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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 11417.6-2012

Ophthalmic optics - Contact lenses - Part 6: Mechanical properties test methods

眼科光学 接触镜 第6部分：机械性能试验方法

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1 Scope

GB/T 11417.6-2012 is the Chinese national standard on ophthalmic optics - contact lenses - part 6: mechanical properties test methods, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 31 December 2012 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 June 2013. Classification: ICS 11.040.70, CCS C40. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

GB/T 11417.6 gives test methods for the mechanical properties of contact lenses including dimensions. This Part is applicable to the testing of mechanical properties of contact lenses.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2411-2008, Plastics and ebonite - Determination of indentation hardness by means of a durometer (shore hardness)

GB/T 11417.1-2012, Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labeling specifications

GB 11417.2-2012, Ophthalmic optics - Contact lenses - Part 2: Rigid contact lenses specification

GB 11417.3-2012, Ophthalmic optics - Contact lenses - Part 3: Soft contact lenses

GB/T 11417.4-2012, Ophthalmic optics - Contact lenses - Part 4: Saline solution for contact lens testing

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/T 11417.1-2012 apply.

4 Determination of radius of curvature

4.1 General Mechanical scales can be equipped with some devices to reduce empty back. If the reading is in one direction, the error source can be ignored. Illumination measurements usually contain 4 intersecting lines around the center. Adjacent angle is 45°. The spherometer shall be equipped with a lens holder that allows the lens to be placed on a reference plane, usually on the optical axis of the instrument. The holder shall be adjustable laterally so that the apex of the rear surface of the lens falls on the optical axis. The holder shall be able to suppress the reflection of the non-measuring surface of the contact lens. NOTE: The term "scale" refers to both analog and digital instruments.

4.2.3 Calibration

4.2.3.1 It shall use the optical glass concave spherical surfaces with the following 3 kinds of curvature radius for calibration: Concave spherical surface 1: 6.30mm~6.70mm; Concave spherical surface 2: 7.80mm~8.20mm; Concave spherical surface 3: 9.30mm~9.70mm. The precision of the radius of curvature of the concave spherical surface is ±0.0075mm.

4.2.3.2 Calibrate at room temperature of 20°C ± 5°C. The equipment shall be preheated until equilibrium.

4.2.3.3 Place the concave spherical surface 1 on the measuring head so that the optical axis of the microscope is perpendicular to the test surface. Adjust the distance between the microscope and the head until the image is focused on the concave spherical surface [Figure 1a]]. Observe a clear image of measuring mark in the microscope. Set the scale to 0. Pull apart the distance between the head and the microscope until a clear image of measuring mark is observed for the second time in the microscope. The position of the microscope and surface is shown in Figure 1b). 2 images shall be in the center of the field of view. If not, move the test surface laterally, and/or tilt until a clear image is produced. Record the reading shown on the scale at this time, which shall be the radius of curvature of the concave spherical surface. Each piece is measured 10 times independently. Calculate its arithmetic mean. Repeat the above steps for the other 2 concave spherical surfaces. If the result is outside the precision range of the instrument, the result is depicted as a calibration curve and the results obtained in

4.2.4 are corrected. NOTE: "Independent" is to remove the concave spherical surface from the test stand after each test 6 - eyepiece; 7 - object mirror plane = eyepiece plane; 8 - solution; 9 - prism; 10 - front surface of silver-plated lens; 11 - movable cover. Figure 4 -- Schematic diagram of measurement in keratometer solution

4.3.4 Test method

4.3.4.1 General Hard contact lenses are generally measured in air. But if required, it can also be measured in solution.

4.3.4.2 Measurement in air After balancing the lens and instrument under test at room temperature of 20°C ± 5°C, then measure. Fix the rigid contact lens on the holder and perpendicular to the optical axis of the keratometer. Perform independent measurement 3 times. The measured value is rounded to 0.01mm. For the spherical surface, calculate the arithmetic mean of the three test values (if necessary, correct with the calibration curve of 4.3.3). For the ring surface, measure the two main meridians three times and calculate the average. Record the test results. Correct them separately if needed.

4.3.4.3 Measurement in solution This method is only applicable for measurements in the central area. Soft lenses are equilibrated in a standard salt solution at 20°C ± 0.5°C. And suspend and measure in the same standard salt solution at the same temperature. Position the soft contact lens on the holder and perpendicular to the optical axis of the keratometer. Perform independent measurement 3 times. The measured value is rounded to 0.01mm. For spherical lenses, calculate the arithmetic mean of 3 measurements. For the toroidal lens, measure the two main meridians three times respectively. Calculate the average and record the test results. Correct them separately if needed.

4.4 Vector height measurement r - radius of curvature of the lens; s - vector height; y - external chord diameter of the lens holder. Figure 5 -- Curvature radius measurement geometry

4.4.2 Equipment requirements

4.4.2.1 Optical projector The magnification of the optical projector shall be greater than 10 times. There shall be a measuring cell with a hollow cylindrical contact lens holder. As shown in Figure 5, the contact lens is centered downwards, horizontally stationary. And the chord length provided by the holder shall be 10 mm (as shown in Figure 5). The minimum scale of the engraved line shall be 0.01mm. When measuring the center of the contact lens (the contact lens is already centered), the repeatability of the visual measurement of the vector height is ±

0.02 mm or better. The instrument shall be equipped with a temperature control device.

4.4.2.2 Mechanical spherometer The spherometer shall project the contour of the contact lens, the lens holder and the probe onto a screen (see Figure 6). The magnification of the projection system is not less than 10 times. The projection system shall have the lens, lens holder and probe on the same focal plane. And it shall enable the operator to observe the center of the lens to ensure that the probe and the mirror axis are close together. Finally, the probe just touches the back apex of the lens (see Figure 7). The end point is the test value. The distance between the solid mechanical probe from the plane of the contact lens holder to the apex of the back surface is the vector height (s). The precision of the analog or digital meter shall be no less than 0.01mm. See

4.4.2.1 for requirements for measuring pool and holder.

4.4.3 Calibration Calibration (precision measurement) shall use at least 3 concave hard spherical calibration sheets made of plexiglass or glass. The curvature between the calibration sheets is spaced to ensure the precision of the entire measurement range. The calibration sheet shall include 7.50mm ± 0.10mm, 8.50mm ± 0.10mm, 9.50mm ± 0.10mm. The exact value of the curvature shall be within 0.01mm. NOTE: It is convenient to make the calibration block into a flat concave type. Recommended center thickness is 3mm. Recommended diameter is 12mm. After the equipment is warmed up, the calibration block shall be balanced in a standard salt solution. Calibrate optical projector and spherometer at room temperature of 20°C ± 5.0°C. Calibrate ultrasound system at room temperature of 20°C ± 0.5°C. Each calibration piece shall be measured at least 20 times in the same direction. And calculate the arithmetic mean. If applicable, the deviation between the calculated and actual values shall establish a calibration curve.

4.4.4 Measurement method The contact lens to be tested floats on the lens holder in a self-weight manner and is centered. When measuring the aspherical height, it shall pay more attention to the center of the lens. Prior to testing, the lens shall be equilibrated for at