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**NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA**

**GB 10152-2009**

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**B mode ultrasonic diagnostic equipment**

**B型超声诊断设备**

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### Foreword

All technical content of this standard is mandatory. This standard replaces GB 10152-1997 "B mode ultrasonic diagnostic equipment". The main changes of this standard, as compared with GB 10152-1997, are as follows: - ADD 8 new definitions; - In Chapter 4 "Requirements", ADD 5 technical index, including slice thickness, perimeter and area measurement deviation, M-mode time display error, 3D reconstruction volume calculation deviation, use functional requirements; - The technical requirements in Table 1 are the minimum requirements for the technical performance of the equipment, according to the probe type and nominal frequency; the manufacturer can publish the requirements, which are better than the above index, in the accompanying document; - In Chapter 5 "Test methods", SPECIFY the corresponding test methods, for the added technical index; - SIMPLIFY Chapter 6 "Inspection rules"; DELETE the content of exit-factory inspection; - DELETE the contents of Chapter 7 "Marking and instructions for use", from the original standard; - Fully IMPLEMENT the general safety standard GB 9706.1; DELETE the original normative appendix A "Safety"; CHANGE the original informative appendix C "Technical requirements for phantoms" to appendix A, making certain modifications; - DELETE the original normative appendix B "Grading and performance requirements of B mode ultrasonic diagnostic equipment". ADD the informative appendix B "B-ultrasound settings during performance testing". Appendix A and Appendix B of this standard are informative appendixes. This standard was proposed by the State Food and Drug Administration. This standard shall be under the jurisdiction of the National Standardization Technical Committee of Medical Electrical Appliances (SAC/TC 10). Drafting organization of this standard. National Wuhan Medical Ultrasonic Instrument Quality Supervision and Testing Center. The main drafters of this standard. Wang Zhijian, busy Anshi. This standard replaces the standard previously issued as follows: - GB 10152-1988, GB 10153-1988; - GB 10152-1997. B mode ultrasonic diagnostic equipment

## 1 Scope

China's mandatory national standard for B-mode ultrasonic diagnostic equipment. B-mode is the familiar grey-scale image, and it is the workhorse of medical imaging because it is the only modality that is cheap, portable, real-time and free of ionising radiation at once - which is why it is the first instrument reached for in obstetrics, abdominal and cardiac examination, and why it reaches into clinics that will never have a CT scanner. The requirements are almost entirely about image quality expressed in measurable terms rather than in impressions: the depth of penetration at a given frequency, the lateral and axial resolution that determine what can be distinguished, the geometric accuracy that decides whether a measured foetal dimension is right, and the dead zone near the transducer. Alongside them sits acoustic output, because ultrasound deposits energy in tissue and the limits exist to keep that safe. Being a GB without /T, compliance is compulsory for equipment sold in China.

This standard specifies the definition, requirements, test methods, inspection rules of B mode ultrasonic diagnostic equipment (hereinafter referred to as B-ultrasonics). This standard applies to B mode ultrasound diagnostic equipment, which has a nominal frequency in the range of

1.5 MHz ~ 15 MHz, including the two-dimensional grayscale imaging part of color Doppler ultrasonic diagnostic equipment (color ultrasonics).

## 2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Standard; however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

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## 3 Terms and definitions

The following terms and definitions apply to this standard. The distance, between the phantom scanning surface (acoustic window) and the nearest clearly imaged phantom target line.

## 4 Requirements

The deviation, between the acoustic operating frequency and the nominal frequency, shall be within  $\pm 15\%$ .

## 5 Test method

For variable frequency probes or broadband probes, if the manufacturer has special requirements in the instruction manual, the probe frequency can also be set to the optimum state for testing, according to the requirements of the instruction manual. The measurement of the acoustic operating frequency and frequency range shall be carried out, in accordance with the provisions of YY/T 1142.

## 6 Inspection rules

Product inspection is divided into exit-factory inspection and type inspection. The inspection items and judgment rules of the exit-factory inspection are stipulated by the manufacturer.

## Appendix A

(Informative) Technical requirements for phantoms When carrying out the test of B-ultrasonics dead zone, penetration depth, axial resolution, lateral resolution, accuracy of longitudinal and lateral geometrical position, the technical parameters of the phantom, which is used in the test, are as follows: