STANDARD OPERATING PROCEDURE

“electronic non-contact ocular tonometers”

This document is based on the General Measure No. 0111-OOP-C038-13.

1 Basic definitions

For the purposes of this Procedure, the terms and definitions according to VIM and VIML and the definitions below shall apply.

1.1 ocular tonometer
an apparatus for measuring intraocular pressure

1.2 non-contact ocular tonometer
an ocular tonometer using an air pulse to determine intraocular pressure

1.3 intraocular pressure (IOP)
the pressure inside the eye measured in millimetres of mercury (mmHg) or kilopascals (kPa).

2 Metrological requirements

The metrological requirements are based on the requirements under the Government Order on Medical Devices. Medical devices with a measuring function must be designed and manufactured in such a way as to provide adequate accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy shall be indicated by the manufacturer so that the devices do not compromise the clinical condition, health or safety of the patient when used under the specified conditions and for their intended purpose.

If the limits of accuracy and the conditions under which they apply are not indicated by the manufacturer, the metrological requirements provided below shall be applied.

2.1 Rated operating conditions

The rated operating conditions shall be specified by the manufacturer. If not specified by the manufacturer, the requirements for the maximum permissible error must be complied with at least within the ambient temperature range of 10°C to 35°C and relative humidity range of 30% to 90%.

2.2 Measuring interval

A non-contact ocular tonometer must have an intraocular pressure measuring interval from 0 mmHg to at least 40 mmHg, unless specified otherwise by the manufacturer.

2.3 Maximum permissible error

The maximum permissible error of indication of intraocular pressure shall be specified by the manufacturer. If not specified by the manufacturer, the maximum permissible errors given in Table 1 shall apply.

Table 1 – Maximum permissible errors

Measurement range	Maximum permissible error
0 mmHg to 19 mmHg	±2 mmHg
over 19 mmHg to 35 mmHg	±3 mmHg
over 35 mmHg	±4 mmHg

3 Technical requirements

The technical requirements are based on the requirements under the Government Order on Medical Devices.

If not indicated by the manufacturer in the specifications of the measuring instrument or if not indicated differently from those provided below, the technical requirements provided below shall apply.

3.1 Construction of the measuring instrument

A non-contact ocular tonometer consists of an optical tracking system, an air pulse generating device, an evaluation unit and an indicating device.

The optical tracking system is used to place the air pulse generating device at the desired distance and position relative to the eye being measured. It must always clearly identify that the air pulse generating device has reached the ideal position relative to the eye being measured.

If the course of the measurement is evaluated as non-standard by the evaluation unit, the measured value shall either not be displayed at all or shall be displayed in a manner clearly and unambiguously indicating that it is non-standard.

4 Measuring instrument markings

Electronic ocular tonometers must bear, at least, the following markings:

- trade mark or name of the manufacturer,
- measurement unit (mmHg or kPa),
- power supply information,
- type approval mark or the CE marking with the identification number of the notified person.

In addition, any further information provided by the manufacturer of the medical device, including the appropriate graphical symbols, shall be attached to these tonometers.

5 Subsequent verification

5.1 General

5.1.1 Overview of the tests performed

Subsequent verification of non-contact electronic ocular tonometers shall comprise the following tests performed sequentially:

a) visual inspection,

b) accuracy test.

5.1.2 Test equipment

The following equipment shall be used for the tests:

a) the test equipment specified by the manufacturer for testing the relevant non-contact ocular tonometer,

b) a thermometer able to measure within the temperature range of 10 to 35°C in increments of 0.1°C.

5.2 Visual inspection

The purpose of the visual inspection shall be to check:

- that the ocular tonometer submitted for verification conforms with the approved type or design of the measuring instrument for which conformity was declared when it was placed on the market,
- that it shows no obvious signs of damage or contamination,
- completeness and legibility of the required labels and marks referred to in Chapter 4.

5.3 Accuracy test

The test shall be performed at the operating conditions specified under Article 2.1. Prior to the test, the measuring instrument must be left at room temperature for at least 3 hours and turned on for at least 10 minutes.

The accuracy test shall be performed by directly comparing the data from the non-contact ocular tonometer being verified with data from standard test equipment. In this test, 10 measurements shall be taken with the non-contact ocular tonometer on all standard test equipment designed for the relevant type of non-contact ocular tonometer. If measurement can be made in an automatic, semiautomatic or manual mode, measurements shall be taken in all modes.

The error of measurement detected by any of the measurements must not exceed the maximum permissible error given in Article 2.3.

ANNEXES

Annex 1: Sample test protocol for non-contact tonometers