ICS 11.040.50
CCS C41

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0938-2014

Guide for the check of B mode ultrasonic diagnostic equipment

B型超声诊断设备核查指南

Issued on: June 17, 2014 **Implemented on: July 1, 2015**

Issued by: National Medical Products Administration

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. Please note that some of the content of this document may involve patents. Distribution of this document Institutions do not assume the responsibility to identify these patents. This standard was proposed by the China 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. State Food and Drug Administration of Hubei Medical Device Quality Supervision and Inspection Center, Institute of Acoustics, CAS The study. The main drafters of this standard. Wang Zhijian, cattle Fengqi, Jiang Shilin.

This standard is intended for internal medical use of B-type ultrasonic diagnostic equipment performance verification, establish a standardized approach to technology Requirements and test methods provide guidance. To ensure the B-type ultrasonic diagnostic equipment in normal use, the need for periodic verification. This standard specifies the acceptance inspection, Weekly and annual inspection verification testing three kinds of forms. Receiving inspection and verification equipment and/or performance of the repaired equipment delivery; weekly test is simple The verification of equipment operation; the annual survey is a supplement to the weekly inspection, provides more detailed verification of the content. This standard provides weekly Examples of annual inspection reports and test. Weekly inspection shall be borne by the tester medical institutions, such as medical practitioners and so on. Receiving inspection, annual inspection by a skilled testers, Such as biomedical engineers, medical physicists, medical equipment maintenance personnel, professional testers, inspection agencies or manufacturers, etc. bear. B-mode ultrasound diagnostic equipment verification Guide

1 Scope

YY/T 0938 is the guide for checking B-mode ultrasound equipment in service. Unlike a type test standard, it addresses the machine already installed in a department: how to verify

periodically that image quality has not drifted, that the transducer has not developed dead elements, and that the geometric and measurement accuracy the clinician relies on still holds. Ultrasound degrades quietly, through cable damage, transducer wear and element failure, and the images stay plausible while measurements move, which is why a defined check procedure matters more here than for modalities with obvious failure modes. For a hospital physics or biomedical engineering team in China, and for service organisations supporting ultrasound fleets, this is the reference the periodic check follows.

This standard specifies the medical institutions B-type ultrasonic diagnostic apparatus (hereinafter referred to as "B super") acceptance inspection, weekly inspection and annual inspection Requirements and test methods. This standard describes the method used to assist the B-user performance verification of such equipment, which is mainly applied to medicine Practitioners, biomedical engineers, medical physicists, medical equipment maintenance personnel, professional testers, inspection agency or the manufacturer and the like.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 10152-2009 B-type ultrasonic diagnostic equipment

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Phantom phantom And wherein the tissue mimicking material embedded in one or more groups target structure composed of B-test device.

3.2 Tester tester Trained, appropriately qualified, authorized to B super performance testing or inspection personnel, including medical practitioners, Biomedical engineers, medical physicists, medical equipment maintenance personnel, professional testers, inspection agency or the manufacturer and the like.

3.3 Baseline baselinevalues Baseline values specified by the tester B-quality indicators. Baseline data and numerical tests and annual tests weekly, and determines B-off is in normal working condition. NOTE. You can use the new purchase or repair the B-test results received as a baseline; you can also use the results of the annual survey as a baseline for the next year.

3.4 Verification check System actions to ensure the safety of medical institutions B-effective and taken, including receiving inspection, weekly inspection and annual inspection.

4.1 Receiver test

4.1.1 After the B-delivered to the user for the first test, the performance when verification equipment delivery and/or equipment after the repair.

4.1.2 In addition to the content of the test carried out by the contract, but also including at least content of the annual inspection.

4.1.3 The test results received test as a baseline value B super performance.