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Contents

Page

Introduction 1

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Requirements 2
4.1 General 2
4.2 Design compliance testing (certification) 3
4.3 Verification (instrument compliance) 3
4.4 Construction and function 3

5 Test method 4

6 Accompanying documents 4

7 Additional information 4

8 Marking 4

Annex A (normative) Reference tonometer and method for determining reference IOP 5

Annex B (normative) Design compliance testing 12

Annex JA (informative) Comparison table between JIS and corresponding International Standard 16

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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**:2005 is replaced with this Standard.

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Introduction

This Japanese Industrial Standard has been prepared based on the second edition of **ISO 8612** published in 2009 with some modifications of the technical contents.

The portions with dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard, together with **JIS T 15004-1**, 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 for applanation tonometers which are single-use sterilized apparatus used in combination with applanation tonometers to evaluate a cornea contact surface (hereafter referred to as "single-use prisms for applanation tonometers").

This Standard takes precedence over **JIS T 15004-1**, if differences exist.

NOTE 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.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 8612:2009 *Ophthalmic instruments—Tonometers* (MOD)

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 21-1**.

Moreover, **JIS T 7312**:2005 may be applied until March 31, 2018.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the editions of the indicated year shall be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent edition (including amendments) shall be applied.

JIS T 0601-1:2012 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*

NOTE : Corresponding International Standard: IEC 60601-1:2005 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* (MOD)

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