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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0865.1-2024

Replacing YY/T 0865.1-2011

Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields

超声 水听器 第1部分：医用超声场的测量和特征描述

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Table of Contents

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document is Part 1 of YY/T 0865 Ultrasonic Hydrophones. YY/T 0865 has been published in the following parts.

1.Measurement and characterization of medical ultrasound fields;

2.Calibration of hydrophones in ultrasonic fields below 40 MHz;

3.Characteristics of hydrophones for ultrasonic fields below 40 MHz. This document replaces YY/T 0865.1-2011 "Ultrasonic hydrophones Part

1.Measurement and characteristics of medical ultrasound fields below 40 MHz" Compared with YY/T 0865.1-2011, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

--- Changed the scope of application (see Chapter 1, Chapter 1 of the.2011 edition);

--- Changed the normative references (see Chapter 2, Chapter 2 of the.2011 edition);

--- Changed the terms and definitions (see Chapter 3, Chapter 3 of the.2011 edition);

--- Changed the symbols (see Chapter 4, Chapter 4 of the.2011 edition);

--- Changed the bandwidth (see 5.1.7,

5.1.7 of the.2011 edition);

--- Changed the basic sound pressure parameters (see Chapter 7, Chapter 7 of the.2011 edition). This document is modified to adopt IEC 62127-1.2022 "Ultrasonic hydrophones Part

1.Measurement and characterization of medical ultrasound fields". The technical differences between this document and IEC 62127-1.2022 and their reasons are as follows:

1 Scope

YY/T 0865.1 is the standard for measuring what an ultrasound transducer actually emits. It covers the use of hydrophones to measure and characterise medical ultrasonic fields: the acoustic pressure distribution, the derived intensity and power quantities, and the measurement conditions that make one laboratory's numbers comparable with another's. Those measurements are the basis of the acoustic output limits that every diagnostic and therapeutic ultrasound device is held to, so the method sits underneath the safety case for the whole modality. At 42,500 words it is among the longest standards in the Chinese medical device catalogue. For a manufacturer of ultrasound systems or transducers, or an acoustic test laboratory serving them, this is the method the output characterisation follows.

This document describes a method for measuring the acoustic field produced by medical ultrasound equipment in liquids using calibrated hydrophones, including Bandwidth standards and calibration frequency range requirements for the spectral components of the sound field to be characterized. This document.

--- A set of measurable acoustic parameters based on acoustic foundations is given;

--- A set of auxiliary acoustic parameters that can be derived under specific assumptions of these measurements are given, called derived acoustic parameters;

--- Gives the measurement steps that can be used to determine the sound pressure parameters;

--- Gives the conditions for measuring acoustic parameters using calibrated hydrophones;

---Procedures for correcting for limitations caused by using hydrophones with limited bandwidth and limited sensitive element size are given, and the to estimate the corresponding uncertainty. This document applies to the measurement and characterization of medical ultrasound fields using ultrasound hydrophones. NOTE

1.The International System of Units is used in this document. For certain parameters, such as beam area and sound intensity, decimal multiples or sub-multiples are used for simplicity. For example, the sound beam area is expressed in cm2, and the sound intensity is expressed in W/cm2 or mW/cm2. NOTE

2 By definition, hydrophones may be of either piezoelectric or fibre optic type.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 3359 Statistical processing and interpretation of data - Determination of statistical tolerance intervals (GB/T 3359-2009, ISO 16269-6. 2005, IDT)

YY/T 0750 Requirements and measurement methods for sound fields in the frequency range of 0.5MHz to 5MHz for ultrasonic therapy equipment (YY/T 0750- 2018, IEC 61689.2013,MOD)

YY/T 0865.2 Ultrasonic hydrophones Part

2.Calibration of hydrophones for ultrasonic fields below 40 MHz (YY/T 0865.2- 2018, IEC 62127-2.2013,IDT)

YY/T 0865.3 Ultrasonic hydrophones Part

3.Characteristics of hydrophones for ultrasonic fields below 40 MHz (YY/T 0865.3- 2013, IEC 62127-3.2007,IDT)

JJF1059.1-2012 Evaluation and expression of measurement uncertainty (ISO /IEC Guide98-3, MOD) IEC 60565-