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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1919-2023

Test methods of performance for ultrasonic contrast imaging

超声造影成像性能试验方法

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the Medical Ultrasound Equipment Sub-Technical Committee (SAC/TC10/SC2) of the National Technical Committee for Standardization of Medical Electrical Appliances. This document was drafted by: Shenzhen Mindray Biomedical Electronics Co., Ltd., Hubei Medical Device Quality Supervision and Inspection Institute. The main drafters of this document. Zhu Lei, Wu Chengzhi, Wang Zhijian, Yang Pengfei, Sang Maodong, Jiang Shilin. Test methods for contrast-enhanced ultrasound imaging performance

1 Scope

YY/T 1919 specifies how the contrast imaging performance of an ultrasound system is tested. Contrast-enhanced ultrasound uses microbubbles that respond non-linearly to the beam, and the scanner has to separate that signal from ordinary tissue echo without destroying the bubbles in the process. This document sets out the measurements that characterise how well a system does that, and the phantoms and conditions under which they are made, so that a contrast capability claimed by one manufacturer can be compared with another. Contrast ultrasound is used in China for liver lesion characterisation and increasingly beyond it, as a cheaper and radiation-free alternative to contrast CT. For a manufacturer, this is the method a Chinese registration expects a contrast imaging claim to be substantiated by.

This document describes the test conditions and test methods for ultrasound contrast imaging imaging performance of ultrasound imaging equipment. This document applies to ultrasound imaging equipment with contrast capabilities. This document does not apply to ultrasound imaging equipment that uses gastrointestinal visualization aids for signal

enhancement.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB 10152 Type B ultrasonic diagnostic equipment

YY/T 0458 Technical requirements for ultrasonic Doppler blood imitation fluid model

3 Terms and definitions

The following terms and definitions as defined in GB 10152 apply to this document.

3.1 The shell contains inert gas, which is similar in size to red blood cells. It can pass through the pulmonary circulation but cannot penetrate the blood vessel wall. It can be injected through intravenous injection. It is injected into the blood circulation system or directly injected into the body cavity after being diluted with physiological saline. It has strong backscattering and can improve the analysis of ultrasound imaging diagnosis. Microbubble preparation with high resolution, sensitivity and specificity.

3.2 With the help of ultrasound contrast agent to enhance the backscattering intensity in blood vessels or body cavities, the enhanced ultrasound echo is collected in real time for contrast signal detection, The function of imaging processing and display. Note

1.This function can display the ultrasonic echo from the ultrasonic contrast agent and the ultrasonic echo from the tissue side by side or superposed in image form according to the spatial position. Note

2.See Appendix A.

3.3 It consists of an ultrasonic tissue-imitation material and a pipeline embedded in it, and an ultrasonic contrast agent is added to the imitating blood fluid flowing in the pipeline. A device for testing the performance of contrast-enhanced ultrasound imaging.

Note. The function of the ultrasound contrast imaging phantom can be achieved by adding a certain amount of ultrasound contrast agent to the ultrasound Doppler imitation blood fluid phantom.

3.4 In the contrast imaging mode, the device under inspection can clearly observe the maximum depth of the ultrasound contrast agent signal using the ultrasound contrast imaging phantom.

Note. The unit of the maximum depth of contrast imaging is millimeters (mm).