of 0.17 mm, considering the proposed uncertainty model. Moreover, the procedure presented here can be useful to metrological evaluate the dead zone periodically. Hence, carrying out periodical tests and evaluating the uncertainty of dead zone, it is possible to estimate eventual variations in that value, which may indicate a possible change in image quality.

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