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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0767-2023

General technical requirements for colour ultrasound imaging equipment

彩色超声影像设备通用技术要求

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1 Scope

YY/T 0767 is the general technical specification for colour Doppler ultrasound systems, the scanners used across cardiology, obstetrics, vascular medicine and general imaging in every Chinese hospital. It sets the requirements such a system has to meet and the test methods that verify them, covering the imaging performance in grey scale and in colour flow, the accuracy of the velocity measurements the clinician acts on, the acoustic output limits, and the general construction and safety of the equipment. Colour ultrasound is the highest-volume imaging modality in China, and this is the document that makes one manufacturer's performance claims comparable with another's at registration and at acceptance testing. For a manufacturer entering the market, it is the baseline text a Chinese registration is assessed against.

This document specifies the requirements for color ultrasound imaging equipment (referred to as "color ultrasound") and describes the corresponding test methods. This document applies to color ultrasound imaging equipment.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 9706.1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

GB 9706.237, Medical electrical equipment -- Part 2-37: Particular requirements for the

basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

GB 10152, B mode ultrasonic diagnostic equipment

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

YY 9706.102, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic compatibility -- Requirements and tests

YY/T 0458, Technical requirements for ultrasonically blood-mimicking Doppler phantom

YY/T 0705, Ultrasonics. Continuous-wave Doppler systems. Test procedures

YY/T 1420, Environmental requirement and test methods for medical ultrasonic equipment blood flow model or the string Doppler test piece and the set speed.

3.7 directional discrimination The ability that color Doppler ultrasound identifies the direction of blood flow and expresses the direction in terms of the color of the blood flow map and/or the position of the Doppler spectrum relative to the baseline.

4 Requirements

4.1 General The manufacturer shall publish the indicators of all applicable technical parameters in this chapter in the accompanying documents according to the actual probe configuration of the equipment. For multi-purpose color ultrasound, manufacturers can give different indicators for the same probe for different expected application ranges.

4.2 Color Doppler mode

4.2.1 The penetration depth of Doppler of color ultrasound shall comply with the specifications published by the manufacturer in the accompanying document.

4.2.2 The color Doppler image shall match the grayscale image of the pipe in which it is located.

4.2.3 It shall have directional discrimination.

4.3 Spectral Doppler mode

4.3.1 The penetration depth of Doppler of color ultrasound shall comply with the specifications published by the manufacturer in the accompanying document.

4.3.2 The error of flow velocity shall be within ±20%.

4.3.3 The cursor position of the sampling area in pulse wave Doppler mode shall be accurate.

4.4 Power Doppler mode

4.4.1 The penetration depth of power Doppler of color ultrasound shall comply with the specifications published by the manufacturer in the accompanying document.

4.4.2 The power Doppler image shall match the grayscale image of the pipe in which it is located.

4.5 Safety Color Doppler ultrasound is generally equipped with multiple probes. A probe may have several intended uses. There are many combinations of color ultrasound host control terminal (acoustic output, gain, focus position, etc.) settings and probe selection. It is not possible to test all combinations of states. In this document, the main unit and probe combinations are tested only in the specified settings. When testing, it is recommended to simulate the most commonly used states of the device and probe in expected clinical imaging. During the test, it is recommended that the manufacturer provide the best setting status in the accompanying document, or use the one-click optimization setting function of color ultrasound, and avoid setting the device's display brightness, contrast, etc. to the extreme state, see Annex B.

5.2 Color Doppler mode

5.2.1 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain clear color Doppler images. Move the probe in a deeper direction along the direction of the simulated blood vessel until the colored signal disappears. Thereafter the probe is moved back to the position before the color signal disappeared. Freeze the image. Use the ranging function of the equipment to measure the distance between the acoustic window and the farthest end of the inner wall at this time, which is the penetration depth of color Doppler of color ultrasound.

5.2.2 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain clear color Doppler images. Observe and verify that the color blood flow image shall be consistent with the grayscale image of the pipeline where it is located, that is, there is no obvious lack of filling, no obvious misalignment, and no obvious color overflow.

5.2.3 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain clear color Doppler images. By changing the blood flow direction relative to the probe, the device shall be able to correctly identify the blood flow direction without aliasing. For a blood-simulating fluid model containing two parallel pipes with opposite directions, the

beam scanning plane can be used to intercept the cross-sections of the two pipes for inspection. Convex array and phased array probes can also use simulated blood fluid models containing horizontal pipes. It is not necessary to turn the probe at this time. Hold the

5.3.3 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain a clear spectral Doppler signal. First, place the sampling area outside the superficial wall of the simulated blood vessel. The Doppler spectrum shall not be displayed at this time. Then, in small steps of

0.5 mm or 1 mm, the sampling area is advanced from shallow to deep, across the blood vessel wall toward the blood vessel center, and finally to the outside of the deep blood vessel wall. The Doppler spectrum display shall be from weak to strong. The spectrum display reaches its maximum at the center of the blood vessel, and then decreases from large to small. After crossing the outside of the distal blood vessel wall, the spectrum display disappears (little discrete information is not counted), then the accuracy of the cursor position in the sampling area meets the requirements. NOTE: When testing in spectral Doppler mode, unless otherwise specified, the flow rate of the simulated blood fluid model can be set to 50 cm/s. Verification tests are performed at half the maximum indicated depth.

5.4 Power Doppler mode

5.4.1 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain clear power Doppler images. Move the probe in a deeper direction along the direction of the simulated blood vessel until the colored signal disappears. Thereafter the probe is moved back to the position before the color signal disappeared. Freeze the image. Use the ranging function of the device to measure the distance between the acoustic window and the farthest edge of the color edge at this time, which is the penetration depth of power Doppler of the color ultrasound.

5.4.2 The probe is well coupled to the simulated blood fluid model acoustic window. The ultrasound beam axis is aligned with the simulated blood vessels in the phantom. Under the prescribed settings, keep the simulated blood vessel image clearly visible and obtain clear power Doppler images. Observe and verify that the color image shall be consistent with the grayscale image of the pipe where it is located, that is, there is no obvious underfilling, no obvious misalignment, and no obvious color overflow. NOTE: During the power Doppler mode test, unless otherwise specified, the simulated blood flow model can be set to a lower flow rate, such as 10 cm/s. Verification tests are performed at half the maximum imaging