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

GB/T 16846-2008

Replacing GB 16846-1997

**Requirement for the declaration of the acoustic output of
medical diagnostic ultrasonic equipment**

医用超声诊断设备声输出公布要求

(English Translation)

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Foreword

This standard is equivalent to using the International Electrotechnical Commission standard IEC 61157:1992 "the acoustic output of medical diagnostic ultrasonic equipment disclosure requirements." this standard replaces GB 16846-1997 "acoustic output of medical diagnostic ultrasonic equipment disclosure requirements." the main changes compared to the Standard and GB 16846-1997 are as follows.

--- Not to the revised mandatory standard GB 9706.9 conflict, this revised standard recommended standards;

--- Remove the IEC foreword;

--- Chapter 3, "Definitions and symbols" in order to be consistent with GB 9706.9, 3.11 and 3.22 for medical ultrasonic diagnostic equipment transducer Component two definitions, where the direct use of the definition of GB 9706.9 2.1.143 and 2.1.145 of;

--- Chapter 5, "announced sampling values" for a description of uncertainty, according to JJF1059-1999 "Measurement Uncertainty in He said that "the provisions of the" random and systematic uncertainty "was changed to" A Class A and Class B uncertainty ";

--- Chapter 7, "Test Method" content amended as follows. "acoustic output measured according to GB/T 16540 using hydrophone method, or sound power Measured according

to IEC 61161 using radiation force balance method ";

--- Annex C (informative) "set forth the principle of" a description of the uncertainty, according to JJF1059-1999 "Measurement uncertainty Evaluation and expression "requirement, the" random and systematic uncertainty "was changed to" A Class A and Class B uncertainty ";

--- Deleted Appendix D (informative) "hydrophone measurement example sound intensity computing", Appendix D is not the original IEC 61157.

1992 technical content;

--- The original standard translation is not accurate provision was amended on several characters, so the revised standard is more faithful to the IEC 61157:1992 original.

Appendix A of this standard is a normative appendix, Appendix B, Appendix C are informative appendices.

This standard was proposed by the State Food and Drug Administration.

This standard by the National Standardization Technical Committee medical ultrasound equipment.

This standard was drafted. medical ultrasound equipment Wuhan National Quality Supervision and Inspection Center.

Introduction

This standard specifies the announcement by the manufacturer of medical ultrasound diagnostic equipment acoustic output requirements, the technical description of the numerical representation of a given single the maximum output level or composite mode of operation, and the value is measured in water and Export.

Produce low levels of acoustic output device may waive the full disclosure requirements of this standard.

The acoustic output of medical diagnostic ultrasonic equipment disclosure requirements.

GB/T 16846-2008/IEC 61157:1992 the acoustic output of medical diagnostic ultrasonic equipment disclosure requirements

1 Scope

This standard applies to medical ultrasound diagnostic equipment.

This standard establishes the following acoustic output published information requirements.

--- Information manufacturer in the technical data tables provide to potential buyers of equipment;

- Manufacturer random file/manual published information;
- Manufacturer in the unit after a request, provided background information.

The standard for generating low sound output level of equipment, given the conditions of the exemption from publication.

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.

Characterization of ultrasonic fields in the GB/T 16540-1996 Acoustics 0.5 ~ 15MHz frequency range and its measurement method hydrophone (Eqv IEC 61102:1991) IEC 61161:2006 ultrasonic sound power measurement - Radiation force balances and performance requirements

3 Definitions and symbols

The following definitions apply to this standard.

Figures 1 to 4 are given the following definition of certain parameters of the icon.

Operating and instruction manual with each manufacturer of medical diagnostic ultrasound devices together.

Sound system peak negative pressure in the initial mode, and under a given mode of operation any system set a maximum ratio of peak negative acoustic pressure value. At a position to generate the maximum pulse square sound pressure integral value (or continuous wave system, the maximum average sound pressure squared value) was measured to determine the ratio. This ratio represents the percentage of the common.

NOTE: The system operating mode in the initial mode may be different from the specified mode.

No ultrasonic echo information is updated in real time, the system is sound output disabled state.

Peak negative sound system is switched on when the pressure mode, with a specified mode of operation under any system set a maximum ratio of peak negative acoustic pressure value. At a position to generate the maximum pulse square sound pressure integral value (or continuous wave system, the maximum average sound pressure squared value) was measured to determine this ratio, the ratio is commonly expressed as a percentage.

NOTE: The system mode boot mode may be different from the specified mode.

GB/T 16846-2008/IEC 61157:1992