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JJF 1780-2019

Program of Pattern Evaluation of Non-contact Tonometers

非接触式眼压计型式评价大纲

(English Translation)

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12 Table of measuring instruments and equipment used in the test project (9)

Appendix A Non-contact Tonometer Type Evaluation Record Format (11)

Introduction

This type evaluation outline is based on JJG1143-2017 "Non-Contact Tonometer" and refers to ISO 8612.:2009 "Ophthalmology tonometer" was developed. JJF 1001-2011 "General Measurement Terms and Definitions", JJF 1015-2014 "General Specification for Type Appraisal of Measuring Instruments", JJF 1016-2014 "Guidelines for Compiling Outlines of Type Appraisal of Measuring Instruments", JJF 1059.1-2012 "Measurement Uncertainty Evaluation and Representation" together constitute the work to support the formulation of this type of evaluation outline the basic series of documents.

This specification is the first release.

Outline of Type Evaluation of Non-Contact Tonometer

1 Scope

This type evaluation program is applicable to the type evaluation of the non-contact tonometer with air-jet measurement method.

2 Reference documents this specification refers to the following documents.

JJG1143-2017 non-contact tonometer GB 4824-2013 Industrial, Scientific and Medical (ISM) Radio Frequency Equipment Disturbance Characteristics Limits and Measurements method GB 9706.1-2007 Medical electrical equipment Part 1: General requirements for safety GB/T 14710-2009 Environmental requirements and test methods for medical appliances YY0505-2012 Medical electrical equipment Part 1-2.General requirements for safety Parallel standards. Electromagnetic and Capacity requirements and testing ISO 8612.:2009 Ophthalmic instruments tonometer (Ophthalmicinstruments-Tonometers) for dated reference documents, only the dated version is applicable to this type of evaluation outline; those that are not dated the latest version (including all amendments) of the cited documents is applicable to this type evaluation outline.

3 Terms and definitions the following terms and definitions apply to this type of evaluation outline.

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3.1 intraocular pressure; IOP the pressure in the eyeball, referred to as intraocular pressure. The unit is kilopascal (kPa).

[ISO 8612.:2009, definition 3.1]

3.2 Standard analog human eye referencephantomofIOP it has been traced back to the simulated human eye in SI units, and is used as the reference standard for the tonometer's intraocular pressure indication.

3.3 Reference standard IOP pressureofreferencephantomofIOP the standard obtained through the traceability of the value simulates the overall standard intraocular pressure of the human eye.The sources of pressure include the influence of the cornea.

Inside, it is not just the nominal pressure of the internal pressure sensing element that simulates the human eye.

4 Overview

Non-contact tonometer (hereinafter referred to as tonometer) is an instrument for measuring intraocular pressure, mainly used for intraocular pressure screening, Using the Imber-Fick principle, a controlled air pulse is used to squeeze the center of the cornea to deform the cornea, and the light beam reflected by the cornea is detected by a photodetector until the cornea is flattened to a diameter range of about 3.6mm at that time, the light energy it received also reached the maximum value, and the pressure of the air pulse was equal to the intraocular pressure. How it works as shown in Figure 1.

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