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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0703-2008

Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications

超声实时脉冲回波系统性能试验方法

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Foreword

This standard is equivalent to using the International Electrotechnical Commission Technical Report IEC 61390.1996 "real-time ultrasound pulse-echo system performance test side law". This standard and IEC 61390.1996 is the main differences.

--- The original text of the "technical report" to the "standard";

--- IEC 61102.1991 "in the

0.5 to 15MHz frequency range hydrophone to measure and describe the ultrasound field" has been transformed equivalent Of GB/T 16540-1996 "acoustic characterization of ultrasonic fields in the frequency range 0.5 ~ 15MHz and measuring hydrophone Law ", IEC 61157.1992" medical diagnostic ultrasound equipment requirements published by the acoustic output "has been translated into equivalent GB/T 16846- 2008, IEC 60854. 1986 "pulse-echo ultrasound diagnostic equipment performance measurements" has been translated into equivalent YY/T 0643- 2008, so the standard is a direct reference to the correspondence of the above criteria. Appendix A of this standard is a normative appendix. This standard was proposed by the State Food and Drug Administration. This standard by the standardization of medical ultrasound equipment for medical appliances National Standardization Technical Committee Technical Committee (SAC/TC10/SC2) Centralized. This standard was drafted. medical ultrasound equipment Wuhan National Quality Supervision and Testing Center, Institute of Acoustics. The main drafters of this standard. Wang Zhijian, busy Ashmore, cattle Fengqi. YY/T 0703-2008/IEC 61390.1996

Ultrasonic pulse echo scanner with a pulsed ultrasonic beam sweeps were thin body region of interest, and received back from the tissue interface Waves, thereby generating an image within the scanning plane of the tissue. The use of various types of transducers are working in the transmit/receive mode of the ultrasonic signal. in Medical practice, widespread use of ultrasound scanners for the human body in many soft tissues and organs imaged. Test methods described in this standard has been widely recognized and for all types of devices. Manufacturers can use this standard side Method to develop the technical performance of their products specifications, users can use this standard method to test the performance of

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these technologies, these measurements are not available in Movies Carried out under the conditions of the instrument sound working properly. Phantom structure have not been detailed provisions, applicable only describes the general type in Appendix A And internal structure, along with the style, test results and test common phantom phantoms of the specific structure to be released together with. These phantom has Similar goods. Technical performance parameters specified and the corresponding measurements chosen for diagnostic applications as expected and manufacturers of similar equipment Providing technical performance comparison between the foundation. The manufacturer's published technical performance should be able to present the results of standard test methods employed with each other than Included. Due to the continuous development of technology, it is not recommended technical performance parameters specific values and tolerances. However, it is contemplated that the use of the recommended way to get Package and numerical results will provide a useful basis for the application of appropriate diagnostic evaluation of device performance. This standard test procedures recommended in accordance with GB 9706.1. When the diagnosis system in a specific system components, such as transducers have more than one option when each option are believed to form a Separate system. However, if the instrument most commonly used settings, and control terminal attachment combinations were measured, it is considered the performance of the instrument has been Fully tested. Of course, the equipment also for further evaluation, but only as an exception rather than the rule should be requested. Measurement methods used with this standard in two or more parts, equipment information on the principles and in Appendix A. Measurement and evaluation of acoustic output electrical safety standards, the implementation of relevant national standards and industry standards, this standard does not include the content. YY/T 0703-2008/IEC 61390.1996 Real-time ultrasonic pulse echo system Performance test method

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1 Scope

YY/T 0703 is the test procedure standard for real-time pulse-echo ultrasound systems, that is, for B-mode imaging equipment. It defines how the performance specifications a manufacturer declares are to be measured: penetration, spatial resolution in each direction, contrast and geometric accuracy, using phantoms and conditions that make one system's figures comparable with another's. Without a common procedure, published resolution and penetration numbers reflect the test setup as much as the scanner. It is the companion to YY/T 0705 for continuous-wave Doppler systems, and the type-test counterpart of YY/T 0938, which covers checking equipment already in service. For a manufacturer of ultrasound systems or a laboratory testing them in China, this is the reference procedure.

This standard specifies within 0.5MHz to 15MHz frequency range, real-time performance test method for medical ultrasound imaging equipment. This standard applies to the following types of real-time using pulse-echo ultrasound scanner principle.

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--- Mechanical sector scanner;

--- Electronic phased array sector scanner;

--- Electronic linear array scanner;

--- Electronic convex array scanner;

--- Any water bath scanner based on the four scanning modes.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB/T 16540-1996 acoustic characterization of ultrasonic fields in the frequency range 0.5 ~ 15MHz and its measurement method hydrophone (Eqv IEC 61102.1991)

GB/T 16846-2008 acoustic output of medical diagnostic ultrasound equipment requirements published (IEC 61157.1992, IDT)

YY/T 0643-2008 ultrasonic pulse echo diagnostic equipment Methods for measuring performance (IEC 60854. 1986, IDT)

IEC 60866. 1987 calibration and characteristics of the hydrophone is described in the frequency range of 0.5MHz to 15MHz

3 Terms and Definitions

The following terms and definitions apply to this standard.

3.1 A scan A- Ju Ba Rao shape Data acquisition type one-dimensional mode, collecting echo information from a single point in the axis of the ultrasonic beam. Echo amplitude information display. [See YY/T 0643-2008 (IEC 60854. 1986)

3.20 Change]

3.2 B- mode image and the acquired echo transmission/reception period corresponding to a direct line. 3.3 [See GB/T 16540-1996 3.5, Change]

3.4 Hydrophone placed in the sound field, the sound signal frequency peak position at peak time space-based observations, the zero-crossing signal frequency or mining law YY/T 0703-2008/IEC 61390.1996

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