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JIS T 7312 : 2005 (JMOIA/JSA) **Tonometers**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Medical-optical Equipment Industrial Association (JMOIA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently JIS T 7312 : 1988 is replaced with this Standard.

This revision has been made based on ISO 8612:2001 *Ophthalmic instruments — Tonometers* for the purpose of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Tonometers

Introduction This Japanese Industrial Standard has been prepared based on the first edition of ISO 8612 *Ophthalmic instruments—Tonometers* published in 2001 with some modifications of the technical contents.

The portions underlined with dots are the matters modified from the original International Standard. A list of modifications with the explanations is given in annex 1 (informative).

1 Scope This Standard, together with JIS T 7332, specifies minimum requirements and the design compliance procedure for tonometers intended for routine clinical use in the estimation of intraocular pressure (IOP) (hereafter referred to as “tonometers”) and the single-use prisms applanation tonometers which is a single-use sterilization apparatus used in combination with the applanation tonometer to evaluate a cornea contact surface (hereafter referred to as “a single-use prism for applanation tonometers”).

This Standard takes precedence over JIS T 7332, if differences exist.

NOTES 1 The true intraocular pressure is seldom directly measured since it would require invasion of the eye.

Since the true IOP cannot be known, the instrument (annex A) and method (annex B) for determining a reference IOP are instead specified.

- 2** Clinical tonometers may employ different parameters or correlates in the indirect assessment of measured IOP. The manufacturer states the exact design parameters of the specific tonometer, and then, on the basis of design compliance testing as specified in 4.2, demonstrates that the specific design performs acceptably compared to the reference method. This process is referred to as certification.

The manufacturer also demonstrates, by methods specified in 4.3, that individual manufactured instruments perform the same (within defined limits) as the test tonometer. This process is referred to as verification.

- 3** The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21.

ISO 8612:2001 *Ophthalmic instruments—Tonometers* (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. If the indication of the year of coming into effect (or the year of publication) is given to these referred standards, only the edition of the indicated year constitutes the provision of this Standard but the revision and amendment made thereafter do not apply,

JIS T 0601-1:1999 *Medical electrical equipment—Part 1: General requirements for safety*

Remarks : IEC 60601-1:1988 *Medical electrical equipment Part 1: General requirements for safety*, Amendment 1: 1993 and Amendment 2:1995 are equivalent to the said standard.

JIS T 7332:2005 *Ophthalmic instruments—Fundamental requirements and test methods*

Remarks : ISO 15004:1997 *Ophthalmic instruments—Fundamental requirements and test methods* is equivalent to the said standard.

3 Terms and definitions For the purposes of this Standard, the following terms and definitions apply.

3.1 intraocular pressure (IOP) pressure within the eye

NOTE : It is expressed in millimetres of mercury (mmHg), where 1 mmHg = 1.333 hPa.

3.2 reference IOP IOP that is measured with a reference tonometer, as specified in annex A, in accordance with the procedures given in annex B

3.3 measured IOP IOP reading provided by the tonometer when used in accordance with the manufacturer's instructions

3.4 reference tonometer tonometer as described in annex A

3.5 test tonometer verified tonometer used in design compliance testing

4 Requirements

4.1 General ~~Tonometers and single-use prism for applanation tonometers shall be based on provisions of JIS T 7332 : 2005 (except for the particular requirements of clause 6 for active type ophthalmic instruments), and particular requirements specified in 4.2 to 4.4. However, a single-use prism for applanation tonometers shall be confirmed as a tonometer in combination with the appointed applanation tonometer specified in the accompanying documents.~~

~~In addition, when the test tonometers conform to provisions of A.1 and A.2 of annex A, it is allowed to omit 4.2 by proving the conformity. Instead of implementation of 4.3, it may be confirmed that the tonometers manufactured meet the design requirement specified in 4.2 by verifying that the test tonometers conform to provisions of A.1 and A.2 of annex A.~~

4.2 Design compliance testing (certification)

4.2.1 The manufacturer shall demonstrate, on the basis of design compliance testing as specified in clause 5, that the test tonometer measurements, when compared to the reference tonometer measurements, meet the requirements as given in table 1.

The requirements are met if not more than 5 % of the paired differences between the reference tonometer reading and the test tonometer reading for each pressure range are greater than the tolerance for that range in table 1.

Table 1 Requirements for tonometers

Unit : mmHg

IOP range	Tolerance	Minimum number of eyes
7 to 16	± 5.0	40
> 16 to < 23	± 5.0	40
≥ 23	± 5.0	40

NOTE : The tolerances given in table 1 represent 1.96 times the standard deviation allowable for the paired measurement, and so account for not only the allowable error of the tonometer under test but also the unavoidable error associated with the reference tonometer.

4.2.2 The manufacturer shall analyse the data, taken in the course of design compliance testing as specified in clause 5, using the total least squares method for the regression, and make available, as required in 7 a), the slope, the offset and the standard deviation of the regression line.

4.3 Verification (instrument compliance)

4.3.1 The manufacturer shall develop a method and test apparatus to confirm that the design requirements of 4.2 are met by each manufactured tonometer. Each tonometer shall be verified with this method and apparatus. This method and test apparatus shall be the same that were used to measure and verify the test tonometer in 4.2. Details of the method and test apparatus shall be made available in accordance with the requirements of clause 7.

4.3.2 The permissible error of the test apparatus shall be one-half of the permissible tolerance as given in table 1.

4.4 Construction and function

4.4.1 The surfaces of the tonometer that are intended to come into contact with the cornea shall be:

- composed of non-toxic, stable and non-oxidative material which is inert to ocular tissue, tears and appropriate pharmacological agents;
- designed either to facilitate disinfection or for single patient use;
- smooth when felt with the finger, and be free of surface imperfections that would damage the eye or prevent adequate disinfection, when examined by unmagnified corrected vision under specular reflection.

4.4.2 The tonometer shall permit the measurement of IOP throughout the range 7 to 50 mmHg. The scale or display shall either provide a direct measurement of a value whose relationship to IOP is known or give a numerical reading corresponding to the IOP value.

Readings of IOPs less than 7 mmHg shall be displayed either by their numerical value or by a “low reading” indication. Readings of IOPs greater than 50 mmHg shall be displayed either by their numerical value or by a “high reading” indication.

5 Test methods

5.1 All tests described in this Standard are type tests.

5.2 The reference IOP shall be determined as described in annex A.

5.3 Design compliance testing shall be performed as described in annex B.

6 **Accompanying documents** The tonometer shall be accompanied by documents containing instructions for use together with maintenance procedures and their frequency of application. In particular, this information shall contain:

- a) name and address of the manufacturer;
- b) instructions for effective disinfection of the tonometer where applicable, with particular reference to the disinfection of instruments to be returned to the manufacturer for repair and maintenance;
- c) any contra-indications for the use of the tonometer;
- d) a list of accessories suitable for use with the tonometer;
- e) if appropriate, a statement that the tonometer in its original packaging conforms to the transport conditions as specified in JIS T 7332 : 2005;
- f) if appropriate, any additional documents as specified in 6.8 of JIS T 0601-1:1999;
- g) a reference to this Standard, i.e. JIS T 7312, if the manufacturer or supplier claims compliance with it.

7 **Additional information** The manufacturer shall provide the following information upon request:

- a) information on the operating principles of the certified tonometer, specific protocol for design compliance testing (annex B), specific results of design compliance testing with statistical evaluation;
- b) documentation describing the verification test apparatus, verification procedures and its own verification test results for that tonometer;
- c) a full specification for the apparatus required for verification, sufficient to allow the purchaser or purchaser's representative to construct or acquire such test apparatus.