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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0675-2023

Replacing YY/T 0675-2008

Ophthalmic instruments - Synoptophores

眼科仪器 同视机

(English Translation)

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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 0675-2008 "Ophthalmic Instrument Simultaneous Vision Machine". Compared with YY/T 0675-2008, except for structural adjustment and compilation in addition to editorial changes, the main technical changes are as follows.

---Deleted the requirement that the corresponding optical radiation safety standards should be met in the general requirements (see 4.1 of the 2008 edition);

---Changed the requirements for adjustment range and scale graduation (minimum scale) (see Table 1 of 4.2, 4.2 of the 2008 edition);

---Deleted the requirement for "private information" (see 4.4 of the 2008 version);

---Deleted the "material" requirement (see 4.5 of the 2008 version);

---Deleted the requirement for "cleaning, disinfection or sterilization measures" (see 4.6 of the 2008 edition);

---Deleted the requirement for "environmental conditions" (see 4.7 of the 2008 edition).

---Added the "diffusion screen brightness change" test method (see 5.2.4);

---Added the "brightness difference between left and right diffuser screens" test method (see 5.2.5);

---Added the "brightness adjustment" test method (see 5.2.6).

This document has been modified to adopt ISO 10944:2009 "Ophthalmic Instrument Simultaneous Vision Machine".

The technical differences between this document and ISO 10944:2009 and their reasons are as follows.

---Changed the interpupillary distance grid value requirements (see 4.2 Table 1) to adapt to

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my country's technical conditions;

---Added the test method for the brightness change of the diffuse screen (see 5.2.4), the test method for the brightness difference between the left and right diffuse screens (see 5.2.5), and brightness adjustment Test methods (see 5.2.6) increase operability and facilitate the implementation of standards;

---Replaced IEC 60601-1:2005 (see Chapter 6 and Chapter 7) with normatively cited GB 9706.1-2020, the second of the two documents the degree of consistency between them is modified to adapt to my country's technical conditions.

This document also has the following editorial changes.

---Replaced ISO 15004-1:2006 with ISO 15004-1:2020 (see Chapter 6).

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

1 Scope

This document specifies the minimum requirements and test methods for telescopes.

This document is applicable to synoptic machines used to examine, measure, train and correct binocular vision of patients and measure the horizontal and vertical angles at different gaze positions.

Straight and rotational deviation.

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 9706.1-2020 Medical electrical equipment Part 1: General requirements for basic safety and basic performance (IEC 60601-1.

2012,MOD)

ISO 15004-1:2020 Basic requirements and test methods for ophthalmic instruments Part 1: General requirements for ophthalmic instruments (Ophthalmic

3 Terms and definitions

The following terms and definitions apply to this document.

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Synoptophore

majoramblyoscopes

synoptometer

It is an instrument designed to display alternating optotypes for each eye, and the displayed optotypes can be displayed in different forms and with different convergences.

Positions move individually.

Note: Optotype configuration and positioning, along with other instrument features, are used to test, measure and train binocular vision.

It is used to form two different images on the retinas of both eyes (one on each retina) and cannot be fused into a single image.

Used to form two similar images on the retinas of both eyes (one on each retina) that can be fused and often contain controls points to evaluate whether either eye inhibits the optotype pair of the associated image.

A pair of visual targets used to test and/or measure stereoscopic acuity that have a common reference point and form an image pair that is visually integrated.

combined to produce a three-dimensional effect.

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