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

YY/T 0107-2024

Replacing YY/T 0107-2015

A-mode ultrasonic biometer for ophthalmology

眼科A型超声测量仪

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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 replaces YY/T 0107-2015 "Ophthalmic Type A Ultrasonic Measuring Instrument". Compared with YY/T 0107-2015, except for structural adjustments and In addition to editorial changes, the main technical changes are as follows:

- Changed the description of "Classification by power source used" (see 3.2, 3.2 of the.2015 edition);
- Changed the requirements and test methods for "measurement range" (see 5.1 of the.2015 edition);
- Changed the requirements and test methods for "measurement error" (see 5.3 of the.2015 edition);
- Changed the requirements for "effective number of displayed digits" (see 4.3, 4.3 of the.2015 edition);
- Changed the requirements for "additional functions" (see 4.4, 4.4 of the.2015 edition)
- Changed the requirements for "internal power supply working time" (see 4.5, 4.5 of the.2015 edition);

1 Scope

YY/T 0107 is the product standard for the ophthalmic A-scan biometer, the ultrasound instrument that measures axial length and the other distances inside the eye. It specifies

the product classification and the requirements for ophthalmic A-mode ultrasonic measuring instruments and the corresponding test methods. Its output feeds directly into the intraocular lens power calculation before cataract surgery, where an error of a fraction of a millimetre in axial length becomes a refractive error the patient lives with, so measurement accuracy and the calibration that supports it are the whole of the standard. For a manufacturer or an importer of A-scan biometers and combined pachymeter units seeking Chinese registration, this is the standard the type test is run against.

37. Basic safety and essential performance of ultrasonic diagnostic and monitoring equipment Require

YY/T 1420 Environmental requirements and test methods for medical ultrasonic equipment

YY 9706.102 Medical electrical equipment Part 1-

2. General requirements for basic safety and essential performance Collateral standard. Electromagnetic compatibility Requirements and tests

2 Normative references

The contents of the following documents constitute the 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 9706.1 Medical electrical equipment Part

GB 9706.237 Medical electrical equipment Part 2-

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

3 Product categories

3.1 Classification by function Measuring instruments are mainly divided into the following types.

- a) Ophthalmic A-type ultrasonic measuring instrument for corneal thickness measurement (keratometer);
- b) ophthalmic A-type ultrasonic measuring instrument for measuring axial length (axial length measuring instrument);
- c) Ophthalmic A-type ultrasound measuring instrument for measuring corneal thickness and axial length.

3.2 Classification by power source Measuring instruments are mainly divided into the

following types.

- a) Type A ophthalmic ultrasonic measuring instrument operated by mains power;
- b) Type A ophthalmic ultrasonic measuring instruments operating with an internal power supply;
- c) Ophthalmic Type A ultrasonic measuring instrument that can operate using both mains power and internal power supply.

4.1 Measurement range

4.1.1 The measuring range of corneal thickness of the measuring instrument should cover 0.300mm~1.200mm.