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B mode ultrasonic diagnostic equipment

B 型超声诊断设备

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Table of Contents

B mode ultrasonic diagnostic equipment

1 Scope

This standard specifies the definition, requirements, test methods, inspection rules of B mode ultrasonic diagnostic equipment (hereinafter referred to as B-ultrasonics).

This standard applies to B mode ultrasound diagnostic equipment, which has a nominal frequency in the range of 1.5 MHz ~ 15 MHz, including the two-dimensional grayscale imaging part of color Doppler ultrasonic diagnostic equipment (color ultrasonics).

This standard does not apply to ophthalmic professional ultrasound diagnostic equipment and intravascular ultrasound diagnostic equipment.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Standard; however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 9706.1 Medical electrical equipment - Part 1: General requirements for safety (GB 9706.1-2007, idt IEC 60601-1:1988)

GB 9706.9 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (GB 9706.9-2008, idt IEC 60601-2-37:2001)

GB 9706.15 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (GB 9706.15-2008, idt IEC 60601-1-1:2000)

GB/T 14710 Environmental requirement and test methods for medical electrical equipment

YY/T 0108-2008 Testing methods for M-mode of ultrasonic diagnostic equipment

YY/T 1142-2003 Methods of measuring the frequency of medical ultrasonic equipment and probe

The manufacturer shall publish the specification of slice thickness, in the accompanying documents.

4.2.7 Accuracy of lateral geometrical position

The accuracy of lateral geometrical position shall meet the requirements of Table 1, OR meet the manufacturer's published index, in the accompanying document. If the type and nominal frequency of the probe are not included in the range, which is listed in Table 1, the manufacturer shall publish the index of the probe, in the accompanying document.

4.2.8 Accuracy of longitudinal geometrical position

The accuracy of longitudinal geometrical position shall meet the requirements of Table 1, OR meet the manufacturer's specifications, which are published in accompanying documents. If the type and nominal frequency of the probe are not included in the range, which is listed in Table 1, the manufacturer shall publish the index of the probe, in the accompanying document.

4.2.9 Measurement deviation of perimeter and area

The measurement deviations of perimeter and area shall be within ±20%, OR in accordance with the manufacturer's published specifications, in accompanying documents.

4.2.10 M-mode performance index

For B-mode ultrasonic probes which have M mode, the performance test of M mode time display error shall be carried out.

The performance index of M mode shall conform to the index, which is published by the manufacturer, in the accompanying document.

4.2.11 Calculation deviation of 3D reconstruction volume

For B-ultrasonics, which are equipped with 3D reconstruction function, the deviation of volume calculation shall be within the range of ±30%, OR in line with the index, which is published by the manufacturer in the accompanying document.

4.2.12 Adaptable range of power supply voltage

Within the range of ±10% of the rated voltage, B-ultrasonics shall be able to work normally.

4.2.13 Continuous operating time

The continuous operating time of B-ultrasonics shall be greater than 8 h.

The specified setting simulates the most commonly used state of B-ultrasonics in clinical use. The clinical use state usually requires a deep penetration capability; the focusing range of the ultrasonic beam is expanded as much as possible; it has the best average resolution capability for the entire target.

The properties are tested at the nominal frequency of the probe.

For the variable frequency probe, set it at different nominal frequencies, according to the instruction manual, to conduct the performance index test of the probe.

For broadband probes, the performance index of the probe shall meet the basic performance requirements, within the frequency band corresponding to the probe's center frequency.

For variable frequency probes or broadband probes, if the manufacturer has special requirements in the instruction manual, the probe frequency can also be set to the optimum state for testing, according to the requirements of the instruction manual.

5.2.2 Setting of B-ultrasonics during the test

The recommended test setup is as shown in Informative Appendix B.

This standard allows the manufacturer to specify the setting conditions of the B-ultrasonics, during the performance test. However, the setting state of the B-ultrasonics (focus, brightness, contrast, frequency, suppression, output power, gain, TGC, automatic TGC, etc.), in the test report, shall be published, together with the test results.

5.3 Performance test

5.3.1 Acoustic operating frequency test

The measurement of the acoustic operating frequency and frequency range shall be carried out, in accordance with the provisions of YY/T 1142.

5.3.2 Penetration depth test

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the phantom acoustic window, through the couplant. Aim at the longitudinal depth target group. Keep the target line image clearly visible, under the specified setting conditions. Move the probe slightly, to observe the target line on the image, which is farthest from the surface of the probe, that can be distinguished. The distance, between the target line and the probe surface, is the penetration depth of the probe.

5.3.3 Lateral resolution test

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the phantom acoustic window, through the couplant. Aim at the lateral resolution target group, at a specific depth. Keep the target line image clearly visible, under the specified setting

conditions. Move the probe slightly. The minimum distance, between the two target lines, that can be displayed separately as two echo signals, is the lateral resolution at this depth.

If the lateral resolution requires multiple target groups within the specified depth range, it shall test each target group separately; take the maximum value of the test results as the lateral resolution of the probe; meanwhile record the testing data of all target groups, within the depth range.

5.3.4 Axial resolution test

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the phantom acoustic window, through the couplant. Aim at the axial resolution target group, at a specific depth. Under the specified setting conditions, keep the target line image clearly visible. Move the probe slightly. The minimum distance, between the two target lines, that can be displayed separately as two echo signals, is the axial resolution at this depth.

If the axial resolution requires multiple target groups, within the specified depth range, each target group shall be tested separately. Take the maximum value of the test results, as the axial resolution of the probe. Meanwhile record the testing data of all target groups, within the depth range.

5.3.5 Dead zone test

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the phantom acoustic window, through the couplant. Aim at the target group in the dead zone. Keep the target line image clearly visible, under the specified setting conditions. Translate the probe, to observe the target line, which is closest to the probe surface AND the image behind of which can be distinguished. The distance, between the target line and the probe surface, is the dead zone of the probe.

5.3.6 Slice thickness test

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the phantom acoustic window, through the couplant. Aim at the thin layer of the scattering target. The scanning plane is perpendicular to the ultrasonic phantom window. The intersection line, between the scanning plane and the phantom window, is parallel to the thin scattering target layer, as shown in Figure 1. Under the specified setting conditions, adjust the intersection line of the scanning plane and the thin scattering target layer, to locate it at a specific depth. Use an electronic vernier, to measure the thickness of the thin scattering target layer. Calculate the slice thickness t at this depth (see Figure 1).

target groups. Keep the target group images clearly visible, under the specified setting conditions. Keep the center of the target group in the center of the field of view. Draw a closed figure (rectangle or circle), in the area of the displayed center, which is approximately equal to 75% of the field of view. Measure the perimeter and area. Calculate the percentage error.

5.3.10 M-mode performance test

The performance test of B-ultrasonic M mode is carried out, in accordance with the provisions of YY/T 0108.

5.3.11 Calculation deviation of 3D reconstruction volume

Turn on the B-ultrasonics to be tested. Place the probe on the surface of the acoustic window of the ultrasonic phantom, through the couplant. Scan the oval target of known volume value. Follow the three-dimensional reconstruction volume steps and volume measurement steps, under the specified setting conditions, to obtain the measured volume of the oval target. Calculate the percentage error; the deviation shall be within ±30%.

5.3.12 Adaptable range of power supply voltage

Set the power supply voltage at 110% and 90% of the rated value, respectively. The equipment shall work normally.

5.3.13 Continuous operating time

B-ultrasonic is in the operating state of scanning and displaying. It shall be able to work normally, after 8 hours of continuous startup.

If the B-ultrasonic is an internal power supply device, the continuous operating time test shall be carried out, according to the index, which is published by the manufacturer, in the accompanying document.

If the manufacturer specifies the operation requirements of the probe, in the accompanying document, then during the continuous operating time test, the operation duration rate of the probe shall be carried out, according to the manufacturer's requirements.

5.4 Safety test

The general safety requirements of B-ultrasonics shall be implemented, in accordance with the provisions of GB 9706.1.

If applicable, the system safety requirements of B-ultrasonics shall be implemented, in accordance with the provisions of GB 9706.15.

The special safety requirements for B-ultrasonics shall be implemented, in accordance

with the provisions of GB 9706.9.

5.5 Appearance and structural inspection

It is verified by visual observation and practical operation.

5.6 Use function inspection

Check the main functions one by one, according to the provisions of the instruction manual of the B-ultrasonics to be tested, to verify whether it can work normally.

Note: The use function inspection does not include product design parameters or functional items, that cannot be verified by intuitive test means.

5.7 Environmental test

The environmental test of B-ultrasonics shall be carried out, according to the methods and procedures, which are specified in GB/T 14710. The test time and conditions shall comply with the supplementary provisions of Table 2.

6 Inspection rules

6.1 Inspection classification

Product inspection is divided into exit-factory inspection and type inspection.

6.2 Exit-factory inspection

The inspection items and judgment rules of the exit-factory inspection are stipulated by the manufacturer.

6.3 Type inspection

6.3.1 Type inspection shall be carried out, in one of the following situations:

a) Registration inspection;

b) Not less than once a year, in continuous production;

c) Production resumed after long-term shutdown;

d) When there are major changes in design, process or materials, that may cause changes in the safety or performance of B-ultrasonics;

e) When requested by the national quality supervision and inspection department.

6.3.2 The items of the type test are all the required items of this standard; the number of samples for the type test is one set.

Appendix A

(Informative)

Technical requirements for phantoms

A.1 Technical requirements for general phantoms

When carrying out the test of B-ultrasonics dead zone, penetration depth, axial resolution, lateral resolution, accuracy of longitudinal and lateral geometrical position, the technical parameters of the phantom, which is used in the test, are as follows:

Sound velocity of tissue-mimicking material: 1540 m/s ± 10 m/s, 23 °C ± 3 °C;

Sound attenuation of tissue-mimicking material: 0.7 dB/(cm • MHz) ± 0.05 dB/(cm • MHz), 23 °C ± 3 °C;

Nylon target wire's diameter: 0.3 mm ± 0.05 mm;

Target line's position tolerance: ±0.1 mm;

The spacing between adjacent target lines, in the longitudinal linear target group: 10 mm;

The spacing between adjacent target lines, in the lateral linear target group: 10 mm or 20 mm;

The depth of the resolution target group shall be able to meet the test needs.

A.2 Technical requirements for slice thickness phantoms

Sound velocity of background tissue-mimicking material: 1540 m/s ± 10 m/s, 23 °C ± 3 °C;

Sound attenuation of background tissue-mimicking material: 0.7 dB (cm • MHz) ± 0.05 dB/(cm • MHz), 23 °C ± 3 °C;

Scattering target's layer thickness: Not more than 0.4 mm.

A.3 Technical requirements for volumetric phantoms

Sound velocity of background material: 1540 m/s ± 10 m/s, 23 °C ± 3 °C;

Sound speed of ovoid material: 1540 m/s ± 10 m/s, 23 °C ± 3 °C;

At a minimum, it shall indicate the volume data for calibrated ovoid.

Appendix B

(Informative)

B-ultrasonics setting for performance test

B.1 Test setup

B.1.1 Overview

Various combinations of B-ultrasonics settings and probes make it impossible to test in all combinations. Therefore, for each probe, it is only tested at the specified settings. The prescribed settings are similar to the probes, which are most commonly used in clinical use; the simulating clinical use often requires deeper probing capabilities. B-ultrasonic is set by the following steps; the focusing range of the ultrasonic beam is expanded as much as possible; it has the best average resolution for the entire target, to achieve the best scanning state for common soft tissue structures. Initially, the phantom is imaged, using the typical B-ultrasonic settings for imaging soft tissue. Follow the steps of B.1.2 ~ B.1.4, to carry out the test setup.

B.1.2 Display settings (focus, brightness, contrast)

Turn the brightness and contrast controls all the way down, focus to sharp. Then increase the brightness, until it becomes the lowest perceptible grayscale, in the echo-free areas around the edges of the image. Then increase the contrast, so that the image contains the largest possible grayscale range. Finally, check the sharpness of the focus. If further adjustments are required, repeat the entire procedure.

B.1.3 Sensitivity setting (frequency, suppression, output power, gain, TGC, automatic TGC)

The sensitivity setting shall meet the following requirements:

a) Indicate the nominal frequency of the B-ultrasonic probe;

b) If there is a suppression or limitation control terminal, it is adjusted, so that the smallest possible signal can be displayed;

c) The output power and gain shall be set to the maximum value, to obtain the echo signal at the maximum depth, in the highly attenuated scattering material; the small ultrasonic echo shall be distinguishable from electrical noise;

d) The adjustment of the near-field gain level of the Time Gain Compensation (TGC) control terminal should make the echo signal, within the initial 1 cm or 2 cm range in the phantom, display a medium gray level;

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