

ICS 11.040.60
CCS C 41

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0750-2026

Replacing YY/T 0750-2018

**Ultrasound - Physiotherapy equipment - Sound field
requirements and measurement methods in the frequency
range of 0.5MHz to 5MHz
(English Translation)**

Issued on: March 9, 2026

Implemented on: March 1, 2027

Issued by: National Medical Products Administration

Table of Contents

Foreword
Introduction
1 Scope
2 Normative references
3 Terms and Definitions

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces YY/T 0750-2018 "Sound Field Requirements and Measurement for Ultrasonic Therapy Equipment in the Frequency Range of 0.5MHz~5MHz".

Compared with YY/T 0750-2018, the main technical changes in the "Methods" are as follows, except for structural adjustments and editorial modifications.

---The requirements for dissolved oxygen content in degassed water during testing have been changed (see 6.1, 2018 version 6.1);

---The requirements for the test container have been changed (see 6.2, 2018 version 6.2);

---The nature of Appendix A has been changed (see Appendix A, Appendix A of the 2018 edition);

---The description in Appendix D has been changed (see Appendix D, Appendix D of the 2018 edition).

This document modifies and adopts IEC 61689:2022 "Ultrasound therapy equipment - sound field requirements and measurement in the frequency range of 0.5MHz to 5MHz".

Quantification method.

The technical differences between this document and IEC 61689:2022, and the reasons therefor, are as follows.

---IEC 60601-1 has been replaced with the normatively referenced GB 9706.1. The degree of consistency between the two documents is modified to adapt...

my country's national conditions;

---IEC 60601-2-5 has been replaced with the normatively referenced GB 9706.205. The consistency between the two documents is [modification level].

Adapting to my country's national conditions;

---IEC 61161 has been replaced with the normatively referenced GB/T 7966, and the two documents are considered equivalent to meet my requirements.

The country's national conditions;

---IEC 62127-1 has been replaced with the normatively referenced YY/T 0865.1. The consistency between the two documents is considered a modification to adapt.

In accordance with my country's national conditions;

---The descriptions of "solid Y line" and "dashed Y line" under Figure A.1 have been revised to be consistent with the descriptions in Figure A.1 and A.4.2.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the Medical Ultrasonic Equipment Subcommittee of the National Technical Committee on Standardization of Medical Electrical Appliances (SAC/TC10/SC2).

Introduction

The ultrasound therapy device consists of a high-frequency electric power generator and a handheld treatment head. The treatment head contains a disc typically made of piezoelectric material.

It is made into a transducer used to convert electrical energy into ultrasound waves. The treatment head is often designed to come into contact with the human body.

Ultrasonic therapy equipment 0.5MHz~5MHz Sound field requirements and measurement methods within the frequency range

1 Scope

This document stipulates that.

---Methods for measuring and characterizing the output of ultrasound therapy equipment based on benchmark testing methods;

---Characteristics specified by the ultrasound therapy equipment manufacturer based on benchmark test methods;

---Safety guidelines for ultrasonic sound fields generated by ultrasonic therapy equipment;

---Measuring and characterization methods for the output of ultrasound therapy equipment based on conventional experimental methods;

---Acceptance criteria for the output of ultrasound physiotherapy equipment based on conventional testing methods.

This document applies to continuous or quasi-continuous waves (such as burst waves) generated by ultrasonic transducers within the frequency range of 0.5MHz to 5MHz.

This is an ultrasound device designed for therapeutic purposes. The device uses a single-planar, non-focused circular transducer as the treatment head.

The generated static sound beam is perpendicular to the end face of the treatment head.

Note 1: This document does not include the treatment parameters and usage methods of the ultrasound therapy equipment.

Note 2: Ultrasonic therapy equipment with a frequency range of 20kHz to 500kHz is specified by IEC 63009.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 7966 Acoustic ultrasonic power measurement - Radiation force balance method and its requirements (GB/T 7966-2022, IEC 61161.

2013, IDT)

GB 9706.1 Medical electrical equipment - Part 1: General requirements for basic safety and basic performance (GB 9706.1-2020) IEC 60601-1:2012, MOD) GB 9706.205 Medical electrical equipment - Part 2-5.Particular requirements for basic safety and basic performance of ultrasound therapy equipment (GB 9706.205-2020,IEC 60601-2-5:2009,MOD) YY/T 0865.1 Ultrasonic hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields (YY/T 0865.1-2024, IEC 62127-1:2022, MOD)

3 Terms and Definitions

The following terms and definitions apply to this document.

Rated output power, total uncertainty of rated output power at 95% confidence level, and rated grid voltage fluctuation under $\pm 10\%$ conditions.

The sum of the three factors that determine the maximum increment of the fixed output power.

Note 1: The possibility of rated output power fluctuation under a rated grid voltage fluctuation of $\pm 10\%$ should be addressed by adjusting the voltage between the grid power supply and the ultrasound therapy equipment.

Verify by adjusting the output transformer; detailed guidelines can be found in Appendix A, section A.2.