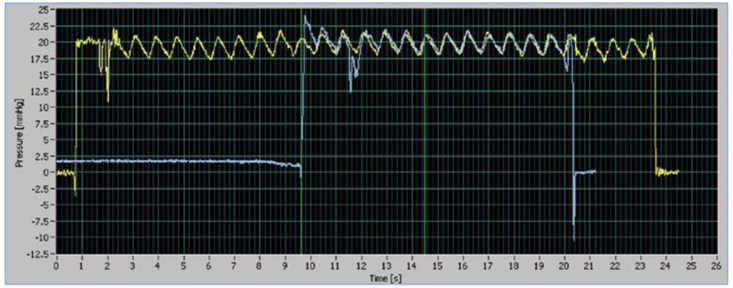
The PASCAL is the most accurate tonometer ever designed.

Every Study done to date supports the accuracy of the PASCAL Dynamic Contour Tonometer, including multiple independent intracameral cannulation studies done at the time of cataract surgery.



Comparison plot of intracameral manometric measurement (yellow curve) and trans-corneal measurement with the PASCAL Dynamic Contour Tonometer (blue curve). *Courtesy of A.G.Boehm, MD, Department of Ophthalmology, Dresden, Germany.*

True IOP. No doubt.

"For my diagnostic decisions, the PASCAL is much more important than Pachymetry or correction tables." *Prof. Dr. Th. Neuhmann, Munich, Germany*

Additional references:

1. McDonald J: Annals of Ophthalmology. 2006 Spring; 38(1): 5–8. Measuring Intraocular Pressure.
2. Liu J, Roberts CJ: JCRS. 2005 Jan; 31(1):146–155. Influence of corneal biomechanical properties on intraocular pressure measurement: Quantitative analysis.
3. Kanngiesser HE, Kniestedt C, Robert YC: J Glaucoma. 2005 Oct; 14(5):344–50. Dynamic contour tonometry: presentation of a new tonometer.
4. Kniestedt C; Nee M, Stamper RL: Graefe's Arch Clin Exp Ophthalmol. 2005 Apr; 243(4):359–66. Accuracy of Dynamic Contour Tonometry Compared to Applanation Tonometry in Human Cadaver Eyes of Different Hydration States.
5. Kaufmann C, Bachmann LM, Thiel MA: IOVS. 2004 Sept; 45(9):3118–3121. Comparison of Dynamic Contour Tonometry with Goldmann Applanation Tonometry.
6. Siganos DS, Papastergiou GI, Moedas C: JCRS, 2004 April; 30:746–751 Assessment of the PASCAL dynamic contour tonometer in monitoring intraocular pressure in un-operated eyes and eyes after LASIK.

Technical Data

- Class IIa medical device. CE-marked. FDA 510(k) cleared.
- Device mounts on tonometer bracket or accessory footplate of slitlamp.
- Dimensions: Housing: 170 mm (H) × 88 mm (W) × 40 mm (D)
- Weight: ca. 210 grams.
- Display of results: backlit LCD 58 × 24 mm (2.2' by 1')
- Detection range: IOP 5 – 80 mmHg; OPA >1.0 mmHg (numerical precision ±0.2 mmHg).
- Analog/digital conversion: 100 Hz sampling rate; 12 bit resolution.
- Recording time: ca. 3 secs up to 120 secs.
- Calibration: self-calibrating; automatic compensation of atmospheric pressure. Optional Test Kit is available for checking tonometer calibration and performance.
- Appositional force: 1 gram.
- SensorTip diameter: 7 mm (pressure sensor: 1.2 mm)
- Contact surface: concave, shaped to match corneal contour.
- Cleaning/sterilization: SensorTip is protected from direct eye contact by sterile, single-use SensorCap covers.
- Power: battery-operated; 3V disposable battery packs (standard), or rechargeable battery pack with battery charger (optional).
- Wireless interface capability to connect to the optional printer or to user's of PC or EMR system.

ziemer OPHTHALMOLOGY

Marketed by Ziemer Ophthalmic Systems AG
a Ziemer Group Company
Allmendstrasse 11, 2562 Port, Switzerland

Tel. +41 (0)32 332 70 50
Fax +41 (0)32 332 70 71
innovation@ziemergroup.com

www.ziemergroup.com

www.pascal-tonometer.com

Accessories, Consumables:

- Slitlamp adapter kit (required for different types of slitlamp attachment; please check with your distributor).
- Wireless interface for connecting to an optional printer, or to a Personal Computer (with optional DataWizard software).
- Test Kit for checking tonometer calibration and performance.
- Sterile SensorCap disposable tip covers in AppliPack packaging (package of 240 ea).
- Disposable Battery Packs (standard), or Rechargeable Battery Pack with battery charger (optional).

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Product Information

CE 0297

- Manufacturer: SMT Swiss Microtechnology AG, CH-2562 Port, Switzerland (a Ziemer Group Company).
- Sales & Service: Ziemer Ophthalmic Systems AG, CH-2562 Port (Switzerland) and its network of established ophthalmic equipment distributors. Visit www.pascal-tonometer.com for details.
- Availability: Europe: CE-marked. USA: FDA 510(k) cleared. For other countries, availability may be restricted due to local regulatory requirements; please contact Ziemer Ophthalmics for details.
- Configuration: single unit, completely assembled (self-installed by user) screws onto available tonometer bracket, or fits onto pivotal axis of most Haag-Streit-type slitlamps. Adapter Kits for other slitlamps (Zeiss, Rodenstock) are available. SensorTip may be detached for cleaning. Basic configuration includes attachment kit for mounting the unit on swiveling bracket of slitlamp (swiveling bracket not supplied), two battery packs, and initial supply of sterile, single-use SensorCaps. With aluminum carrying case and operating manual.
- Service: Regular Maintenance and Repair Service is available from the manufacturer and from local certified Service Centers (please contact your local distributor or consult the PASCAL Tonometer website for address information).
  Regular performance checks are recommended and may be performed by the user by means of the optional Test Kit, or by service centers and distributors. If the test reveals a need for recalibration, the device must be sent to a Service Center for maintenance.
  Convenient Maintenance and Service Contracts are available.
- Warranty: The PASCAL Dynamic Contour Tonometer comes with a 12- month limited warranty on parts and workmanship. Please consult Ziemer Ophthalmic Systems' Warranty Terms for details.

PASCAL®

DYNAMIC CONTOUR TONOMETER

The Precision Tonometer

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Ziemer Group

We develop and produce diagnostic and surgical products for the ophthalmic market that distinguish themselves from established standards in terms of usability, precision, quality, and productivity.

PASCAL®

DYNAMIC CONTOUR TONOMETER

The PASCAL Dynamic Contour Tonometer (DCT) is a third-generation, digital, contact tonometer for ophthalmological applications. The slitlamp mounted device furnishes a numeric output of intra-ocular pressure (IOP) and of ocular pulse amplitude (OPA) upon touching the cornea for a few seconds. It measures pulsatile IOP directly and continuously (dynamically).

PASCAL'S main components:

1. SENSOR TIP
2. Cantilever (spring-loaded arm)
3. Mounting bracket
4. Control switch ("Blue Knob")
5. LCD Display
6. Wireless printer (optional)

Features

- Direct measurement of pressure eliminates systematic errors from force-to-pressure conversion.
- Numerical display of result on LCD screen avoids operator bias and reading errors.
- Audio feedback during measurement aids alignment and data taking.
- Completely objective measurement – no mires to align!
- Quality reading ("Q score") avoids erroneous readings due to poor data quality.
- Attaches to slitlamp like the familiar Goldmann tonometer.
- No need for fluorescein. Room lights can remain on.
- Reads IOP dynamically at 100 times/second.
- All functions are accessed with the unique Blue Knob – easy, single button operation.
- Self-calibrates at the beginning of every measurement – no calibration required.

Clinical Benefits

- Unlike applanation tonometers, which are influenced by corneal thickness and other characteristics of the cornea, and hence may produce misleading estimates of IOP, the PASCAL provides an accurate, direct measurement of true IOP which is independent of inter-individual variations in corneal properties and biomechanics.
- IOP measurement is accurate even on post-LASIK and keratoconic eyes.
- PASCAL detects and accurately measures the dynamic fluctuations in IOP and thus permits a more detailed assessment of the pressure range to which the eye is subjected due to pulsatile ocular blood flow.
- Silicone tip covers prevent cross-contamination and eliminate possibility of corneal abrasion, even with an inexperienced user.
- Convenient documentation and visualization of IOP curve with optional wireless printer or PASCAL DataWizard PC software.

Ocular pulse curve, detected in real-time by PASCAL; visualized with optional PASCAL DataWizard software.

"You can have a thick cornea that's soft, and a thin cornea that's relatively rigid. Rather than compensating for these factors, we want to eliminate them from the equation, and the DCT seems to do that. [...] Goldmann was a valiant effort, but it's outdated. It just doesn't provide the level of accuracy we need for modern-day glaucoma evaluation." *Ike Ahmed, MD**

"We found that the Goldmann measurements weren't significantly different between contralateral eyes in any given [glaucoma] patient. In contrast, the PASCAL DCT showed a higher pressure in the eye with greater damage. The only way we would have noticed a pressure difference is with the PASCAL." *Cynthia Roberts, PhD**

* Catching the Silent Thief in the Act, Review of Ophthalmology, Vol. 12:6, June 2005.

How the PASCAL Tonometer works

PASCAL is always ready for operation; simply swivel it into place before the patient's eye, zero the pressure sensor with a single click of the Blue Knob, advance the SensorTip to rest against the patient's eye. After a few seconds a sound will tell you that sufficient data have been collected. Pull back now, and immediately you will see the numerical result, precise and unambiguous, on the PASCAL's illuminated LCD display.

When the concave surface of the SensorTip touches the corneal surface, a solid-state piezoresistive pressure sensor, built flush with the center of the tip surface, directly measures IOP across the cornea. The contoured surface of the SensorTip has been calculated to generate minimal distortion of the cornea (contour matching) and hence minimize tension forces within the cornea during a measurement.

The PASCAL can be mounted on any slitlamp and is advanced towards the patient's eye by using the slitlamp's joystick. The SensorTip is mounted on a spring-loaded Cantilever which provides a constant appositional force against the cornea of 1 gram, eliminating any concern of over-compressing the cornea as is possible with other tonometers.

The pressure in the eye is detected 100 times per second and is digitized and stored in the PASCAL's memory. A built-in microprocessor determines the intra-ocular pressure (IOP) and its pulsatile fluctuations caused by the patient's heartbeat (ocular pulse amplitude, or OPA.) The IOP and OPA are displayed as numeric values on the LCD display, along with a Q score which reflects the quality of the data obtained during the mea-surement.

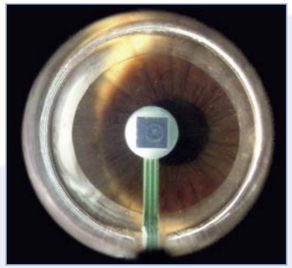
The Ocular Pulse Amplitude ("an often overlooked jewel of information") provided by the PASCAL may furnish additional clinically useful information pertaining to ocular perfusion and its potential relation to ocular, and even systemic, diseases. However, the clinical relevance of OPA and ocular blood flow is not yet fully understood and warrants further clinical investigation. Early evidence appears to show that a low OPA (poor ocular perfusion) is a risk factor for progression of visual field loss in patients already diagnosed with glaucoma. Significantly different OPAs between eyes could indicate carotid obstructive disease.

IOP (mmHg): average of pulse curve minimums (3 – 6 minima are detected in a curve range optimized for data quality).

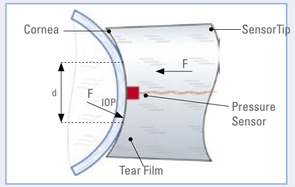
OPA (mmHg): difference between mean minimum and mean maximum of pulse curve.

Q: Quality of data and of results. 1 is optimum; 2 and 3 are accepable; 4 and 5 are questionable and should be repeated.

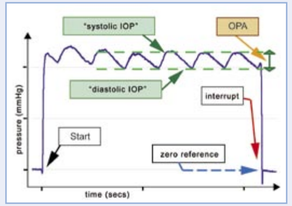
SensorTip with contour-matched contact surface



Contact area of cornea as seen through slit lamp



This is what the PASCAL tonometer measures:



...and this is the result presented on the LCD: