ICS 11.040.50
CCS C41

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0705-2008

Ultrasonics - Continuous-wave Doppler systems - Test procedures

超声连续波多普勒系统试验方法

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Foreword

This document was issued on 17 October 2008 by the National Medical Products Administration and takes effect on 1 January 2010.

It is a YY/T standard: it is recommended rather than compulsory, but it is the method a Chinese reviewer applies when assessing a registration submission.

It is classified under ICS 11.040.50, Chinese classification C41.

This standard is equivalent to using the International Electrotechnical Commission Technical Report IEC 61206.1993 "Continuous Wave Doppler ultrasound test system method". This standard and IEC 61206.1993 is the main differences.

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

--- IEC 61102.1991 "0.5 to 15MHz using hydrophones in the frequency range of the ultrasonic field measurements and descriptions" are equivalent turn Into GB/T 16540-1996 "acoustic characterization of ultrasonic fields in the frequency range 0.5 ~ 15MHz and measuring hydrophone It is Law ", so the standard of a direct reference to the corresponding standards. This standard Annex A, Annex B is informative 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 Inspection Center. The main drafters of this standard. Wang Zhijian, busy Ashmore. YY/T 0705-2008/IEC 61206.1993

Introduction

In clinical practice, widely used continuous wave Doppler flow meter, flow meter or fetal heart rate detector, such medical ultrasound equipment testing The amount of Doppler shift that changes the amount of the scattered wave frequency ultrasonic transducer relative movement between the body and the scattering caused by the ultrasound transducer, the

frequency shift is proportional to In the observed velocity, i.e. toward or away from the diffuser flow transducer velocity component. This standard describes a series of test methods used to determine the performance parameters of continuous wave Doppler ultrasound system. Additional tests within After the introduction, this standard is also applicable to pulsed Doppler system. These test methods based on the use of some special equipment, such as a string type, the strip , Disc, piston and imitation blood flow Doppler test pieces. These methods can be divided into the following three categories. The first category is appropriate to ensure that the system into Line work or sensitive enough, by the clinician or technician routine quality control testing undertaken; second category is not frequent, but More sophisticated testing methods, such as suspected system is not working properly performed; the third category represents the manufacturers based on key performance parameters for the entire A system test. YY/T 0705-2008/IEC 61206.1993 Continuous wave Doppler ultrasound system test method The first chapter outlines

1.1 Scope This standard specifies.

--- Used to measure continuous wave Doppler flow meter, flow meter or test methods fetal heart rate detector performance;

--- Doppler ultrasound system for measuring the performance parameters of a special Doppler test piece. This standard applies to.

--- Doppler ultrasound system for the entire machine, which does not test the system or dismantling disconnected carried out;

--- Continuous wave Doppler ultrasound system testing. After an additional test content, these tests can be used for positioning measurement speed Doppler ultrasound system, such as a pulse wave Doppler system and FM. In this standard, it does not contain content related to electrical safety and acoustic output.

1.2 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)

1.3 Terms and Definitions The following terms and definitions apply to this standard.

1.3.1 A description of the terms of Doppler ultrasound system, showing the scattering body toward or away from the ultrasound transducer.

1.3.2 A description of the terms of Doppler ultrasound system, showing scattering relative to the direction of movement of the transducer, the output of the Doppler system appears At

different output ports, output channel or output devices.

1.3.3 Changing the amount of ultrasound scattering wave frequency by scattering relative motion between the transducer body and caused that transmit and receive frequency waves between wave Rate difference.

1.3.4 Or more in a single Doppler frequency Doppler frequency, the excitation signal voltage output device.

1.3.5 Electrical connectors or parts Doppler ultrasound system, the Doppler output connected to an external output device. Note. Not all available Doppler ultrasound Doppler systems have a physical output connector. YY/T 0705-2008/IEC 61206.1993

1 Scope

YY/T 0705 is the test procedure standard for continuous-wave Doppler systems, the ultrasound instruments that measure blood velocity without range resolution, used in fetal heart detection, peripheral vascular assessment and cardiac gradient measurement. Continuous-wave Doppler has one property no other mode has, an unlimited maximum measurable velocity, and one weakness, that it cannot tell where along the beam the signal came from, so its performance is characterised differently from pulse-echo imaging. The standard defines how sensitivity, velocity accuracy and the acoustic output of such systems are measured. It is the companion to YY/T 0703 for real-time pulse-echo systems. For a manufacturer of Doppler equipment or a test laboratory serving them in China, this is the reference procedure.