Discussion of the quality control and performance testing of ultrasound diagnostic equipment

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Abstract. In recent years, with the rapid development of ultrasonography, the application and popularization of new technology used in ultrasound equipment, the level of providing diagnostic information for doctors enhances unceasingly, which has become the indispensable diagnostic tool for medical institutions. The performance of equipment is directly related to the doctor's diagnosis and the patient's health, therefore, it is very important to choose a good method for quality control and performance testing.

1. Introduction

1.1 Thermal effect (TI) and cavitation effect (MI)
With the wide application of ultrasound diagnostic equipment in gynecology and obstetrics, it has become very sensitive to the possible effects of ultrasound diagnosis on embryonic development during early pregnancy, in order to obtain high-quality images, the acoustic output of some ultrasonic Doppler imaging instrument was significantly higher, the safety of a potential approach is attracting attention. Since 2009, China officially launched GB 9706.9-2008 "medical electrical equipment - Part 2-37: ultrasound diagnosis and monitoring equipment", namely the mechanical index (MI) and thermal index (TI) must be displayed in real time on the monitor of medical diagnosis and monitoring ultrasonic equipment, which is used to characterize the acoustic output level. As shown in figure 1:

![Fig.1 Thermal effect (TI) and cavitation effect (MI) shown in real time](image1)

Users of the equipment should observe the mechanical index and thermal index of the equipment in real time during the scanning, making these indexes as low as possible, if can't be reduced, make sure the inspection time is as short as possible. The British Medical Ultrasound Society published recommendations on mechanical index and thermal index in 2000. As shown in table 1:

| MI > 0.3 | Biological effect | Operator behavior |
|----------|-------------------|-------------------|
|          | It may cause minor damage to the lungs | Minimize the irradiation time |

Table 1   BMUS recommendations on MI and TI
The thermal effect (TI) is the ratio between the acoustic energy produced by the transducer (W) and the energy needed to increase the tissue temperature by 1 DEG C (W_{deg}), the mechanical index MI is defined as the sparse pressure peak (Pr) (negative pressure) divided by the square root of the ultrasonic frequency, as shown in equation 1, 2:

\[ TI = \frac{W}{W_{deg}} \quad \text{Equation 1} \]

\[ MI = \frac{Pr}{\sqrt{f}} \quad \text{Equation 2} \]

Therefore, in the quality control of ultrasonic equipment, we should choose an effective detection method, for the reliably measured and calculated of TI and MI values of ultrasonic equipment, in order to achieve accurate, reliable and unified quantitative value to remind users to minimize possible harm by minimizing exposure time and exposure intensity.

1.2 Electronic and mechanical safety
In the quality control, we should pay attention to the visual inspection of equipment, such as if the transducer and the plastic have fracture and delamination, cable is loose and wore out, whether the supporting equipment is running normally and if the operational environment meet usage requirements, then use the leakage current meter to measure whether the leakage current is safe or not.

1.3 Selection of detection phantom
Under the different nominal frequency and detecting depth, we need to use a different transducer, thus we also should choose different imitation Tissue Mimicking Ultrasound Phantom. If use a low frequency transducer (2 ~ 5 MHz), then a relatively large-structure phantom should be selected, generally speaking it’s about 15cm thickness required. For the high frequency transducer (7 ~ 12 MHz), the penetration distance of acoustic beam is smaller, but the resolution is higher, so the phantom with relatively small-structure should be chosen for evaluation and calculation. When testing, the ultrasonic equipment should be adjusted to B mode, the corresponding transducer should be selected and harmonic imaging should be turned off.

The Tissue Mimicking Ultrasound Phantom should have similar acoustic characteristics with the soft tissues of human body, at least have the following three characteristics:① The speed of sound transmission is 1540m/s;② Attenuation degree of ultrasonic energy: 0.5~0.8dB/(cm · MHz);③ The diffusion properties are similar to the ultrasonic echo signals produced by soft tissues. The phantom contains different structure and target line, which is used to detect various imaging parameters in the scanning range. Figure 2 shows the appearance, internal targets and structural arrangement of the commonly used detection phantom, including target lines used for the detection of image’s resolution, the vertical lines and horizontal lines used for the detection of measurement error, diameter error of the intestines of the newborn

| MI>0.7 | Theoretically, the harm of cavitation effect
The harm of cavitation effect in contrast agents study | Minimize the irradiation time |
| TI>0.7 | Increase thermogenesis hazard | The total exposure time of embryo or fetus should be limited |
| TI>1 | Increase thermogenesis hazard | It is not recommended to scan the eye, the total exposure time of embryo or fetus should be limited |
| TI>3 | Obvious thermogenesis hazard | Scans of embryos or fetuses are not recommended |
cystic mass and the blind spot detection.

Fig. 2 The appearance, internal targets and structural arrangement of the commonly used detection phantom

2. Imaging performance detection

2.1 The detection of measurement error

The ultrasound equipment uses the electronic caliper to measure the structure, measure the straight distance on the frozen b-type image, including measurement of perimeter and area. Quality control officers can detect the measurement error easily by measuring the corresponding structure in the phantom, including vertical distance measure (figure 3), the image is frozen, measures the distance of two target line center of the image, the relative error of the measured value and the actual distance is calculated according to formula 3, measure the horizontal distance in the same way (figure 4). When measuring the diameter of cystic mass, scan the probe to the top of the cystic mass, probes of 4MHz, 5MHz, 7.5 MHz are respectively corresponding to the cystic mass diameter of 10mm, 6mm and 4mm, the longitudinal and transverse diameter of the cystic mass of the image can be measured with the electronic caliper, comparing the measurement results with the actual distance, the formula (4) is used to calculate the value error:

\[
\text{Position indication error} = \left| \frac{\text{Measured value} - \text{Actual value}}{\text{Actual value}} \right| \times 100\% \quad \text{Equation 3}
\]

\[
\text{Diameter error} = \left| \frac{\text{Measured value} - \text{Actual value}}{\text{Actual value}} \right| \times 100\% \quad \text{Equation 4}
\]

Fig. 3 Measurement of vertical distance

Fig. 4 Measurement of horizontal distance

2.2 Blind spot detection

Fig. 5 Diameter measurement of cystic mass

Fig. 6 Measurement of blind spot
Blind spot is the most shallow distance that the equipment can detect under the probe, the detection of blind spot can prevent the user from missing the shallow lesion of human body, which may resulting in misdiagnosis. Focus the device in the near field, adjust the total gain, TGC, contrast and brightness of the detected instrument, making the target line image clearly visible, then reading the depth of the position of the most shallow target line in the blind target group, as the blind area of the device in this probe. The number of the blind area is smaller, the ability of the equipment to detect shallow lesions is stronger as shown in figure 6.

2.3 Detection of image resolution

Image resolution, often referred to as spatial resolution, is divided into two main parts: axial resolution and lateral resolution, which is an important parameter to measure the image performance of medical ultrasonic diagnostic equipment. There are two detection methods: object isolation and single point method. Method of object isolation is often used, detection phantom contains a set of different depth of target group for assessing the axial and lateral resolution of the equipment, reading the minimum distance that can be resolved in the axial and lateral target images, which is the axial and lateral resolution of the instrument when equipped with the probe, as shown in figure 7, within the effective depth of detection, these operations are repeated from shallow to deep for the spatial resolution target group. Axial resolution is generally better than the lateral resolution, this method has some shortcomings in the routine verification, and the space measurement of the target in the model is limited. Most of all, it is difficult for us to determine whether the target can be distinguished.

Fig. 7 The detection model evaluates the axial and lateral resolution images at a specific depth.

Single line method can choose any locus of the target line, measuring the length and width of different depth of single target in the corresponding transducer at near field, middle field and far field, which can indirectly evaluate the axial and lateral resolution, when using a single method, the target image can be magnified by local magnification of the instrument to ensure the minimum measurement error, the main disadvantages of this method is sometimes difficult to define the fuzzy target boundary, as shown in Figure 8,9, therefore, two methods should be integrated in the structure design of the test model, so that the verification personnel have a variety of choices to improve the accuracy of the measurement.

Fig.8 Use single-line method to evaluate axial resolution
2.4 Detection of penetration depth
Penetration depth, known as sensitivity, clinically because of the transmission attenuation of ultrasound beam in the process, echo is very weak, the ability of ultrasonic system to detect, display and identify these faint echoes from background noise is important. Still use detection model, according to the nominal frequency of the instrument with transducer, choose the corresponding Tissue Mimicking Ultrasound Phantom, adjust the instrument to maximize the energy operation, and use the depth of focus area set up to obtain the maximum penetration depth distance; as shown in figure 9, then use the caliper gauge to determine and measure the deepest part of the scattering echo can be detected, and identify the background electronic noise, the maximum depth of the target line visible in the vertical target group is the depth of detection of the instrument equipped with the probe.

3. Discussions and Conclusions
In terms of ultrasonic safety, TI and MI are not absolute values, but rather rough calculations of the effects of some biological effects, the higher the index, the greater the possibility of biological effects. Calculation of ultrasonic instrument on the two indexes, based on the many assumptions, consider the worst case scenarios, so it is very difficult for us to achieve uniform value in the detection process, and we look forward to developing a better detection method for ultrasonic safety.

In terms of instrument performance, with the development and application of new technology, use of a higher performance transducer, the performance of ultrasonic equipment has been improved in a certain range, many instruments can easily distinguish the target points in the model and present good image quality, therefore, it is necessary to constantly update the internal structure of the Tissue Mimicking Ultrasound Phantom, update the detection method to better detect the performance of the new equipment. As end users of ultrasonic equipment, you need to make sure that the use of equipment can meet the needs, and be able to obtain and maintain high quality ultrasonic diagnostic images, so as to realize the quality control of ultrasonic equipment.

References
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