Metrological traceability for the measurements of the intraocular pressure

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Glaucoma and intra-ocular pressure

- **Glaucoma is the world's leading cause of irreversible blindness.**
- **The only treatable risk factor is the ocular hypertension, an increase of the pressure of the aqueous humor in the anterior chambre of the eye.**
- **Non-invasive intra-ocular pressure (IOP) measurement is inevitable for glaucoma prevention.**
- **Normal IOP is from 10 mmHg to 20 mmHg (1.3 to 2.7 kPa). Pathophysiological range up to 80 mmHg (10.7 kPa).**

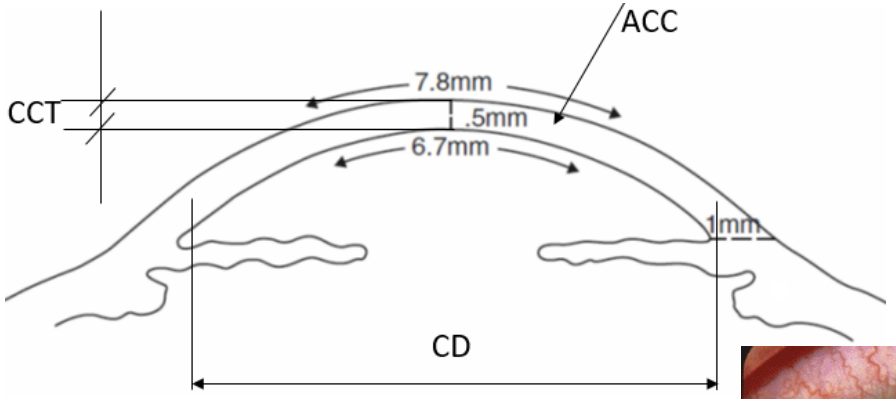
CD (corneal diameter) ranges from 10.50 mm to 12.75 mm,

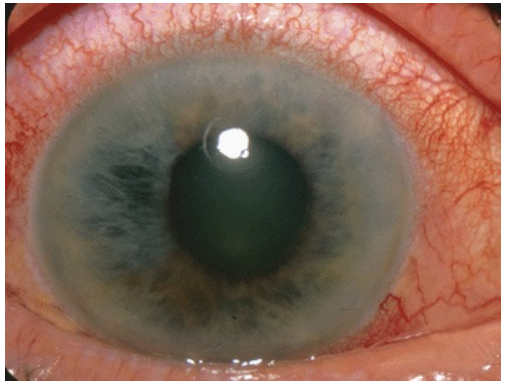
CCT (central corneal thickness) ranges from 512 µm to 570 µm,

ACC (anterior corneal curvature) ranges from 7.06 mm to 8.66 mm,

Poisson´s ratio cca 0.48,

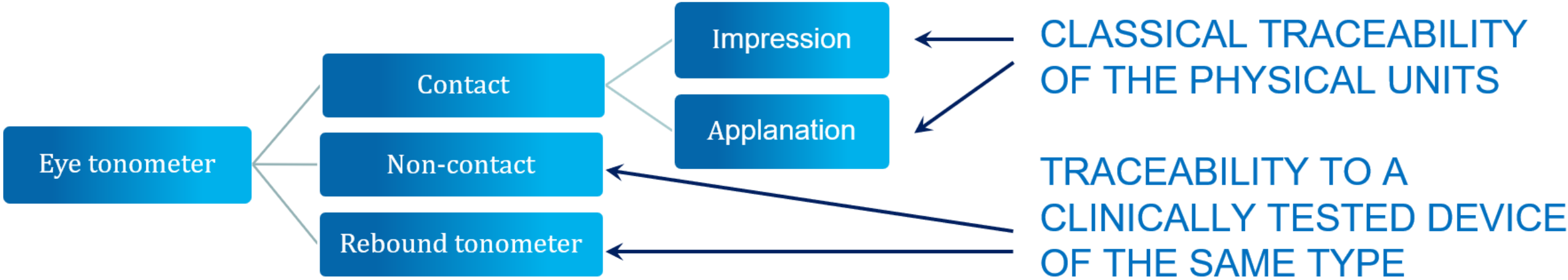
Young´s modulus from 50 kPa to 360 kPa.





Traceability of the eye-tonometers

Regular verifictaions in Czechia (contact 1 year period, non-contact 2 year period), Germany and Lithuania.



Maximum permissible error			
	Contact tonometer	Non-contact tonom.	Rebound tonometer
Low range	± 1,5 mmHg	± 2,0 mmHg	± 1,0 mmHg
Medium range	± 2,0 mmHg	± 3,0 mmHg	± 2,0 mmHg
High range	± 3,0 mmHg	± 4,0 mmHg	

Building capacities at the CMI

Starting situation: *medical-metrology is usually a mere appendix of the physical quantities metrology; only the isolated accuracy checks of the physical sensors; ignoring that the sensor is only one link in a chain, the first step towards a medically relevant measurand.…*

- **State-of-the-art expertise of PTB in the field of the IOP metrology was transferred to CMI and a competence and training centre was established at CMI and successfully audited in 2020.**
- **CMI is now able to provide IOP traceability and training for the other European metrology institutes.**
- **A Smart Specialisation Concept (SSC) in the field of the IOP metrology was created to ensure a coordinated approach.**

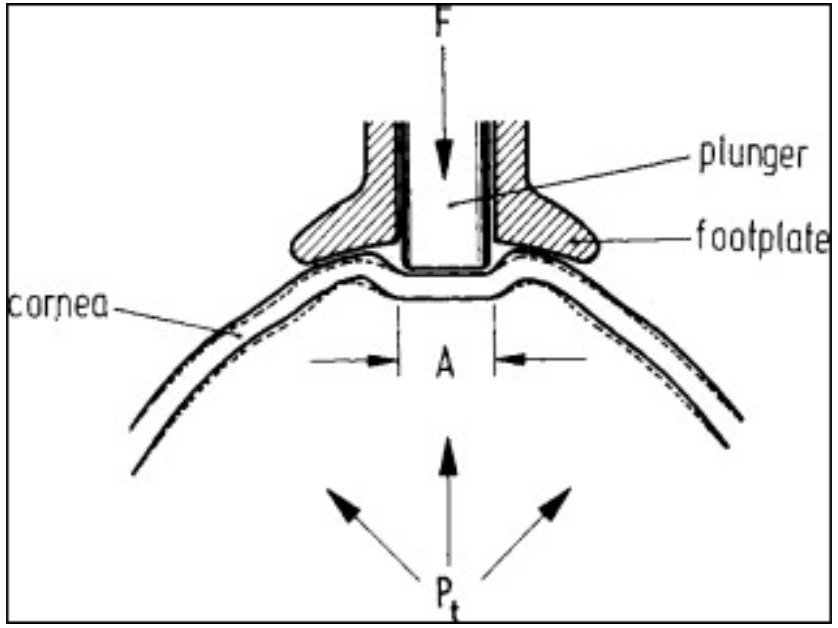
Developing the SSC

- The first training for a German company and a Slovak student took place in 2020. In 2022, the colleagues from Bosnia and Herzegovina, Moldova and North Macedonia took part.
- Thus, other NMIs have an opportunity to enter this field in the extent most suitable and/or profitable for them and to rely on the competence centre with the rest.
- In contemporary, the scope of the training centre covers the contact (impression and applanation) tonometers, the contour tonometers, the rebound tonometers and the non-contact tonometers. (Not use on the patients, but calibrations and verifications of the eye-tonometers and of the respective instrumental standards).

Impression eye-tonometer

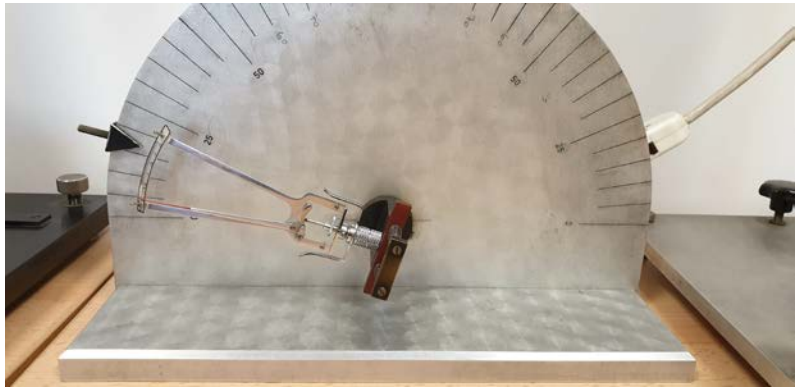
Impression (or indentation or Schiøtz) tonometer is the oldest eye-tonometry principle still in practical utilisation.

- **It determines the IOP by the depth of corneal indentation caused by a plunger with the exactly defined weight and dimensions. In order to measure the very high IOPs, the extra weights can be loaded.**
- **All these instruments are manufactured following the common standardized specifications.**



Verification of impression eye-tonometer

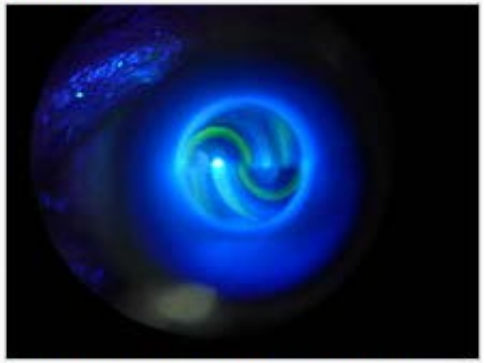
Their traceability consists of the checks of all the prescribed geometrical (e.g. the curvatures of the contact areas of a footplate and of a plunger) and mechanical (e.g. weights and plunger friction) requirements and tolerance limits. The weights can be checked by a mechanical or by an electronic balance in a special set-up.



Applanation eye-tonometer

Applanation (or Goldmann) tonometer is also a long-time established principle but still considered to be a “golden standard.” It determines the IOP by measuring a force needed to reach an applanation (i.e. flattening) of a cornea caused by a transparent probe with a known contact area (a circle of 3.06 mm diameter).

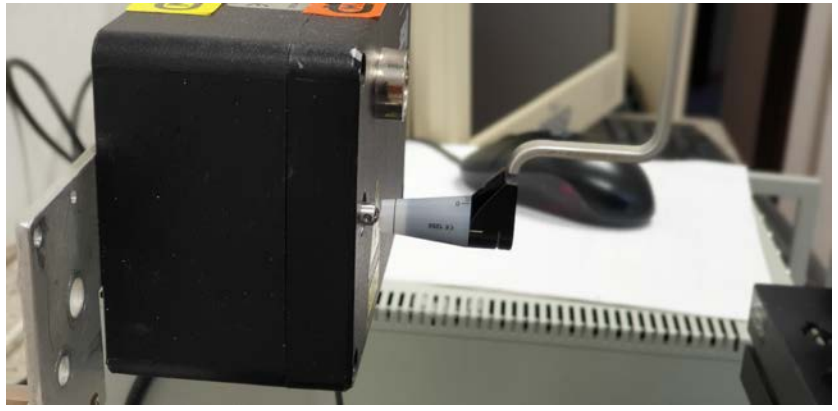
The slit lamp of a Goldmann tonometer

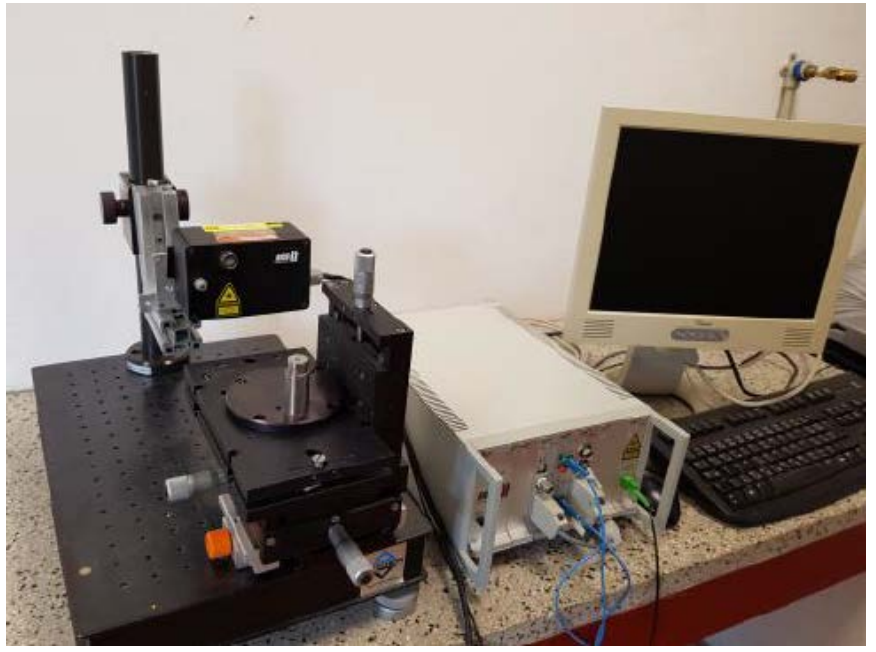


Semicircles seen during Goldmann tonometry through slit lamp

Verification of applanation eye-tonometer

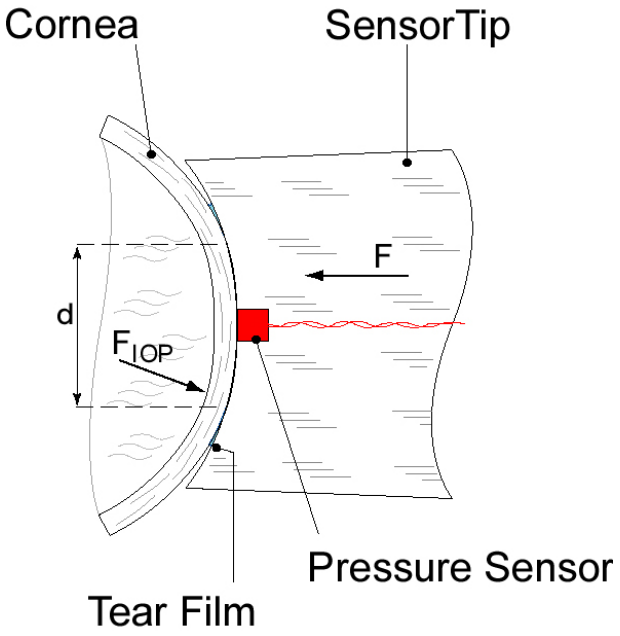
Also, this is ensured in a classical way, by separate checking their geometrical specifications (applanation circle diameter by a limit-gauge) and optical quality and by calibrating the force sensor (by a mechanical balance or by an electronic sensor).

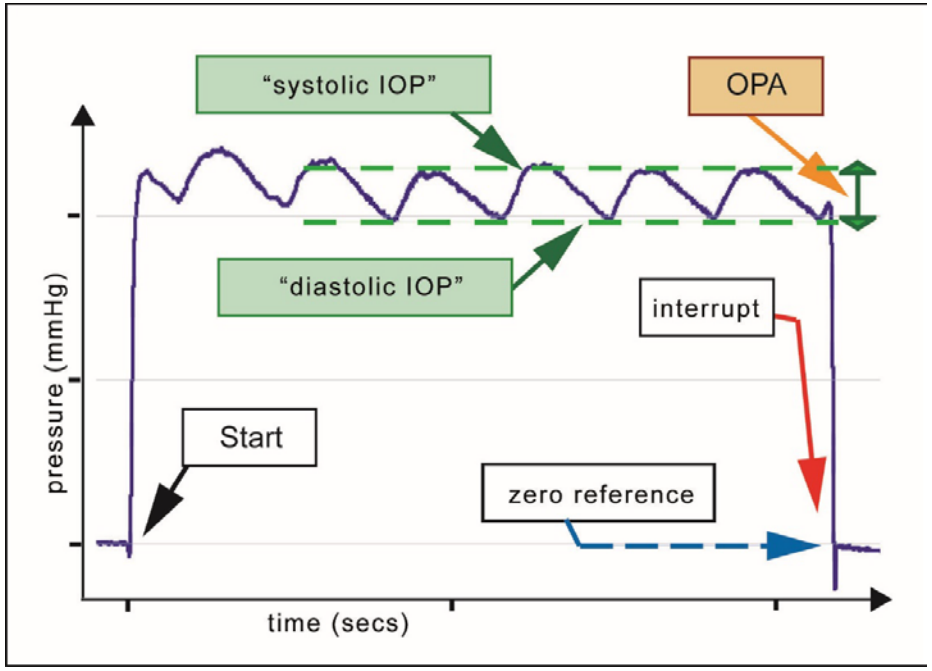




Dynamic contour eye-tonometer

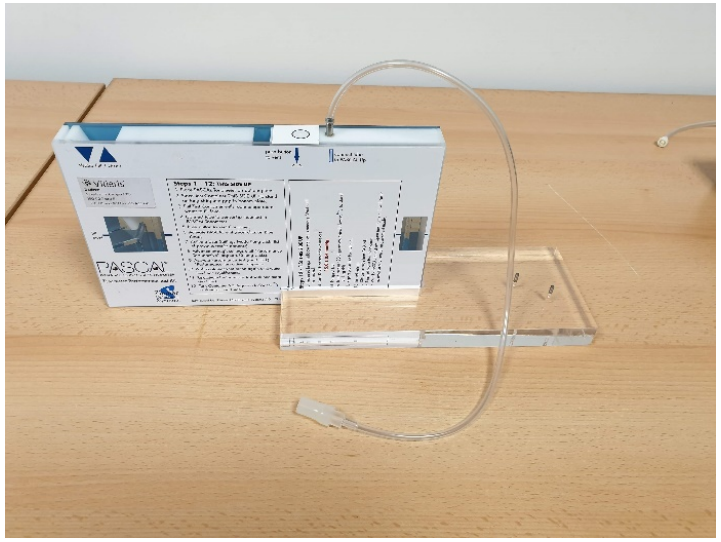
A head of this instrument has a concave shape corresponding to the typical shape and size of the human cornea. The head is pressed to a cornea with a constant force (i.e. in a contact with it but not applanating it). A miniature piezoresistive pressure sensor in the head is then able to detect the IOP with such a sensitivity that it even can detect the minor IOP fluctuations caused by the cardiac cycle. The principle is less influenced by a corneal thickness or a corneal rigidity, but it is rather sensitive to a corneal curvature.





Verification of dynamic contour eye-tonometer

The traceability of this device can be easily and straightforwardly ensured by a direct calibration of its internal pressure sensor.

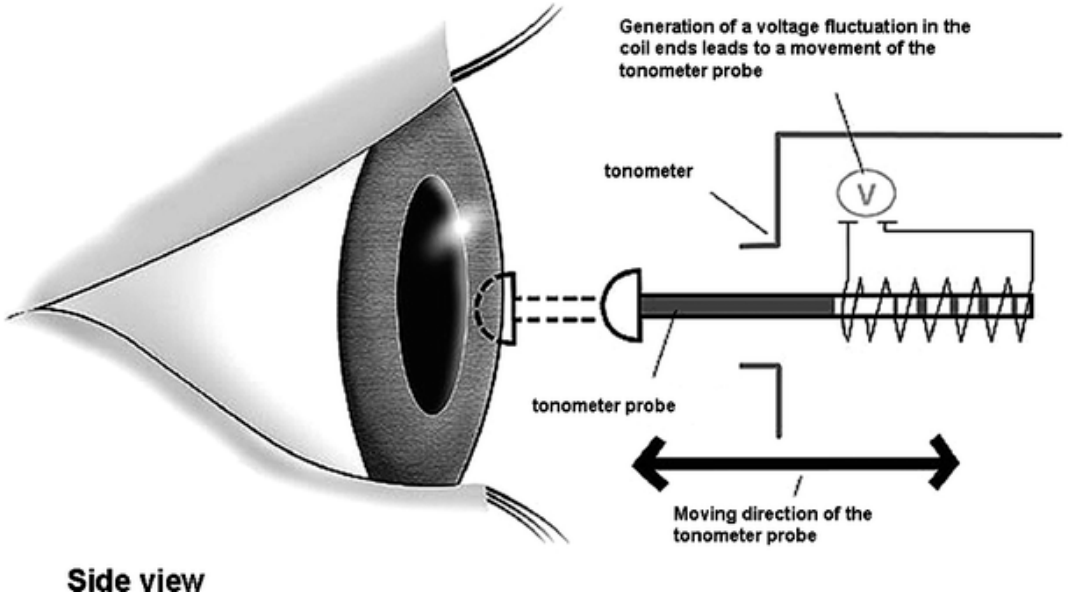


Device by SMT Swiss Microtechnology AG
for checking PASCAL type tonometer
in one pressure point.

A more universal set-up consisting of a manometer with 0.01 mmHg resolution, a pressure source and a buffer vessel.

Re-bound eye-tonometer

The rebound tonometers are recently becoming popular due to their ease of use (vertical and horizontal positions, home diagnostic possible). A very light, non-harming probe (plastic coated metal core with a spherical plastic tip) is ejected from the instrument against a cornea and is then reflected back. The probe movement can be monitored inductively and the time response is used to calculate a value of the IOP.

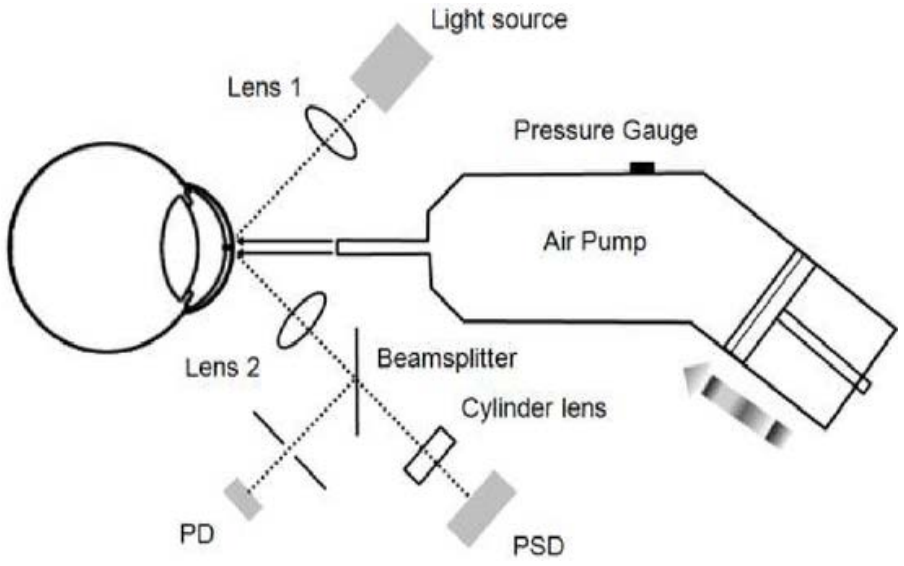


Verification of re-bound eye-tonometer

The traceability of these instruments must be again ensured to a clinically tested rebound tonometer via a testing bench consisting of a silicone membrane surrogating a cornea with an inner pressure regulated by a distilled water column which enables to compare the readings of a reference (clinically tested) tonometer and a calibrated device.

Non-contact eye-tonometer

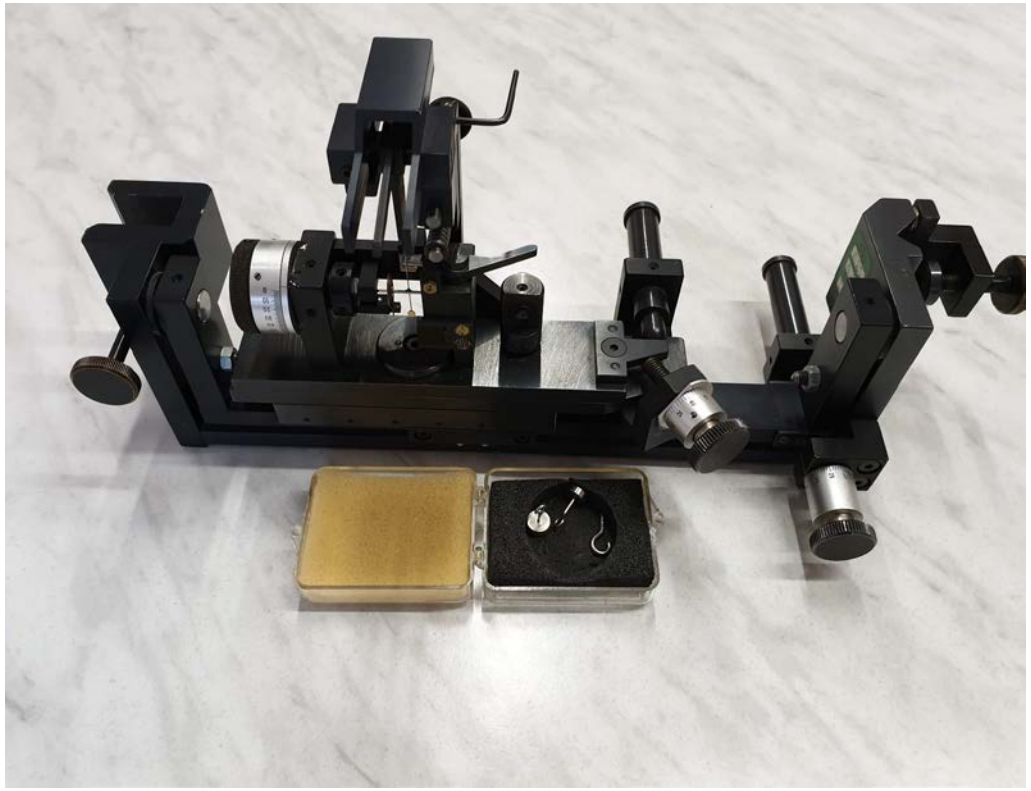
The non-contact (NCT, air-puff) tonometers are the most widely utilized tonometers in contemporary, because there is no mechanical contact with eye during measurement resulting in no need of a topical eye anaesthesia. These instruments also aim at an applanation of a cornea, but they reach it by a rapid (cca 15 ms) pulse of air directed from a nozzle to the middle of a cornea. A moment of reaching the applanation is detected by a reflection of an infrared beam. The state-of-the-art devices are able to determine also other important ophthalmological measurands (e.g. central corneal thickness).



Verification of non-contact eye-tonometer

The traceability must be ensured to a clinically tested NCT (the training laboratory is equipped with one) via a suitable transfer-standard. There are three possible types of transfer-standards available. The laboratory is equipped with all these devices, because none of these can be utilized universally with all the types of the NCTs produced by the various manufacturers.

- **rubber / silicone eye sets (traceable to a manufacturer),**
- **electronic eye (traceable to a manufacturer),**
- **flapper (traceable to our clinically tested NCT).**



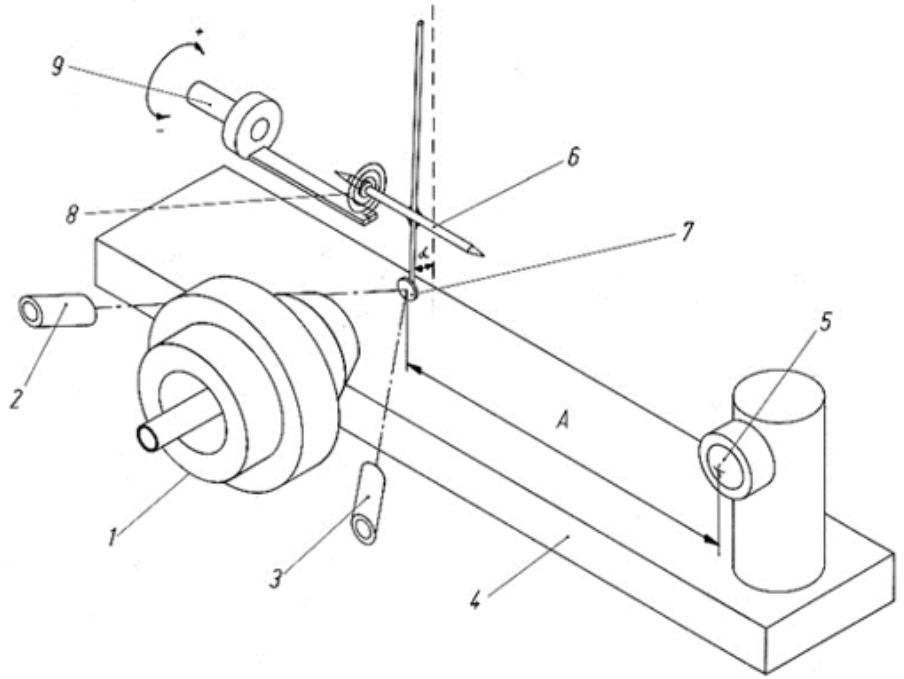
Silicone and electronic eyes

- The silicone eyes are usually not compatible with the NCTs produced by other manufacturers, and sometimes even not with other types of the same manufacturer. They are mounted directly on a headrest and their use is very simple. An NCT needs not to be switched into a special mode.
- The electronic eyes reflect the projected infrared signal back into the tonometer photo-detector. They are produced by the individual NCT-manufacturers for their NCTs while they also ensure their traceability. Their use is always limited to a certain type of NCT.

Flapper

The flapper simulates the course of the corneal application through the kinematic movement of a small flat circular mirror (2.5 mm), where the mirror is deflected from the zero position by the force of the airflow.

- **The lengths, angles and bearing clearances are important for this test device.**
- **Flapper covers three nominal IOP values. It is a very precise standard, but it is demanding for the operator skills. However, it cannot be utilised for all types of the NCTs.**



1: nozzle of the non-contact tonometer

2, 3: light source and light detector of the non-contact tonometer

4: mount

5: lens to adjust the distance non-contact tonometer – mirror

6: rotating axis

7: mirror

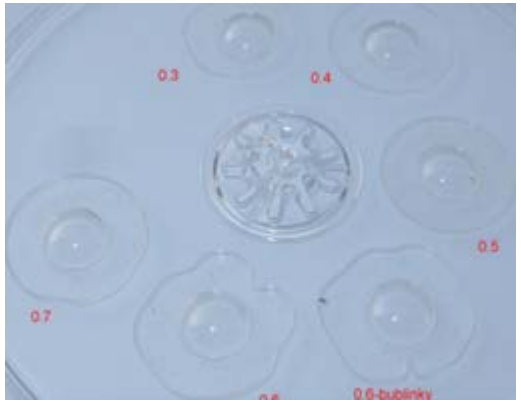
Prospective new transfer-standard by STU/SMU

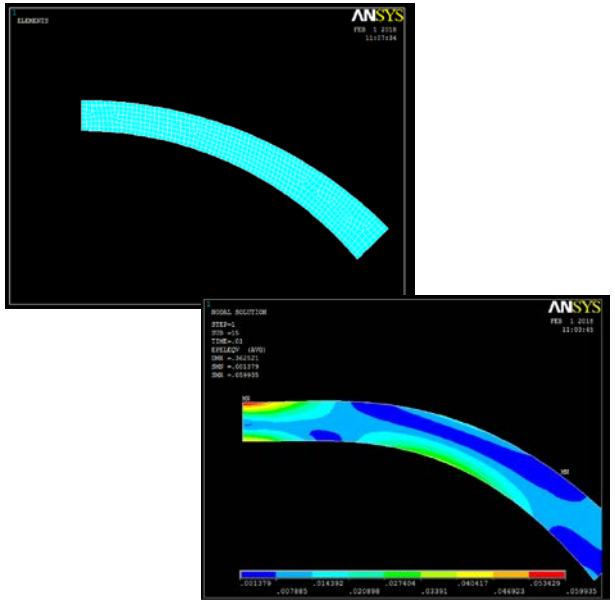
A virtual digital model of the cornea was created at the Slovak Technical University (STU) using Finite Element Method.

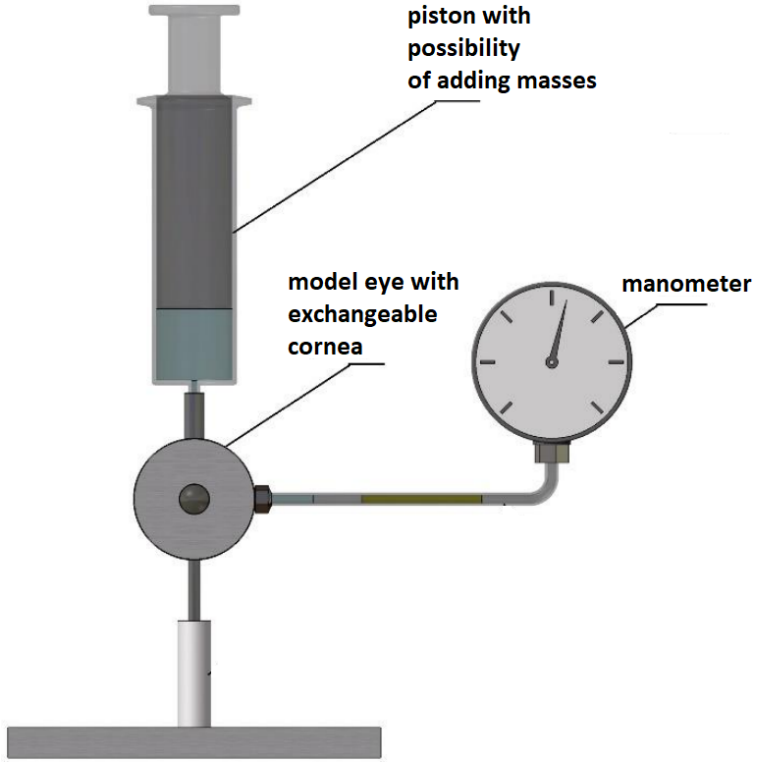
Then a real mechanical model (artificial model eye) corresponding to the virtual model was constructed by SMU/STU for the experimental verifications.

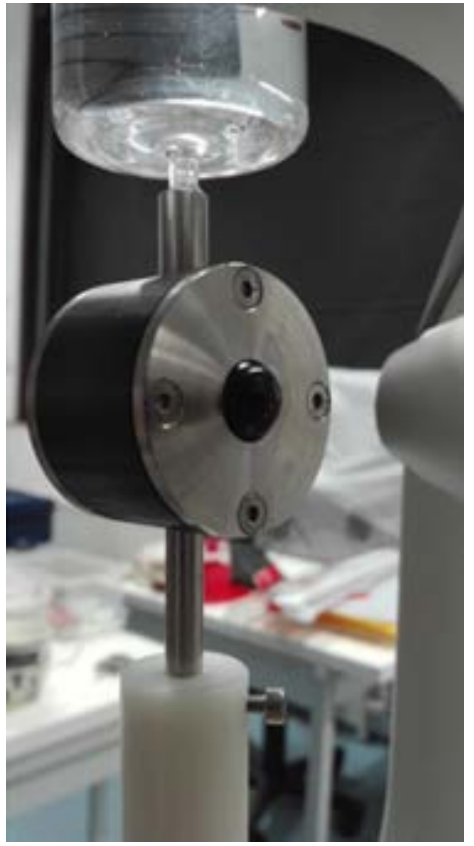
Various thicknesses of artificial corneas were tested.

Strains at max. pressure – after applanation.





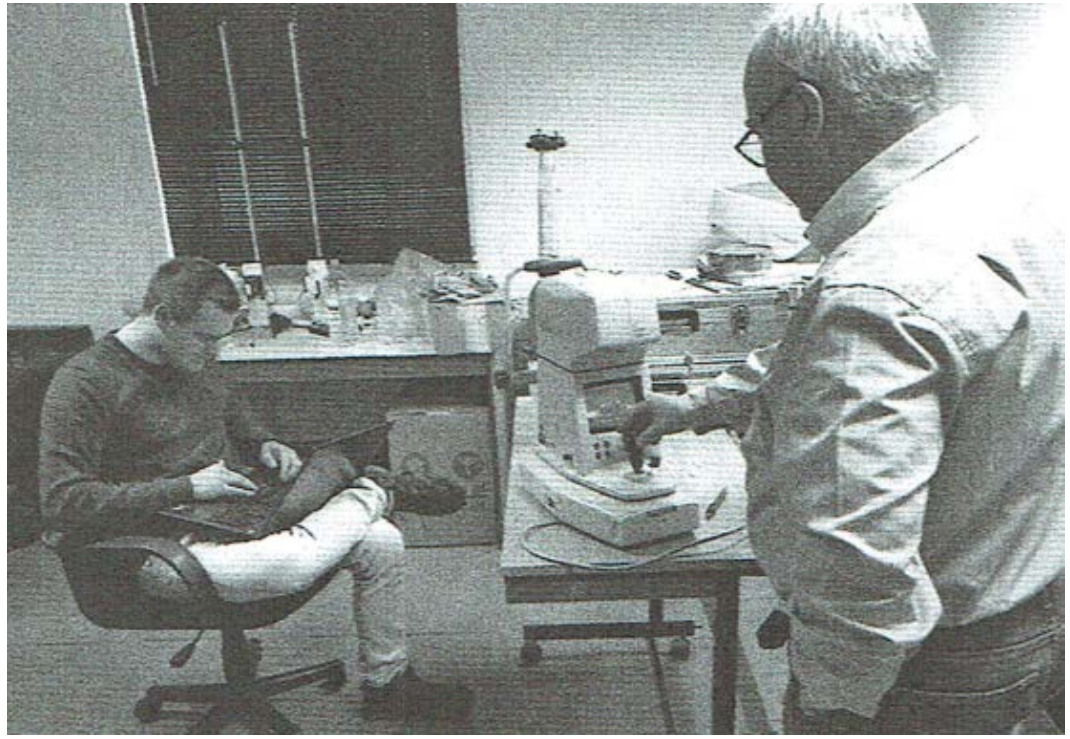


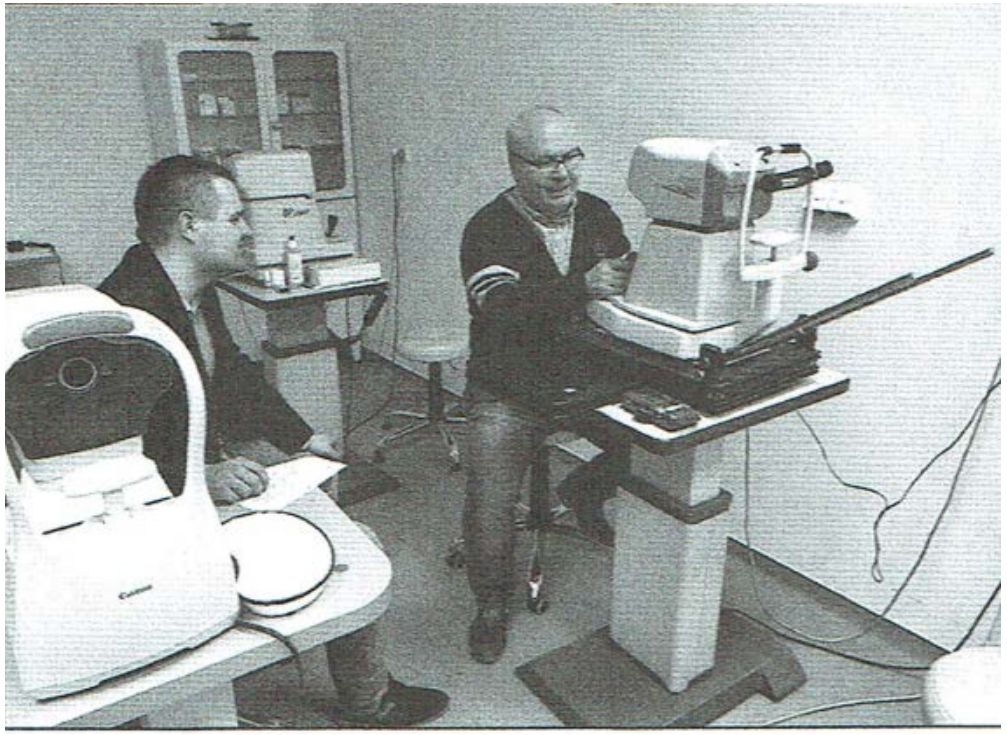


Bilateral comparison

A successful bilateral inter-laboratory comparison in the field of eye-tonometry between CMI and STU in 2020.

Two clinically tested NCTs were mutually compared via a classical set of the silicone eyes and the new artificial model eye.





CMI version of an artificial eye

CMI has the same goal - to develop an artificial eye with exchangeable silicone corneas (***these were made by SMU – many thanks***) of various thicknesses with a hydraulically or pneumatically regulated inner pressure.

We want to have

- **„universal IOP transfer-standard,“**
- **device to study and „test“ multiparametric NCTs.**

Conclusion and future

- As a result of the cooperation of the European NMIs, the training centre for the IOP metrology at the CMI covers the most common eye-tonometry principles.
- We consider it to be a starting nucleus of further cooperation activities in the sector of medical metrology.
- Some modern NCTs are able to determine more eye characteristics than the sole IOP. However, it is still not solved how to ensure a traceability for these. We cooperate with the Slovak colleagues to approach these problems.
- Another comparison of the NCTs is being planned.

Thank you.

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