Report on measurement uncertainty of non-contact eye tonometers

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Uncertainty of non-contact eye tonometeres

Uncertainty determination is one of the crucial indicators of measurement methods, limits and capabilities by means of quantifying each individual factor affecting the generated value.

The overall uncertainty budget that lists the most significant factors affecting the non-contact determination of intra ocular pressure (IOP) is based on the used measurement method principles, procedures and the conditions under which it should be routinely used. For our specific case we have considered a scenario by which a non-contact tonometer is used by an experienced physician in a medical practice environment.

The detailed values based on uncertainty evaluation Type-A can be seen in Table I., the influential factors based on Type-B uncertainty evaluation can be seen in Table II.

All of the provided results have been obtained by measurements using two non-contact eye tonometers, more specifically Nidek NT 2000.

The standard uncertainty evaluated by type-A method was determined by a total of 120 measurements with two types of references that simulated a human eye with the specific static values of IOP (indicated in Table I. as Nominal value reproduced by the standard). The results within Table I. show averaged value of Type-A uncertainty for a specific type of standard and a specific pressure point. The results from two types of references, represented by the commercially available silicone eyes and an independently developed artificial cornea eye model, have shown that the levels of repeatability at each pressure range are comparable. This is an indication of the performance of a specific non-contact eye tonometer type in terms of Type-A uncertainty evaluation.

Table I. *Detailed values based on uncertainty evaluation Type-A*

Evaluation of uncertainties by Type-A method for silicone eyes	
Nominal value reproduced by the standard	U_A values
16,0 mmHg	0,33 mmHg
22,8 mmHg	0,48 mmHg
42,5 mmHg	0,88 mmHg
Evaluation of uncertainties by Type-A method for artificial cornea eye model	
Nominal value reproduced by the standard	U_A values
14,5 mmHg	0,32 mmHg
22,9 mmHg	0,59 mmHg
42,8 mmHg	0,82 mmHg

The standard uncertainty evaluated by Type-B method includes effects on a given measurement without the statistical effects from the repeated measurements of the intraocular pressure values. The overall measurement accuracy associated with the measurements performed by the non-contact eye tonometers depends on their basic principle. This type utilizes the measurement of a time of an applanation of an eye cornea (human eye, silicone eye, artificial cornea eye model). The measurement takes place without a direct contact of the tonometer and the cornea. A pressure causing a jet stream of air from a nozzle is set by the device itself. The device increases the pressure until the cornea reaches the required applanation. This moment is recorded by optical means, more specifically, by an infrared light source that is reflected into a detector upon reflection from the flattened cornea. During an applanation, the detector detects a higher power compares to that reflected from a convex cornea unexposed to an air stream. The intraocular pressure (IOP) calculation is done by the device, by using the time of the applanation at the pressure value generated by the air flow. For each cornea there are always 3 measurements, from which an arithmetic mean is calculated by the device (during patient examination). During the calibration, the measurements are performed at least 10 times.

Based on the study of literature, the experience of the Czech Metrology Institute, the measurements performed at the Ruzinov Hospital, at the Slovak Institute of Metrology, at the Slovak University Of Technology and at the Palacky University, we concluded the sources of uncertainty evaluated by Type-B method as presented in Table II.

Table II. *Detailed values of the listed influential factors (Uncertainty Type-B components)*

Uncertainty component	**Value**		**Distribution**
Time measurement*	u_{B1}	0,001 mmHg	Uniform
Pressure generation	u_{B2}	0,200 mmHg	Gaussian
Distance between the device nozzle and eye surface*	u_{B3}	0,005 mmHg	Uniform
Mechanical properties of artificial cornea (including its thickness)**	u_{B4}	0,700 mmHg	Uniform
Environmental conditions (temperature and humidity)*	u_{B5}	0,100 mmHg	Uniform
Centring of the nozzle*	u_{B6}	0,005 mmHg	Uniform
	u_B	**0,74 mmHg**	

*Estimated value based on literature,
** Values derived from experimental measurements.

Evaluation of an intraocular pressure is based on variables recorded by a tonometer which are afterwards used to calculate the intraocular pressure. These calculations are done by devices' internal algorithms that are unique for each manufacturer. The tonometer uses parameters such as applied pressure, time, elastic modulus of the eye tissue, especially the cornea. These elastic modulus values and the process of calculation is not available to the users or testing bodies.

The most influential factors on the non-contact measurements of IOP are:

- the ideal distance between the eye and the air source (nozzle),
- measurement conditions (accurate time measurement, including regulation of air pressure, more precisely repeatability of the generated pressure during repeated air pulses),
- environment (air temperature, pressure, humidity, illumination),
- measuring range which is set on the instrument,
- automatic or manual measuring mode,
- experience of an operator.

As many of the influential factors on the measurement can be affected by each other, it would be certainly appropriate to consider defining the covariations between each factor. By defining their interaction we can increase the resulting uncertainty, but also significantly reduce it. It all depends on the nature of whether the uncertainty components act in agreement or disagreement on the two uncertainty estimates under consideration; In particular, the values generated from the non-contact eye tonometer will be mutually correlated.

Effect of cornea thickness

One of influential factors that has a potential to affect the measured IOP value are the mechanical properties of the eye cornea. As the biological material properties in the real human eyes have a small variation (in a healthy patient), its thickness affecting the measured IOP is more significant and determining the exact effects in of high interest.

Due to the ethical and technical complications with measuring on biological tissue the results presented in this section demonstrate the effect of thickness on the measured IOP by means of artificial cornea of same geometry and of identical and homogenous material.

A series of measurements with variation in thicknesses of artificial corneas were conducted. Specifically, the silicone based corneas that were investigated were 0.3, 0.4, 0.5 and 0.6 mm thick. The results of these measurements are presented in Fig. 1. Each point on the graph represents an average of 12 measurements performed for each respective pressure.

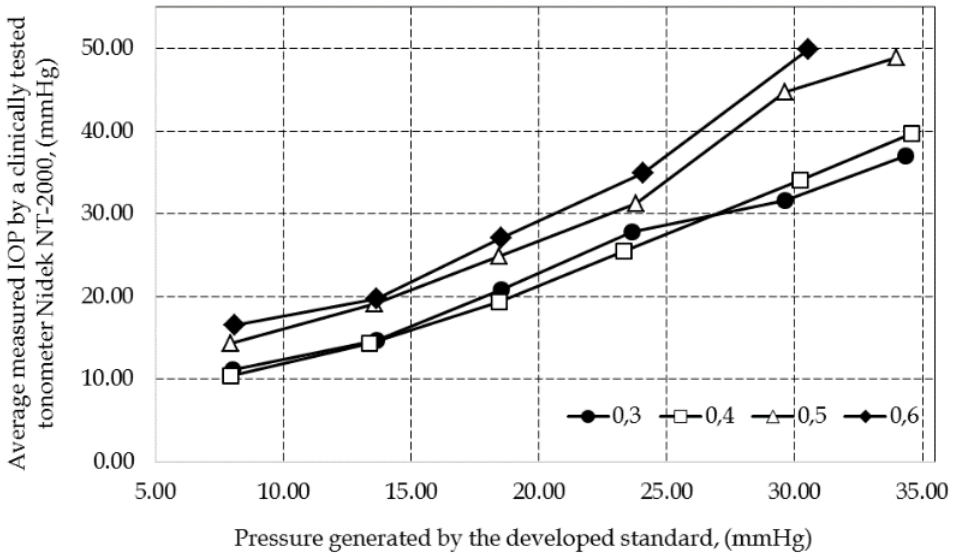

Fig. 1 *Comparison of difference artificial cornea thicknesses and their effect on the IOP measurement by a clinically tested non-contact tonometer NidekNT2000.*

The Fig. 1 shows how the set pressure by the developed standard corresponds with the indicated IOP pressure by a clinically tested non-contact tonometer Nidek NT 2000. As can be seen the smallest differences throughout the whole measurement range between the tonometer device and the developed reference were achieved using the 0.4 mm thick artificial cornea. The use of higher thicknesses had caused a more significant deviation and the decrease of thickness beneath the 0.3 mm had shown no benefit but has caused instability at higher pressures. It should be noted that the 0.7 mm thick cornea has caused the absence of an applanation and therefore no data could be measured.