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

YY/T 0773-2023

Replacing YY/T 0773-2010; YY/T 0849-2011

**General technical requirements for ophthalmic ultrasound
B-mode scanners**

眼科B型超声诊断仪通用技术条件

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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 0773-2010 "General Technical Conditions for Ophthalmic B-type Ultrasound Diagnostic Instruments" and YY/T 0849-2011 "Ophthalmic High-Tech Frequency Ultrasound Diagnostic Instrument". This document is based on YY/T 0773-2010 and integrates the contents of YY/T 0849-2011. With YY/T 0773- Compared with 2010, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

- a) "Composition and basic parameters" are deleted (see Chapter 3 of YY/T 0773-2010);
- b) "Working conditions" is deleted (see 4.1 of YY/T 0773-2010);
- c) "Performance" has been changed (see 4.1, 4.2 of YY/T 0773-2010);
- d) Added "information disclosure" (see 4.3);
- e) "Logo and instructions for use" are deleted (see Chapter 6 of YY/T 0773-2010);
- f) The appendix "Ultrasonic tissue-mimetic phantom and specimens" has been changed (see Appendix A, Appendix A of YY/T 0773-2010); Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the Medical Ultrasound Equipment Sub-Technical Committee (SAC/TC10/SC2) of the National Technical Committee for Standardization of Medical Electrical Appliances. This document was drafted

by: Hubei Medical Device Quality Supervision and Inspection Institute, Tianjin Maida Medical Technology Co., Ltd. The main drafters of this document. Jiang Shilin, Yang Jun, Wang Yanqun, Zhang Yusheng, Wang Zhijian, Lin Sen, and Wu Chengzhi. The previous versions of this document and the documents it replaces are as follows:

---First released in.2010 as YY 0773-2010;

---First released in.2011 as YY 0849-2011;

---This is the first revision. General technical conditions for ophthalmic B-mode ultrasonic diagnostic instruments

1 Scope

YY/T 0773 is the general technical specification for ophthalmic B-scan ultrasound, the instrument used to image the interior of the eye when the view is blocked by cataract, haemorrhage or opaque media. It sets the requirements such a scanner has to meet and the test methods that verify them, covering resolution and geometric accuracy, the acoustic output limits that protect a structure as delicate and as sensitive to heating as the eye, and the display and measurement functions the clinician relies on. B-scan is what tells an ophthalmologist whether a retina is detached behind a dense cataract, which is a decision about whether to operate today. The 2023 edition consolidates and replaces YY/T 0773-2010 and YY/T 0849-2011. This is the text a Chinese registration applies.

This document specifies the requirements and test methods for ophthalmic B-mode ultrasonic diagnostic instruments. This document applies to ophthalmic B-type ultrasonic diagnostic instruments (hereinafter referred to as diagnostic instruments), whose nominal ultrasonic frequency range is usually 10MHz~ 50MHz. UBM).

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in GB 10152 apply to this document.

4.1 Performance

4.1.1 B-type scanning performance The diagnostic instrument B-scan performance

requirements are shown in Table 1. Table

1 Type B performance requirements Performance nominal frequency $10\text{MHz} \leq f \leq 13\text{MHz}$
 $13\text{MHz} < f \leq 25\text{MHz}$ $25\text{MHz} < f \leq 40\text{MHz}$ $f > 40\text{MHz}$ Detection depth mm ≥ 50 ≥ 20 ≥ 6 $\geq$

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