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

YY 0673-2008

Ophthalmic instruments - Optometers

眼科仪器 验光仪

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Foreword

This revised standard adopts the International Standard ISO 10342.1997 "ophthalmic instruments refractometer." This standard and ISO 10342.1997 international standard main differences are as follows:

- a) updating national mandatory safety standard requirements GB 9706.1 as "electrical safety requirements" indicators;
- b) to ISO 10342. ISO 15004 1997 standard referenced in.1997 standard content, in this standard, in addition to optical radiation safety content In addition, combined with other requirements of the relevant standards applicability of provisions made directly described in this standard. This standard is based on ISO 10342.1997 after the re-drafting changes, modifications and technical differences made have been incorporated into the text in which they are involved Logo | Terms margin of a single vertical line (). Appendix A normative appendix. This standard by the National Standardization Technical Committee and optical instruments and medical optical instruments Technical Committee (SAC/TC103 / SC1) and focal points. This standard was drafted. State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center. The main drafters of this standard. Wang Jingtao, Wen Yan, JIA Xiao Hang, He Tao. Ophthalmic instruments refractometer

1 Scope

YY 0673 is the mandatory Chinese standard for optometers, the autorefractors that measure a patient's refractive error objectively and produce a starting prescription in seconds. It sets the requirements such an instrument has to meet and the test methods that verify them, covering the accuracy and repeatability of the sphere, cylinder and axis it reports, the measurement range, the fixation target and the alignment. Autorefraction is the first step in almost every eye examination in China and the basis of school myopia screening programmes covering hundreds of millions of children, where the reading is often the only measurement taken. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the requirements and test methods refractometer.

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.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety (IEC 601-1. 1988, IDT)

GB/T 14710-1993 Medical electrical equipment environmental requirements and test methods

GB/T 16886.1-2001 Biological evaluation of medical devices - Part 1. Evaluation and testing (idt ISO 10993-1.1997)

GB/T 16886.5-2003 Biological evaluation of medical devices - Part 5. In vitro cytotoxicity tests (ISO 10993-5.1999, IDT)

GB/T 16886.10-2005 Biological evaluation of medical devices - Part 10. irritation and delayed-type hypersensitivity test (ISO 10993- 10.2002, IDT)

ISO 7944.1998 Optics and optical instruments - Reference wavelengths

ISO 8429. 1986 Optics and optical instruments - Ophthalmology dial

ISO 15004.1997 ophthalmic instruments basic requirements and test methods

3 Terms and Definitions

The following terms and definitions apply to this standard. Or a continuous digital readout for measuring eye refractive error of the instrument.

4 Requirements

4.1 General requirements Refractometer shall meet the appropriate requirements for optical radiation safety standards.

4.2 Optical Requirements Refractometer should be consistent with Table 1 or Table 2 requirements. Refractive power requirement should be given in ISO 7944.1998 requirements of the reference wavelength $\lambda = 546.07\text{nm}$ or $\lambda = 587.56\text{nm}$. If these two wavelengths can not meet the requirements, you should specify the reference wavelength. Cylinder of representation should be as usual using the "+" or "-." Table 1 requires continuous display refractor Measuring range maximum width spacing accuracy

--- two standard deviations project content Spherical and cylinder vertex $0.00D \sim \pm 10.00D$
 $0.25D \pm 0.25D > | \pm 10.00D | 0.50D \pm 0.50D$

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