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PASCAL[®]

DYNAMIC CONTOUR TONOMETER

User Manual

Version 2.0

For PASCAL[®] Dynamic Contour Tonometers

November 2004

REF 311.951.001

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



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Supplementary Material on CDROM

This Manual is distributed on CDROM for interactive online use, as well as a template for generating your own printed version.

On the CDROM, the following additional material is available:

Quick reference Guide. This single sheet document, which is also supplied as a laminated sheet with every PASCAL system, provides a brief summary of the essential steps of taking an IOP measurement with the PASCAL. [\(Click to open\)](#).

PASCAL instructional video. A series of video sequences illustrates some of the key steps involved in setting up and using the PASCAL tonometer. Using the QuickTime Movie Player (Ver.s 6 and up), these video sequences may either be viewed sequentially or at random, or they may be accessed from within the manual wherever a "click here to play movie clip" note is displayed. This video material was written and produced by Elliot Kirstein OD, FAAO, Ziemer Ophthalmic Systems AG.

Video contents [\(click on titles to view\)](#):

- 1 **Introduction**
- 2 **Understanding the data**
- 3 **Assembly**
- 4 **Cover application**
- 5 **Testing the patient**
- 6 **LCD readout**
- 7 **Additional Adjustments**



Literature reference list, with a brief synopsis and hyperlink to full papers, featuring scientific and clinical research relating to PASCAL as well as review papers and news articles. [\(Click to open\)](#).

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1. Introduction

1.1. PASCAL[®] Systems covered in this Manual

This manual covers two versions of the PASCAL[®] Dynamic Contour Tonometer:

1. The standard PASCAL[®] System

- **REF** 311.001.001 has an S1-type mounting bracket
- **REF** 311.001.002 has an S2-type mounting bracket

2. The PASCAL[®] WIRELESS System; enabled for wireless communication with printers and computers

- **REF** 311.011.001 has an S1-type mounting bracket
- **REF** 311.011.002 has an S2-type mounting bracket

Most of the information provided applies equally to both types of PASCAL system.

Additional functionalities available only with PASCAL WIRELESS systems are marked with this symbol:



1.2. Indications for use

The PASCAL[®] Dynamic Contour Tonometer is a diagnostic device that serves for measuring intra-ocular pressure (IOP) according to the Dynamic Contour Tonometry method (see Appendix, section 8.1). The device is also capable of measuring short term pressure fluctuations within the eye. PASCAL is especially indicated in Glaucoma.

1.3. General description

The PASCAL Dynamic Contour Tonometer is a novel kind of Contact Tonometer intended for use by ophthalmologists and optometrists and any professional eye care staff trained in the use of diagnostic devices based on superficial eye contact.

PASCAL is an accessory device for a slit lamp. Installed into the optical axis of the slit lamp, it gives the user a view of the contact interface between cornea and tonometer tip. A pressure-sensing tip with a contoured contact surface, called the SENSORTIP, is applied to the center of the patient's cornea with a small, constant force. The pressure sensor built into the contact surface of the SENSORTIP generates an electrical signal which is proportional to the IOP. As an audible feedback, the Main Unit generates an audio signal whose pitch is proportional to the IOP detected; the higher the pressure, the higher the pitch. The pressure signal is detected for a period of about 5 seconds (corresponding to approximately 5 to 10 heartbeats); then the tip is pulled away from the eye ("the Interrupt Maneuver", or simply "the Interrupt").

PASCAL software computes IOP and its variation (modulation) caused by cardiac pulsation (Ocular Pulse Amplitude, OPA) from the pressure-dependent electrical signal and from the signal level after the Interrupt. These signals are stored and processed in the Main Unit and the numerical results are displayed on an LCD display screen.

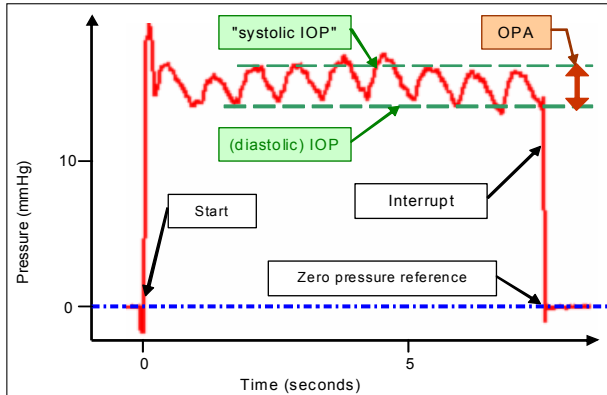


Fig. 1 Typical pressure curve, recorded for approx. 7 seconds. Several ocular pressure pulsations are recorded, from which PASCAL software computes IOP (referenced to zero pressure as detected after the Interrupt), and OPA.

Note: Pressure curve as illustrated here cannot be observed with the basic PASCAL device. Only the numerical result is presented to user. Curve may be viewed as an output of the optional Printer accessory.

1.4. How to use this manual

Before using the PASCAL Dynamic Contour Tonometer, study this User Manual carefully to develop a thorough understanding of instrument assembly and function, and of safety and hygiene precautions.












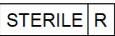


This manual is about using the PASCAL Tonometer. It does not provide instructions on how to use IOP measurement data as an element of clinical diagnosis or on how to clinically interpret the results of IOP measurements.



To just learn how to take a measurement, go directly to Sections [4.3 "Preparations"](#), and [4.4, "Taking Measurements"](#).

- Section 2** (page 8) ***System Components*** provides an overview of the major components of the PASCAL Tonometer System, with illustrations showing all system components.
- Section 3** (page 12) ***Safety Instructions*** specifies the intended use of the PASCAL Tonometer and provides important guidelines for patient safety and operational safety. Please study this section carefully.
- Section 4** (page 14) ***Procedures*** provides step-by-step instructions on setting up and using the PASCAL device.
- Section 5** (page 23) ***PASCAL Operating Instructions*** contains systematic reference information on all procedures (IOP measurement, instrument settings, etc...).
- Section 6** (page 31) ***Care and Maintenance*** contains information on how to perform system checks and calibrations, on cleaning the device, and on maintenance and repairs.
- Section 7** (page 36) ***Troubleshooting*** contains a troubleshooting guide, a complete listing of error messages and status messages, and a "Frequently asked Questions" section.
- Section 8** (page 45) The ***Appendix*** contains background information on Dynamic Contour Tonometry, on system software, and on technical specifications.

1.4.1. Explanation of symbols

Symbols used in this manual:	Symbols used on product and package labeling:
 Warning	 User must consult User Manual before operating the device.
 Caution	 Type BF applied part.
 Note	 CE-Mark (Conformité Européenne)
 Recommendation, helpful tip	 Consumable item for single use. Do not reuse.
 Video clip available	 Expiration date (do not use product after indicated date)
 Features available on PASCAL WIRELESS systems only	 Sterile product (gamma sterilized)
	 Recycle after use.
	 Manufacturer's part no. / order no.

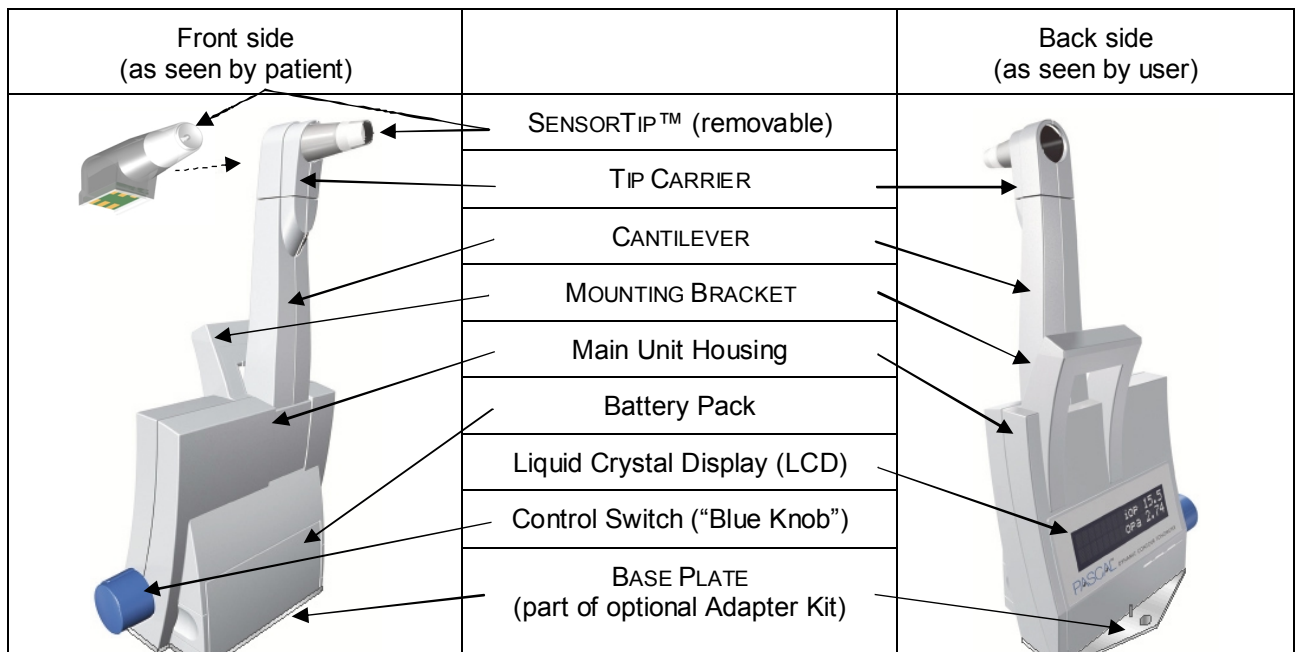
2. System Components

2.1. Main Unit

The PASCAL system is contained in a single, slit lamp-mounted housing (the Main Unit), and includes several single-use and multi-use components that are attached by the user to the Main Unit.

The Main Unit contains the system's electronics and mechanics. It features a Liquid Crystal Display (LCD), a Control Switch ("Blue Knob"), and the integrated CANTILEVER, which in turn supports the Tip Carrier. The CANTILEVER is a spring-loaded arm which applies the SENSORTIP™ to the patient's eye with a constant, defined appositional force of approximately 1 gram throughout its range of motion. An integrated micro-processor controls all system functions and performs the computation of results from recorded data.

Fig. 2 PASCAL Main Unit components



For a complete working arrangement, the Main Unit is mounted on your slit lamp using either the FOOTPLATE and BASE PLATE (packaged together as the optional ADAPTER KIT), or a swing arm, depending on the type and manufacturer of your slit lamp. Furthermore, a Battery Pack must be inserted into the Main Unit and a SENSORTIP must be inserted into the Tip Carrier.

SENSORCAP[™] Disposable Tip Covers are placed over the SENSORTIP in order to prevent contamination and infection, and to protect the pressure sensor from the corrosive effects of the patient's tear film. The APPLIPACK sterile packaging of each SENSORCAP serves as an applicator for easy fitting of the SENSORCAP over the SENSORTIP.

An optional Test Kit is available for users who wish to periodically check calibration of the PASCAL pressure sensor.

2.2. Accessories and Consumables

(see the table in the [Appendix \(section 8.6\)](#)).

2.2.1. PASCAL Wireless Printer



A small, portable, wireless printer is available as an optional accessory. It is compatible with "wireless-enabled" PASCAL WIRELESS Tonometer systems only.

2.2.2. Adapter Kit for Haag-Streit-type Slit Lamps

An ADAPTER KIT, consisting of a BASE PLATE and a FOOTPLATE, is available, as an optional accessory, for mounting the PASCAL device on Haag-Streit slit lamps. The FOOTPLATE has a peg that fits into the hole on the central slit lamp axis, in lieu of the original Haag-Streit base plate used to align a Hruby Lens. The FOOTPLATE will also fit onto most Haag-Streit-type "clone" slit lamps from other manufacturers. The standard Adapter Kit will be appropriate for all Haag-Streit-type slit lamps where the vertical distance from the hole on the central slit lamp axis to the optical axis of the microscope is 17.4 cm (approx. 6 ⁷/₈"). For models with different vertical distances, special Adapter Kits are available on request.

2.2.3. Test Kit

The PASCAL Test Kit is an optional accessory. It consists of an apparatus which allows the user to check the proper calibration of their SENSORTIPS. Users who do not purchase the test kit may have these functional tests performed by an SMT-accredited Service Center.

2.2.4. Additional SENSORTIPS

In its basic configuration, a PASCAL system comes with one exchangeable and reusable SENSORTIP. Additional SENSORTIPS may be purchased separately. Each SENSORTIP is individually calibrated at the factory. The appropriate calibration value is stored in the SENSORTIP's circuitry and is automatically recognized by the Main Unit.

2.2.5. SENSORCAP[™] Disposable Tip Covers

SENSORCAP Disposable Tip Covers, made from medical-grade silicone, are placed over the SENSORTIP **for each use** in order to prevent contamination and infection, and to protect the pressure sensor from the corrosive effects of the patient's tear film. The AppliPack packaging serves as a tool to simplify the fitting of a SENSORCAP over the SENSORTIP before use. AppliPacks and SENSORCAPs are single-use and must be discarded after use. An initial supply of SENSORCAP[™] tip covers comes with the system. Additional SENSORCAPs are available in quantities of 240 per box. The PASCAL should always be used with a fresh SENSORCAP for each patient.

2.2.6. Non-rechargeable Battery Packs

Please contact your distributor to purchase additional disposable single-use battery packs (available in packages of 5), and make sure to have at least one battery pack ready as a replacement when the original battery pack runs low. A non-rechargeable battery pack will last for several months, depending on frequency of use.

2.2.7. Rechargeable Battery Packs

As an alternative to the non-rechargeable battery packs supplied with the PASCAL systems, rechargeable battery packs are available as an option. The optional Rechargeable Battery Kit includes a battery charging base and two rechargeable battery packs. Rechargeable battery packs may be left charging in the battery charging base without worry of over-charging.

2.3. Additional required material (not supplied)

The PASCAL Tonometer requires a standard **slit lamp microscope**, on which it is mounted for operation. Most commonly used types of slit lamps may be used in conjunction with PASCAL. The Main Unit can usually be mounted directly, by means of the Mounting Bracket or Base Plate, in lieu of the Goldmann Tonometer.

For cleaning the Main Unit housing, tissue swabs pre-soaked with **Isopropyl Alcohol** are recommended (e.g. "Alcohol Swabs" by Becton-Dickinson).

For cleaning the SENSORTIP, **water only** should be used. If necessary, a few drops of clear **household soap solution** may be added. Avoid getting water on the circuit board of the SENSORTIP. To remove any dust particles from the SENSORTIP surface, a pressurized **inert gas** from a spray can is recommended. Blowing off particles sticking to the tip surface often works best if done while SENSORTIP is still wet. Appropriate products are available under names such as "Dust-Off" or "Dust-Free" from computer/electronics shops, hardware stores or drugstores.

For **topical anesthesia** of eye(s) to be examined, low-viscosity anesthetic eye drops (e.g. proparacaine, tetracaine, oxybuprocaine, novesine) are required. Fluorescein is not necessary.

3. Safety Instructions

3.1. Intended Use

PASCAL is a Class IIa medical device, intended for in-office use by ophthalmologists (and in the USA and UK, by optometrists).

3.2. Patient Safety



Always apply topical anesthesia before using PASCAL on patient's eye.



Caution and professional judgment should be used when attempting to use PASCAL on patients with eye diseases; particularly in cases of exterior eye infections, epithelium damage or corneal damage or pathology.



To avoid infection or contamination, PASCAL must be used only with a SENSORCAP Disposable Tip Cover applied over the SENSORTIP. For each patient, a fresh SENSORCAP taken from the sterile AppliPack must be used. Note that besides putting patients at risk, using the device without a SENSORCAP may also cause damage to the SENSORTIP and may give rise to measurement errors.



Before each use, check the SENSORTIP carefully for any damage to its surface which might expose the patient to a risk of local corneal abrasion.



Do not advance PASCAL towards patient beyond the maximum excursion range of the CANTILEVER. If the alarm sounds (repeated beeping), retract immediately.

3.3. Operational Safety



Do not soak or immerse SENSORTIPS in any liquids. Electrical contacts and electronic components may get irreversibly damaged.



Avoid contact of Main Unit with any liquids other than moderate amounts of alcohol (ethyl or isopropyl alcohol) used for cleaning.



The SENSORTIP may be cleaned cautiously, using water with a few drops of liquid soap added, if it has been inadvertently contaminated. Repetitive, frequent cleaning may damage the tip. Therefore, do not use the SENSORTIP without the protection provided by a SENSORCAP tip cover.



Do not touch the contour surface of SENSORTIP, or any other system components, with any hard objects, abrasive cleaning agents, or any cloth or paper towels containing hard fibers. SENSORTIPS that are not being used should always be stored in their container to prevent damage to the contact surface or to the electrical contacts.



Activate the Blue Knob with a gentle twist (approx. 10° rotation only). Parts may break if excessive force is used.



Handle CANTILEVER gently. Excessive force acting on it may cause improper functioning and may generate erroneous IOP results.



Disposable Battery Packs are not rechargeable. Use only original PASCAL Battery Packs supplied by SMT or accredited dealers.



Do not open the Main Unit. Attempting to do so will void the Warranty.



Only accessories, parts and consumables supplied by SMT should be used. Use of third-party items may pose a safety hazard and may void the warranty.



(Applies to PASCAL WIRELESS systems only:) Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.




This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

4. Procedures



Some of the procedures described in this section (marked with a  symbol) are available as video sequences on DVD. For gaining a better understanding, it is recommended to follow the appropriate sections of the instruction video while studying the user manual.

4.1. System set-up

4.1.1. Attaching PASCAL to your slit lamp [\(Click here to play movie clip\)](#)

There are multiple ways of attaching the PASCAL Main Unit to a slit lamp, depending on type of slit lamp and tonometer attachment bracket available with your slit lamp:

- a) Many slit lamps have a **short swing arm bracket**, attached either on top or on the side of the microscope, from which a tonometer is suspended. The bracket holds the tonometer by either one screw and two centering pins (S1 mount; Fig. 4), or by two screws (S2 mount; Fig. 5) which attach to the top of the tonometer. Unscrew the Goldmann tonometer and attach the PASCAL tonometer in its place, using the fixtures on the Mounting Bracket and the screws provided with the PASCAL system.

Fig. 3 PASCAL mounted on short swing arm bracket

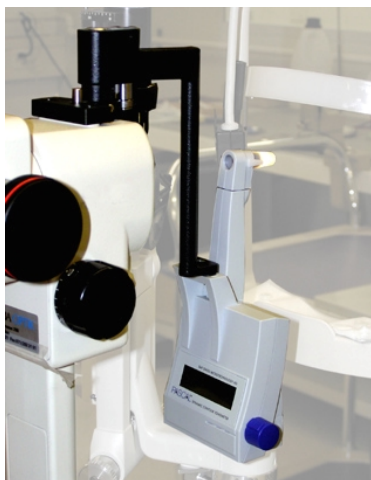


Fig. 4 Mounting Bracket with S1 guides



Fig. 5 Mounting Bracket with S2 guides



PASCAL must be ordered with either S1-type bracket or S2-type bracket, as required, if you plan to suspend the unit from its mounting bracket onto a short swing arm.



The screws used for the Goldmann tonometer are too long and should not be used for attaching the PASCAL to the tonometer bracket.



- b) Some slit lamps have a Goldmann tonometer attached by means of a **long swing arm bracket** which slides onto the accessory mount on top of the microscope and is screwed into the base of the Goldmann Tonometer. To attach the PASCAL in lieu of the Goldmann, the BASE PLATE is required. Unscrew the Goldmann and keep the screw. Screw the PASCAL's BASE PLATE onto the swing arm using the alignment pin and the hole provided in the BASE PLATE. Mount the PASCAL onto the BASE PLATE by aligning the two holes found in the bottom of the PASCAL Main Unit with the two corresponding pegs protruding from the BASE PLATE. Insert the key pin and slide it over to firmly lock the PASCAL to the BASE PLATE. Re-attach the swing arm bracket to the slit lamp. (Fig. 6)

Fig. 6 PASCAL mounted on slit lamp



- c) Using the optional Adapter Kit (311.640.005), the Main Unit may be directly mounted on the central axis of most slit lamp types. Mount the PASCAL onto the BASE PLATE by aligning the two holes found in the bottom of the PASCAL Main Unit with the two corresponding pegs protruding from the BASE PLATE. Insert the key pin (311.640.103) and slide it over to firmly lock the PASCAL to the BASE PLATE. Screw the FOOTPLATE onto the BASE PLATE by means of the screw provided. Then fit the peg of the FOOTPLATE into the hole in the slit lamp axis and turn until the FOOTPLATE drops into place on the alignment bar (Fig. 7; Fig. 8).
- d) **Special Configurations:** Some types of slit lamps require a different kind of FOOTPLATE . For some types of slit lamps, suitable swing arm brackets are also available. Please contact your distributor for details on available special adapter kits.

Fig. 7 Main Unit with attached BASE PLATE and FOOTPLATE being inserted on slit lamp central axis.

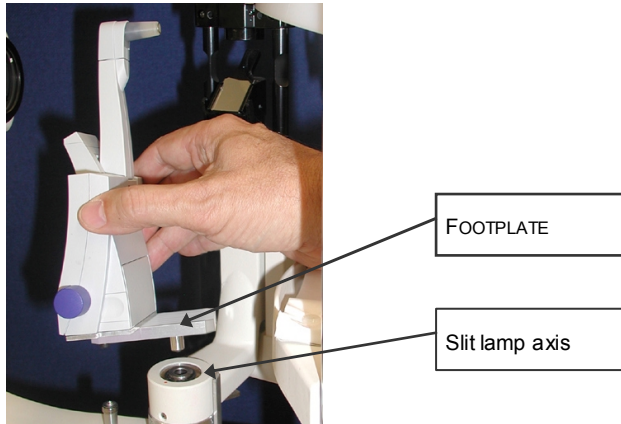


Fig. 8 PASCAL mounted on slit lamp axis by means of BASE PLATE and FOOTPLATE.



On some slit lamps, the receptacle for the FOOTPLATE peg may be corroded, impeding easy insertion of the peg. Use fine sandpaper to remove any corroded material and to ensure an easy fit for the FOOTPLATE.



To store your PASCAL Main Unit in its carrying case, you will need to remove the FOOTPLATE. Carefully store Plate and attachment screw in the carrying case for future use.

4.1.2. Readyng PASCAL for taking measurements

[\(Click here to play movie clip\)](#)

- 1) Remove PASCAL Main Unit from the carrying case.
- 2) Insert a battery pack, making sure it snaps into place and will not fall out when tilting the device.
- 3) Install PASCAL on your slit lamp using one of the procedures described in [section 4.1.1](#) above.
- 4) Prepare a SENSORTIP by fitting a SENSORCAP as described in [section 4.2.1](#) below.
- 5) Holding the prepared SENSORTIP between thumb and forefinger so that the surface with the electrical contacts is facing down, insert the SENSORTIP into the Tip Carrier. To facilitate this process, the Tip Carrier may be rotated out of its operating position to either side (by a maximum of 90°). Supporting the Tip Carrier with your opposite hand, gently push the SENSORTIP into the Tip Carrier all the way. Rotate

the Tip Carrier back into its operating position and make sure it is properly aligned with the optical axis of the slit lamp.

- 6) Looking through the left ocular of the slit lamp microscope, you should now see straight through the SENSORTIP. The microscope's magnification should be set to a moderate level (e.g. 6x). The pressure sensor should be visible as a greenish square in the center of a white circular spot in the center of your visual field. The vertical lines you see below the pressure sensor are the electrical wires that connect to the computer. Any other lines in your visual field are probably wrinkles in the SensorCap which should be remedied before proceeding. If the pressure sensor appears to be substantially off-center, the PASCAL unit may have to be realigned for your slit lamp. Contact your distributor or SMT Service if you need help with the alignment.
- 7) Your PASCAL device is now ready for operation. You may wish to test its operation by activating the start switch: turn the Blue Knob gently in a clockwise direction (by about 10 degrees) until you feel a click. Hold until you hear a beep (about half a second), then release. Upon completion of an internal self-test, which takes approximately 3-5 seconds, the LCD will light up and display "never w/o cap! recording..." The LCD will then dim after a few seconds to preserve battery life, but the PASCAL is still active and awaiting data. You have 20 seconds following the initial activation of the LCD display to begin acquiring data. Do not contact the cornea prior to the LCD initially illuminating.
- 8) If you do not take any data at this time, the device will switch itself off after approximately 60 seconds.

4.2. Disposables and consumables

4.2.1. Fitting a SENSORCAP [Click here to play movie clip\)](#)

- 1) To fit a SENSORCAP over a SENSORTIP, remove SENSORTIP from Tip Carrier (or retrieve SENSORTIP from its container if not yet installed) by holding the Tip Carrier with one hand and pulling SENSORTIP carefully forward (towards patient side). You may turn the Tip Carrier by 90° to either side to facilitate this process.
- 2) Make sure that the SENSORTIP is free of dust and particles. Clean SENSORTIP (if necessary) by wiping gently with a piece of soft tissue that has been moistened with water, or by using a jet of compressed air.
- 3) Peel the cover from the AppliPack. Hold the SENSORTIP in one hand and the AppliPack in the other, and insert the pressure sensor end of the SENSORTIP into the AppliPack. Make sure that you insert the end of the SENSORTIP collinear with the AppliPack, and do not twist or rock the two pieces against each other.
- 4) Push the SENSORTIP into the AppliPack quite forcefully, until it goes no further. This will cause the rubber ball inside the AppliPack to push the cover membrane into the concave shape of the SENSORTIP, and will cause the membrane to adhere to the tip surface, eliminating all wrinkles and air-bubbles. Keep pushing firmly for a few moments, while making sure not to twist the two components against each other.

- 5) Slowly pull the SENSORTIP and AppliPack apart, without twisting or rocking. Remember: “Straight In, Straight Out!”.
- 6) Carefully verify proper fit of the SENSORCAP over the SENSORTIP. For this purpose it is recommended to hold the end of the SENSORTIP into the optical path of the slit lamp, at an angle toward the incipient light, for good visibility of the concave tip surface. No air bubbles should be visible underneath the SENSORCAP, and its membrane should fit snugly, without any wrinkles, against the curved contact surface of the SENSORTIP. (Fig. 9; Fig. 10; Fig. 11)

Fig. 9 SENSORTIP with applied SENSORCAP (**correct fit**): membrane of Cap follows curved tip surface smoothly; no folds or air pockets can be seen.



Fig. 10 SENSORTIP with applied SENSORCAP (**incorrect fit**): membrane of Cap does not adhere to tip surface; stretching folds can be seen.

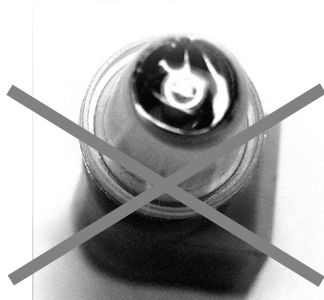
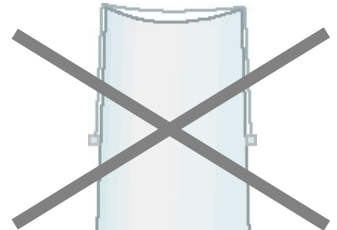


Fig. 11 SENSORTIP with applied SENSORCAP (**incorrect fit**): membrane of Cap does not adhere to tip surface; air bubble fills entire space between tip and membrane.



Never use the same SENSORCAP on more than one patient. Attempting to wipe the SENSORCAP may damage it and may cause instrument malfunction.



It is usually considered safe to use the same SENSORCAP on both eyes of the same patient. This may help expedite your work with the patient and help avoid interruption in your patient session.



Using the SENSORTIP without SENSORCAPs will cause it to deteriorate quickly, and may necessitate expensive replacement. Working with unprotected SENSORTIPS exposes patient to risk of cross-contamination from previous patients.



DISPOSAL: Used SENSORCAPs should be disposed of with other medical office waste. All disposals should be carried out in accordance with applicable local and national regulations.

4.2.2. Replacing the Battery

- 1) Hold the PASCAL Main Unit in one hand. With the other hand, compress the two holding clips of the installed Battery Pack and remove it.
- 2) Insert a new Battery Pack, making sure it snaps into place and will not fall out when tilting the device.
- 3) Dispose of the used Battery Pack according to local requirements for recycling of waste.



Do not attempt to recharge a disposable Battery Pack.

4.2.3. Replacing the SENSORTIP

- 1) To switch from one SENSORTIP to another, simply pull the one out and insert the other one. The individual factory-set calibration value of each SENSORTIP is stored in the SENSORTIP's memory chip. Therefore, PASCAL will measure correctly with each SENSORTIP used, without any calibration adjustment required.
- 2) Before use, any SENSORTIP should be carefully inspected under the microscope for any damage or contamination. Clean the tip if necessary, following the instructions provided in [section 3.3](#). If you are unsure about your tip's integrity, do not use it. You may send it to a PASCAL Service Center for inspection if in doubt, accompanied by a report of your observations.



4.3. Preparations for taking measurements

Once PASCAL has been set up on your slit lamp as described in [section 4.1](#), you are ready to use the device without any further preparations, similar to a conventional Goldmann applanation tonometer:

- 1) Make sure PASCAL is mounted and properly aligned on the slit lamp.
- 2) Set illumination on slit lamp to intermediate, using white light, to allow easy viewing of the SENSORTIP /cornea interface. Avoid uncomfortably bright illumination for patient comfort.
- 3) Install a SENSORCAP Disposable Tip Cover, as per the instructions in [section 4.2.1](#).
- 4) Apply a drop of anesthetic to patient's eye (or both eyes). No addition of Fluorescein is required.
- 5) Bring the patient into proper, comfortable position for slit lamp inspection. Ask the patient to cooperate by holding eye wide open and by looking straight ahead (The fixation light available on some slit lamps may be a useful aid. Also, keeping the room lights on will help with the patient's fixation).
- 6) Proceed with [section 4.4](#) to take an IOP measurement.

4.4. Taking measurements

[\(Click here to play movie clip\)](#)



At this point, if no fresh SENSORCAP is in place protecting the SENSORTIP from direct eye contact, do not proceed. Install a new SENSORCAP Disposable Tip Cover first, as per the instructions in section 4.2.1.

- 7) Have the patient blink a few times and then, looking from the side, align the end of the SENSORTIP close to the apex of the patient's cornea.
- 8) Switch PASCAL unit on by turning Blue Knob gently in clockwise direction (by about 10 degrees) until you feel a click; then release the knob. Upon completion of an internal self-test, which takes approximately 3 seconds, the LCD will display a reminder message "never w/o Cap!". The second line of the LCD display will read "recording...", indicating that the device is now active and ready to record data.
- 9) Now, looking through the left ocular, carefully advance the slit lamp until the surface of the SENSORTIP touches the cornea. Continue advancing until the CANTILEVER is in an upright position. The PASCAL will sound an alert if the CANTILEVER comes too close to the end of its travel range. (Fig. 12)

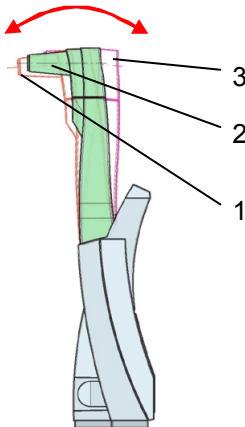


Fig. 12 Motion of PASCAL CANTILEVER and SENSORTIP:

- 1 Before SENSORTIP touches eye, or if patient moves away from the slit lamp, CANTILEVER (red) tilts forward.
- 2 As PASCAL moves towards patient, CANTILEVER (green) will be pushed back vertical and the contact surface will move slightly upwards due to the circular trajectory of the SENSORTIP.
- 3 If the PASCAL is advanced too far, CANTILEVER (pink) will tilt backward, and the end-of-range alert will sound (persistent, repetitive beeps).

Note: Cantilever will be in optimum (green) position for measurements when circular contact area reaches its highest position as seen through the left ocular of the slit lamp.

- 10) Observe the area where the SENSORTIP touches the patient's cornea. This "Contact Zone" will appear as a darker area that becomes circular when the SENSORTIP is properly centered. Using the joystick on the slit lamp, adjust the position of the SENSORTIP slightly until the opaque spot enclosing the blue-green square of the pressure sensor is concentric with the Contact Zone.

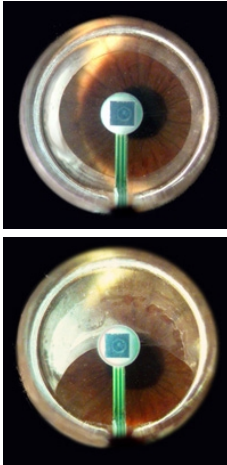


Fig. 13 View of Contact Zone and pressure sensor through slit lamp microscope.

The opaque spot in the center is the pressure sensor obstructing the view of the eye. Notice that for proper alignment the pressure sensor should be centered on the Contact Zone, and not necessarily centered on the pupil.

The circular Contact Zone is darker than the surrounding area, with the tear film border clearly visible. Contact Zone should be centered around sensor (in this photograph, sensor appears very slightly displaced towards nine o'clock, but centration is sufficient for obtaining a good, valid pressure reading).

Fig. 14 Contact Zone misaligned.

In this view, SensorTip is placed too high on the eye. Move slit lamp down to bring Contact Zone into proper alignment.

In a situation as shown, the sensor will not detect any pressure, and no audio feedback sound will be heard. As soon as the sensor moves into the center of the Contact Zone, the sound will be heard and a regular measurement can be taken.

- 11) Listen for a regular continuous oscillating sound, which is generated by the pulsating IOP when the SENSORTIP has established correct contact and alignment with the cornea. Count approximately five to seven consecutive undisturbed waveforms. If during measurement the CANTILEVER is not deflected away from its forward position enough, the oscillating sound will be intermittent and irregular. If this occurs, push the joystick towards the patient, at which time the intermittent oscillating sound will become continuous. If the CANTILEVER is deflected back too far, an alert (persistent repetitive beeps) will sound.



If the Cantilever alert (persistent repetitive beeps) sounds during measurement, pull the PASCAL and slit lamp away from the patient's eye. Advancing the device further towards the patient while the alert sounds might exert excess force on the patient's eye, causing injury.

- 12) After counting approximately five to seven waveforms of the oscillating sound, swiftly retract the slit lamp and the SENSORTIP away from the patient's eye. When the pressure sensed by the PASCAL drops to zero upon interruption of contact with the cornea, the sound will vanish and a double beep will confirm that the zero pressure baseline has been detected. This decoupling of the SENSORTIP from the cornea will be referred to as performing an "Interrupt", or an "Interrupt Maneuver". It is an important concept in taking valid IOP measurements with PASCAL and will be discussed in detail in [section 5.1](#).

- 13) The PASCAL will now compute IOP (Intra-ocular Pressure) and OPA (Ocular Pulse Amplitude) from the pressure curve just recorded. The LCD will illuminate for 20 seconds and display the result for a total of 40 seconds. (Fig. 15)

mmHg:	IOP	19.4
Q=1	OPA	3.2

Fig. 15 LCD display of an exam result after completion of measurement (example):

IOP Intra-ocular Pressure 19.4 mmHg
 OPA Ocular Pulse Amplitude 3.2 mmHg
 Q Quality score 1 (best)

- 14) Make a note of the values being displayed. Display will switch off after 30 seconds and the system will be ready for the next measurement.



In fact, the system will be ready for the subsequent measurement as soon as the result has been computed and displayed. As soon as this has happened, you may initiate the next measurement; but be aware that upon doing so the displayed result will disappear from the LCD.



PASCAL WIRELESS tonometers equipped for wireless communication (optional) will send the result to a printer if a compatible printer is found and if this option is enabled. For details see [section 5.3](#)



Results remain stored in the device's memory even after the display has disappeared. To re-display results from previous measurements, refer to [section 5.2.2](#).

- 15) Restart this procedure [at step 8\)](#) above for the next measurement.

5. PASCAL Operating Instructions

5.1. Basic Procedures

5.1.1. The Blue Knob

PASCAL is operated by means of a single control: the “Blue Knob”. Located on the lower right-hand side of the device (as seen from the operator’s side), the Blue Knob is activated by turning the knob slightly in a clockwise direction. After an approximately 10° turn, you will feel a “click”, which is a sensory feedback telling you the switch behind the knob has been activated.

The Blue Knob responds to “short clicks” and to “long clicks”. Short clicks are performed by holding the knob in the activated position for less than 1.5 seconds and long clicks are performed by holding the knob in the activated position for longer than 1.5 seconds before releasing it.

A single short click will activate the PASCAL to initiate a measurement. Once the message “never w/o cap! Recording...” is displayed on the LCD, you have 20 seconds to start taking data. If no incoming data are being detected within that period, the device will shut itself off to preserve battery power.

If the PASCAL is detecting data points different from zero pressure, it will continue recording these data to memory until pressure readings drop to zero, indicating that the SENSORTIP is no longer in contact with the patient’s cornea, or until memory is full (approx. 3 minutes).

Short clicks and long clicks of the Blue Knob are discussed further in [section 5.2](#).

5.1.2. The Interrupt Maneuver

PASCAL’s built-in software is capable of computing the correct IOP and OPA values from the pressure curve recorded in memory. For this routine to function properly, PASCAL must know the exact position of the zero pressure baseline. This is determined by the software immediately after the user terminates the measurement by pulling the SENSORTIP away from the patient’s cornea during the Interrupt Maneuver.

During a measurement, the software continuously monitors the incoming data, looking for a sequence of data points that will match the characteristic pattern of a correctly performed Interrupt Maneuver. Such an Interrupt Pattern will occur when the operator swiftly pulls the SENSORTIP away from the cornea by retracting the slit lamp. If the pressure signal intermittently drops for other reasons (e.g. because of patient’s movements or blinking, or due to the Contact Zone moving temporarily off-center), no Interrupt will be recognized and the PASCAL will continue taking data (even though the sound may disappear for a short moment).

When a successful Interrupt Pattern is detected, the program will terminate the current measurement and start computation of the results. This is signaled to the operator by two short beeps. If you do not hear the two short beeps when you retract the slit lamp, the software did not recognize a satisfactory Interrupt Pattern and the measurement must be repeated.

5.2. Other operations

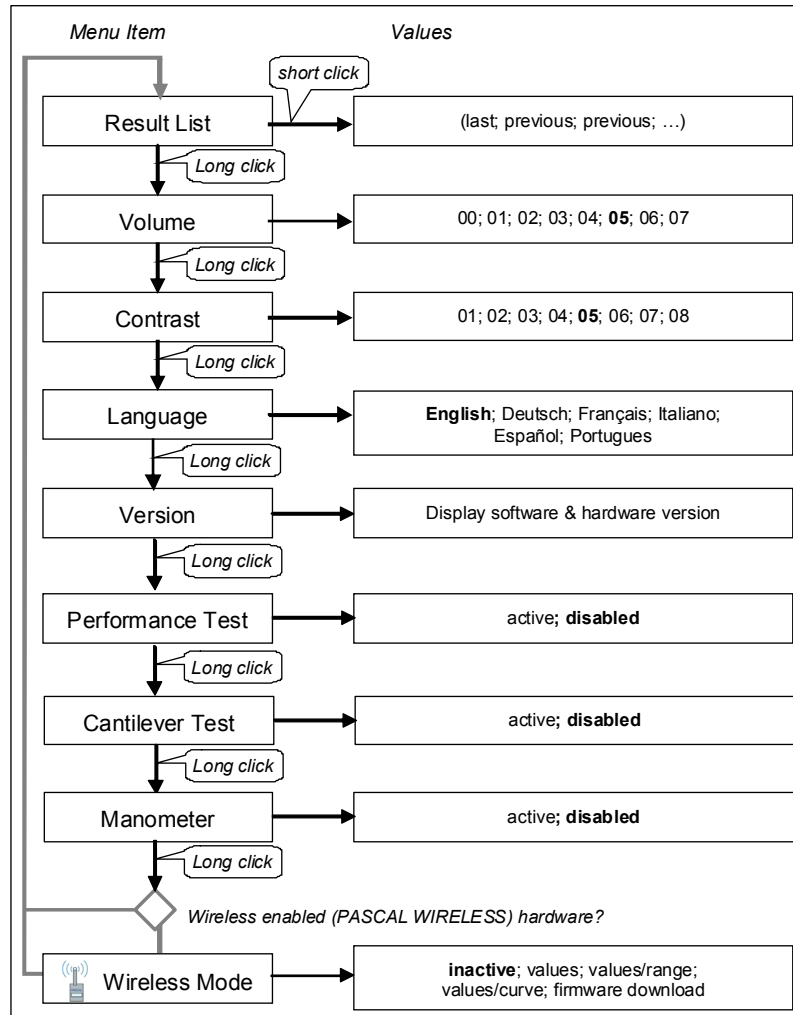
5.2.1. Adjusting PASCAL user settings [\(Click here to play movie clip\)](#)

Several instrument settings may be adjusted by the user to suit individual preferences. User settings are accessed while the PASCAL is active (i.e. is in recording mode and the LCD is active) by a "long click" (holding the Blue Knob in the activated position for approximately 2 seconds). Repeated "long clicks" will toggle through the User Settings Menu as per Fig. 16. When a selected menu item is being displayed, its value may be adjusted within its defined limits by repeated "short clicks". Both menu selections and value settings will cycle; i.e. after the last value, the first one will appear again.

- a) Prior Results List: see next section.
- b) Language: Messages and parameters displayed by the program are available in several languages. Toggle to your preferred language with repeated "short clicks"; then proceed to next menu item with a "long click". Factory setting is "English".
- c) Volume: The loudness of the audio feedback may be adjusted from 0 (off) to 7 (loud) with repeated "short clicks". Factory setting is 4.
- d) Contrast: The contrast of the LCD may be adjusted from 1 (low contrast) to 8 (maximum contrast). Factory setting is 2.
- e) Version: The version number of the installed system software, and the serial numbers / version numbers of Main Unit (M), Battery (B), and SensorTip (T) are displayed in abbreviated form. (These values are for display only; they may not be adjusted by user).
- f) Performance Test: (see [section 6.1.1](#)) A special operating mode for performing a functional test may be activated with one short click. Displayed message will change from "disabled" to "active".
- g) CANTILEVER Test: (see [section 6.1.2](#)) A special operating mode for checking proper mechanical functioning of the CANTILEVER may be activated with one short click. Displayed message will change from "disabled" to "active".
- h) Manometer Mode: (see [section 6.1.3](#)) A special operating mode for checking proper functioning of the pressure sensor may be activated with one short click. Displayed message will change from "disabled" to "active".
- i) Printer Status (see [section 5.3](#)): This item is only displayed on PASCAL WIRELESS systems which are enabled for wireless communication. The currently active mode is displayed and may be changed by "short clicks".



Fig. 16: User Settings and their allowed values:



5.2.2. The Prior Results List

A list containing the results of the last 10 measurements may be accessed via the User Settings Menu as described in section 5.2.1 above. Results are presented in the order in which they were recorded, with the last (most recent) result being shown first. For identification, the unique exam number associated with each measurement is displayed, along with IOP, OPA, Q score, and estimated heart rate. (Fig. 17)

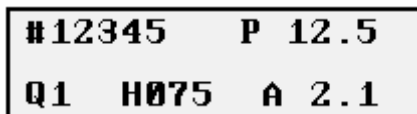


Fig. 17 Display of an exam result in Results List (example):

#	Exam number (12345)
P	intra-ocular pressure (IOP) 12.5 mmHg
Q	Quality score 1 (best)
H	Heart rate 75 beats/min
A	Ocular Pulse Amplitude (OPA) 2.1 mmHg

Note: Heart rate is a rough estimate for the patient's pulse rate, derived from just a few systoles and diastoles. The value provided by the algorithm may not correspond to what is obtained using standard medical procedures.



5.3. Wireless Communication (Printer and PC)

This section only applies to "PASCAL WIRELESS" systems, which have been enabled for wireless data communication. These units are characterized by a part number beginning with 311.111.xxx. For the wireless printing feature to function, a PASCAL wireless printer (p/n 311.660.001) must be available and active, and must be initialized as described in [section 5.3.1](#).

5.3.1. Getting started with the Printer

If the Printer was purchased together with a PASCAL WIRELESS unit, the system should already be set up for printing. In this situation, it is sufficient to turn the printer on, making sure no other printer is active at the same time. Perform a measurement with the PASCAL. A printout will automatically be generated. When this is done the first time, it may take the PASCAL approximately 10 seconds to establish connection, before the printer activates.

If the printer does not react, it may need to be activated and the PASCAL-Printer link initialized as detailed below.

5.3.2. Initializing the Printer

Make sure your PASCAL Tonometer is a wireless-enabled unit by checking the part number (311.111.xxx).

Place the printer in a location close to the PASCAL Tonometer (maximum distance: 10 meters or 30 feet). Verify that paper is loaded, the printer receives power from its batteries, and it is switched on (blue LED should be blinking slowly if printer is running on battery; permanently on if plugged into wall outlet). For the initialization of the printer, make sure any other compatible printers within the transmission range are switched off. For details on printer operation, please refer to manufacturer's manual.

Activate the PASCAL User Settings Menu and toggle to the item "wireless mode" as described in Section 5.2.1. In the "wireless mode" menu, perform "short clicks" of the Blue Knob to activate either one of the available printing modes ("print values", or "print val/range", or "print val/curve"). If no printer address has already been stored in the PASCAL's memory, the unit will now scan for any active PASCAL printers within its detection range. The ID of the first printer found is stored in a temporary "printer address" memory location. Wait for the PASCAL unit to power down to store the printer address permanently. This scan will be repeated in the future only if the installed printer is no longer available

Each time before PASCAL attempts to print, the status of the found printer will be interrogated. The status message received from the printer includes error flags for "open lid", "no paper", "wrong voltage", and "high print head temperature" conditions. Corresponding error messages are sequentially displayed on the PASCAL LCD. If an error shows, correct the condition, then, within 60 seconds, perform a single short click of the Blue Knob to acknowledge.

5.3.3. Setting Print Parameters

Once a printer has been found and stored in the PASCAL's memory, one of three available printing formats must be chosen from the Wireless Mode menu.

- "print values" will generate a basic printout which contains just numerical IOP, OPA, and Q values as displayed on the PASCAL LCD.
- "print val/range" will generate the same numerical values as above, plus a diagram showing a selected, expanded section of the patient's IOP curve.
- "print val/curve" is similar to "print val/range" above, but it will generate two curve views: one showing the entire curve recorded, and the other the expanded curve.

To select the desired printout format, enter the PASCAL User Settings menu with a long click of the Blue Knob, then toggle forward to "Wireless Mode" with repeated long clicks as described in Section 5.2.1. Then select the desired option with repeated short clicks. Confirm your choice with a long click, then wait for your PASCAL to power down.

5.3.4. Printing

When the printer has been initialized and appropriate print settings have been chosen, and if the printer is turned on, the result will automatically print each time a measurement is completed. To suppress printing, either deactivate printing in the User Settings menu, or turn the printer off.

If an error condition is detected, the appropriate error message will be displayed on the PASCAL LCD. Correct the error condition and perform a short click of the Blue Knob to acknowledge. If the result will still not print after 3 attempts to correct the error condition, the message "Aborted. Note result" will appear, and the result will be displayed on the LCD again, allowing the user to record it manually.

5.4. Reference information

5.4.1. Blue Knob Actions

User interaction with the PASCAL is by means of the Blue Knob. It permits switching between different modes of operation, and is used for navigating through the User Settings menu. The various types of Blue Knob actions are summarized in Table 1.

A "short click" has a duration of 200 μ s (minimum) to 1.5 seconds (maximum). A "long click" has a duration of 1.5 seconds (minimum) to 5 seconds (maximum).

Table 1 Summary of Blue Knob Actions

Situation; Operating Status	Blue Knob Action	Audio	Result
all states	brief touch	none	none
PASCAL is OFF	short click (sufficient to activate processor)	single beep	PASCAL starts up, performs internal function test, then (after approx. 3 seconds) switches on LCD backlight and starts receiving data. If no signal above threshold is detected, shut-down after 60 seconds. If no IOP/OPA found, display "IOP=N/A".
PASCAL is activated to take measurement	short click	single beep	start new measurement.
PASCAL is activated to take measurement	long click	none	measurement stopped. User Settings Menu is displayed, beginning with Prior Results list. If an IOP was already detected in current measurement, its result will appear in list.
measurement completed (Adequate Interrupt Maneuver)	none	double beep	Result is displayed for 10s with backlight illumination, plus 20s without illumination.
within 30 seconds after measurement is terminated	short click	none	start new measurement.
within 30 seconds after measurement is terminated	long click	none	User Settings Menu is displayed, beginning with Prior Results list.
User Settings Menu	short click	single beep (double for "Volume")	selected value is incremented.
User Settings Menu	long click	single beep	scrolls to next menu item.
User Settings Menu	no click within 5s	none	LCD goes off, PASCAL shuts down.

5.4.2. User Settings Menu

The parameters listed below may be adjusted by the user to personalize the operating environment of the PASCAL Tonometer. Values may be adjusted by means of the Blue Knob as detailed in Table 1.

- Prior Results List (not an adjustable setting, but accessed in the User Settings Menu)
 - The last 10 results (exam number, IOP, OPA, H, and Q).
- Volume
 - Used for adjusting loudness of audio output.
 - Value range / Format: "00" (mute) – "07" (maximum).
 - Default setting: 04.
- Contrast
 - Used for optimizing readability of the LCD display.
 - Value range / Format: "01" (maximum.) – "08" (minimum.).
 - Default setting: 02.
- Language
 - Used for selecting desired dialog language.
 - Value range / Format: "English", "Deutsch", "Français", "Italiano", "Español", "Portugues".
 - Default setting: English.
- Performance Test
 - Used for switching to Performance Test mode.
 - Value range / Format: "disabled", "active".
 - Default setting: disabled.
- CANTILEVER Test
 - Used for switching to CANTILEVER Test mode.
 - Value range / Format: "disabled", "active".
 - Default setting: disabled.
- MANOMETER Mode
 - Used for switching to Manometer mode.
 - Value range / Format: "disabled", "active".
 - Default setting: disabled.
- Wireless mode (available only on PASCAL WIRELESS systems)
 - Used mainly for initializing a printer and for selecting the type of output desired.
 - The option "firmw. download" is used to update the operating software
 - Value range / Format: "inactive", "print values", "print val/range", "print val/curve", "firmw. Download"
 - Default setting: inactive.





5.4.3. Printer Reference Information

For full details, refer to printer manual.

- To switch the printer on:
 - Push printer button (on top of transparent printer cover) for at least 1 second.
- To switch the printer off:
 - Push printer button twice. LED will flash rapidly, then turn off.
- To activate printer setup mode:
 - If printer is off, push printer button for at least 3 seconds; printer will print a test pattern.
 - Push printer button for 1 second to modify parameters (see printer manual for details).
 - Click on printer button to put printer into "on line" status.
- To change setup / activate parameters in setup mode:
 - To change a single parameter, click on printer button.
 - To confirm a single parameter and move on to next parameter, push printer button for 1 second.
 - When printer configuration is complete, printer will automatically be "on line".
- To replace printer batteries:
 - Remove cover of battery compartment by unscrewing the 2 screws.
 - Remove old batteries and insert 5 new AA alkaline penlight batteries (not rechargeable) as shown on bottom of battery compartment.
 - Close battery compartment by tightening the fastening screws.
- To replace paper roll:
 - Hold new paper roll with the end of the paper pointing towards you from the underside of the roll.
 - Open printer lid. Place paper roll inside paper compartment.
 - Pull paper end towards you and close lid.

5.4.4. Battery Charger Reference Information

The PASCAL battery charger base features a receptacle shaped to accommodate one rechargeable battery pack. The battery pack is inserted into, and removed from, the charger base in the same fashion as on the PASCAL Main Unit. Operating status of the charger base is monitored by means of two LEDs:

- Green LED at left: When lit, charger base is connected to power supply and is receiving correct voltage.
- LED at right: Red: charging. Green: charging complete.

When charging is complete, battery pack will receive a maintenance charge while left in the charger. Charger will recognize type of battery pack inserted. If a disposable, non-rechargeable battery pack is inserted, no charging will occur.

6. Care and Maintenance

6.1. System checks and calibrations

The PASCAL system performs a **self-calibration** each time the device is activated by a “short click” of the Blue Knob, setting its baseline to the prevailing atmospheric pressure. Furthermore, the system performs a **self-test** when activated, checking its settings and the proper functioning of electrical connections.

The user may perform functional tests if desired. The tests consist of two elements: a **cantilever test**, verifying proper mechanical functioning of the CANTILEVER, and a **manometric performance test**, which compares the pressure value detected by the SENSORTIP with that obtained from a reference. For the latter, the PASCAL Test Kit (available as an option) is required. Users who do not wish to perform these functional tests themselves may request their distributor or local service center to perform the tests at recommended intervals.

6.1.1. Performance Test



To perform this test, the PASCAL Test Kit (part no. 311.620.001) is required.

Performance Test mode is usually "disabled". It may be activated by executing a "short click" while the message "Performance test disabled" is being displayed. In active Performance Test mode, PASCAL will measure a static hydraulic pressure generated by the optional Performance Test Kit. In this mode the system software is not looking for pressure pulsations and Interrupt Maneuvers, but instead will detect a static pressure during a fixed time (15 seconds). To check the calibration of PASCAL's pressure sensing performance, remove the tonometer from the slit lamp and perform the following operations (procedure is also printed on the surface of the Test Kit):

- 1) Place PASCAL Tonometer on tonometer holder plate.
- 2) Place Test Container, standing on its long side) into gap in holder plate.
- 3) Fill Test Container with room temperature water to fill level.
- 4) Connect tube to SensorTip mounted in PASCAL Tonometer.
- 5) Push vent button for 2 seconds to vent Test Container.
- 6) Activate PASCAL unit (short click on Blue Knob)
- 7) Enter User Settings Menu (long click on Blue Knob; Prior Results List appears).

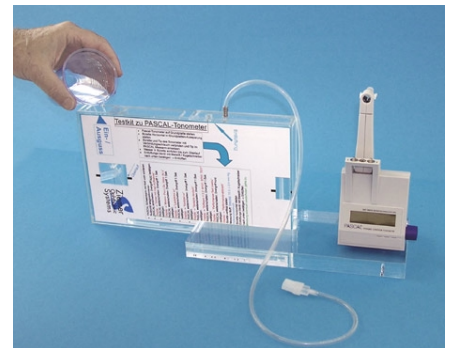


Fig. 18 Performance Test Kit

- 8) Advance through menu settings until "Performance Test disabled" appears (6 long clicks).
- 9) Activate Performance Test (short click); "Performance Test active" appears.
- 10) Turn Container 90 degrees clockwise, to stand on short side.
- 11) Repeated beeps indicate that test is running. Wait until terminated.
Note result: Acceptable values are 15.0 ± 0.4 mmHg
- 12) To repeat test:
Turn Container 90 degrees counter-clockwise, to stand on long side. Repeat procedure from step 5
- 13) To end testing:
 - a) Disconnect tube from PASCAL.
 - b) Drain all water from Container.
 - c) Wait for PASCAL to shut off. Upon next turn-on, it will reset automatically to normal measurement mode.

The result displayed should be in the range 14.6 to 15.4 mmHg. If inconsistent results are obtained from repeated tests, or if the test result is consistently out-of-range, the SENSORTIP and the manometric test kit should be sent to an authorized service center for inspection and repair or re-calibration.

It is recommended that the performance test be performed at regular intervals, at least once a year. The test should be performed on all SENSORTIPS in use. If several or all of your SENSORTIPS fail the performance test, a failure in the pressure detection circuitry of the PASCAL Main Unit must be suspected. If this occurs, the PASCAL and all SENSORTIPS, together with the Test Kit, should be sent to the service center.

6.1.2. Cantilever Test

This test may be performed while the PASCAL Main Unit is mounted on the slit lamp, or by placing the device upright on a flat surface and holding it firmly. Activate the CANTILEVER Test mode from within the User Settings menu as described in [Section 5.2.1](#), then gently move the CANTILEVER back and forth over its entire range of travel. If CANTILEVER is in its resting (forward) position, the PASCAL will be silent. If CANTILEVER is at or near its fully deflected position, an acoustic signal (2000 Hz beep) will be heard. If CANTILEVER is in its correct working position for measuring patients, a lower-pitched acoustic signal (1000 Hz beep) will be heard. The test is successfully passed if the acoustic signals in both sections of the CANTILEVER range of travel are heard correctly. If no signals are heard, or if a signal is heard while CANTILEVER is in its resting position, the test should be regarded as "failed".

It is recommended that the cantilever test be performed at regular intervals, every one to three months. The test should be performed immediately if the PASCAL device was dropped, or if any other unusual force might have been applied to the CANTILEVER.



If CANTILEVER Test fails, the PASCAL device should not be used on patients. Have your PASCAL serviced immediately by an authorized service facility.

6.1.3. Manometer Mode

When PASCAL is in Manometer Mode, it will continuously display the manometric pressure, relative to atmospheric pressure, detected by the pressure sensor. In this mode, the PASCAL may thus be tested directly against a manometric standard.

6.1.4. Calibration of Main Unit and SENSORTIPS

Calibration requires special equipment and can only be performed by an authorized service center. A calibration procedure is only required if the Performance Test has indicated a calibration failure.

6.2. Cleaning

Neither the PASCAL Main Unit nor the SENSORTIPS may be sterilized.

For cleaning the Main Unit housing, tissue swabs pre-soaked with **Isopropyl Alcohol** are recommended (e.g. "Alcohol Swabs" by Becton-Dickinson).

For cleaning the SENSORTIP, **water only** should be used. If necessary, a few drops of clear **household soap solution** may be added. Avoid getting any liquid on the circuit board of the SENSORTIP. To remove dust particles from the SENSORTIP surface, a pressurized **inert gas** from a spray can is recommended. Appropriate products are available under names such as "Dust-Off" or "Dust-Free" from computer or electronics shops, hardware stores, or drugstores.



Frequent contact with alcohol or frequent mechanical cleaning may damage the contact surface of SENSORTIPS and may cause malfunction. Do not immerse Main Unit in water or other liquids. Do not attempt to clean and re-use SENSORCAP disposable tip covers, as this might cause invisible fractures of the protective membrane and hence create a contamination risk.

6.3. Maintenance and repair service



Only original parts supplied by SMT should be used with PASCAL. Using any non-SMT parts will void any warranty and may cause improper functioning of the device.



No servicing of PASCAL may be performed by the user, with the exception of the functional tests described in [sections 6.1.2](#) and [6.1.1](#). All service must be carried out by the manufacturer or by an SMT-authorized service center.



Do not attempt to modify or alter your PASCAL Tonometer.



(PASCAL WIRELESS systems only:) Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Occasionally, system software upgrades for PASCAL may become available. Regularly check the SMT website, or ask your distributor, for upgrade information. Such upgrades may only be performed by an authorized service center.

6.4. Disposal

Used battery packs should be disposed of separately, together with other used batteries. Battery Packs contain aggressive liquids which may be harmful if spilled.

Used SENSORCAP tip covers should be disposed of with other medical office waste.

All disposal should be carried out in accordance with applicable local and national regulations.

7. Troubleshooting

Use the Troubleshooting guide and/or the table of alerts and status messages, provided below, to determine the possible causes of observed system behavior, and to receive suggestions for appropriate action. You may also find the “Questions and Answers” and the “Tips and Tricks” sections useful for getting familiar with your PASCAL Tonometer and for becoming more proficient in its use.




Watching the Video DVD "Working with PASCAL" (available from your distributor) may be useful for identifying and correcting possible problems associated with operating the PASCAL Tonometer.

7.1. Troubleshooting guide

<i>Observed behavior</i>	<i>Possible cause</i>	<i>Action to take</i>
Upon activating the Blue Knob, nothing happens	Battery Pack missing, or not fully inserted.	Insert Battery Pack and make sure it snaps into place.
	Discharged battery	Replace battery
	Click too short	Starting up the device's microprocessor takes a short moment. Hold the Knob in the "ON" position until you hear a beep.
LCD backlight does not stay on	Backlighting is only briefly active at activation and when result is displayed	(None. This is by design, to save battery life).
Can't hear audio feedback when recording data.	Volume may be set too low, or may be off.	Access the User Settings Menu, choose "Volume", and set a higher number. If unsuccessful, contact your distributor.
	Eye may not be touching the pressure sensor; SENSORTIP not aligned correctly on eye.	Move the PASCAL, by using the slit lamp's joystick, in order to have the pressure sensor centered on the contact area, as depicted in Fig. 13 .
	Maybe a wrinkle or air-bubble in SENSORCAP.	Reapply SENSORCAP.
	SensorTip may be touching patient's eyelid or eyelashes.	Verify positioning of SensorTip by looking from the side; instruct patient to open eyes, or assist by holding lid open; re-start procedure.

<i>Observed behavior</i>	<i>Possible cause</i>	<i>Action to take</i>
	PASCAL not turned on.	Remove SensorTip from eye, activate PASCAL, wait for LCD to illuminate before contacting the eye with the SensorTip.
	PASCAL activated after the SensorTip was applied to the eye.	Remove SensorTip from eye, activate PASCAL again, wait for LCD to illuminate before contacting the eye with the SensorTip.
Sound is too loud when recording data.	Volume set too high.	Access the User Settings Menu, choose "Volume", and set a lower number. Set to zero to turn sound off.
Sound is interrupted when recording data.	CANTILEVER has not traveled far enough.	Move slit lamp slightly forward (towards patient).
Intermittent beeps while recording.	CANTILEVER has traveled too far (you are too close to eye).	Move slit lamp slightly back (towards you; away from patient)
Text on LCD is hard to read.	LCD contrast may be set too low.	Access the User Settings Menu, choose "Contrast", and set a lower number. If unsuccessful, contact your distributor.
After lifting off the eye, recording does not stop. (No double beep and no result display on LCD)	Software did not recognize a valid Interrupt Maneuver.	Contact eye again and repeat measurement. Lift off the eye swiftly using slit lamp's joystick.
	PASCAL may be set to record several Interrupts before stopping (non-standard setting for clinical study use only).	Contact SMT Service to reset PASCAL's internal settings.
Result shows Q score of 4 or 5.	Poor quality data (improper eye contact, excessive eye movement, electronic interference)	Discard measurement and repeat.
Result shows a number for IOP but "OPA = n/a" even though you can hear the oscillating sound during measurement.	Poor quality data (improper eye contact, excessive eye movement, electronic interference)	Discard measurement and repeat.
	Observation period was too short	Repeat measurement; keep SENSORTIP on eye for at least five waveforms of the oscillating sound.

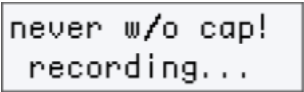



<i>Observed behavior</i>	<i>Possible cause</i>	<i>Action to take</i>
Result shows a number for IOP but "OPA = n/a", and the sound heard during measurement does not seem to oscillate in pitch.	Patient has a very low OPA (OPA < 0.5 mmHg.)	Device unable to detect such a small OPA. Note OPA as "not detectable".
Error Message: "Check Tip"	No SENSORTIP in Tip Carrier	Insert a SENSORTIP
	Bad contact; SENSORTIP not fully inserted into Tip Carrier	Push SENSORTIP fully into Tip Carrier; wipe contacts clean on Tip and in Tip Carrier.
	Defective SENSORTIP (tip will fail Performance Test)	Use another SENSORTIP; send defective tip for examination and (if possible) repair.
	Calibration value out of range or not available, or redundancy check failed	Send tip to Service Center for recalibration or repair.
Black square blinking on LCD (rightmost position)	Battery almost empty	Replace Battery Pack.
Two black squares blinking	Battery empty. No further measurements possible.	Replace Battery Pack immediately.
 Results were printed on the wrong printer	During the printing attempt, your PASCAL could not find its linked printer. It therefore printed to the next available one.	<ol style="list-style-type: none"> 1) Switch the wrong printer off. 2) Ensure your printer is on. 3) Retry by clicking on Blue Knob within 60 secs.



As a "last resort", if your PASCAL seems to be "frozen" or is not responding as expected, you may try to reset the device. To do so, remove the battery, wait a few seconds, then re-insert battery and re-start by turning the unit on (with a short click of the Blue Knob).




7.2. Error Messages and Status Messages

7.2.1. PASCAL Main Unit

Message	Meaning	Action to take
	<i>Status Message.</i> Reminds you to always use a SENSORCAP and indicates that the PASCAL is active and recording data	Do not proceed if you have not installed a SENSORCAP over the SENSORTIP. Otherwise, proceed with measurement.
	<i>Error Message.</i> Tip malfunctioning, or not present.	See troubleshooting guide .
	<i>Alert Message (blinking cursor appears in addition to current display).</i> Battery Warning	Energy left for a few measurements. Have new Battery Pack ready.
	<i>Alert Message (second cursor appears in lower right position).</i> Battery Alert.	No energy left. No further measurements possible. Replace Battery Pack immediately.



7.2.2. Printer status messages (on PASCAL Main Unit):

Message	Meaning	Action to take
	<i>Communications Interface Status:</i> Wireless connection active. (To printer or computer.)	Connection to target device established.
	<i>Communications Interface Status:</i> Wireless data transfer active.	Main Unit is sending data to target device.
	<i>Printer Alert Message:</i> Connection to printer was not established.	Is printer close enough to PASCAL? Try moving it closer, and retry. Is printer switched on? Refer to section 7.2.3 to check printer status.

<div data-bbox="140 229 444 320" style="border: 1px solid black; padding: 5px; text-align: center;">Printer problem</div>	<p><i>Printer Alert message:</i> This alert may be caused by one or several of the following conditions:</p> <p>Printer cover is open.</p> <p>No paper.</p> <p>High temperature.</p>	<p>1) Close transparent cover lid of printer. 2) Click on Blue Knob within 60 sec. 1) Load a new roll of thermal paper. 2) Click on Blue Knob within 60 sec. Print head is overheating. Switch printer off and allow to cool. If problem persists, contact Service Center.</p>
<div data-bbox="140 584 444 675" style="border: 1px solid black; padding: 5px; text-align: center;">Aborted note result</div>	<p><i>Printing Aborted Error:</i> Attempts to print have failed</p>	<p>Perform short click of Blue Knob once to re-display result. Note result manually.</p>



7.2.3. Printer status messages (on printer):

Blue LED always off	<i>Printer is off.</i>	Depress Printer Button for at least 1 second, until LED turns on.
Blue LED always on	<i>Printer is on; connected to wall outlet; batteries are recharging; no error detected.</i>	
Blue LED blinking very slowly	<i>Printer is on; running on batteries; no error detected.</i>	
Blue LED blinking slowly	<i>"Paper roll empty" message.</i>	Insert new roll of thermal paper.
Blue LED blinking rapidly	<i>Resettable error (printer head overheating, or battery voltage error).</i>	Printer batteries may be low. Replace or recharge (if rechargeable). Or: Print head may be overheating. Switch printer off and allow to cool. If problem persists, contact Service Center.
Blue LED blinking very rapidly	<i>Printer is shutting off.</i>	

7.3. Frequently asked questions

Q: *To what position on the pressure curve does the IOP shown correspond?*

A: The IOP value displayed corresponds to the average of a few minimum points on the ocular pulse curve. This value might be termed “diastolic IOP” as it corresponds to the minimum pressure to which internal structures are subjected during the cardiac cycle.

Q: *What is the relevance of the OPA value displayed?*

A: OPA represents the mean difference between minimum and maximum points on the ocular pulse curve, i.e. the range of pressure change during the cardiac cycle. When the OPA value is added to the IOP value, the maximum intra-ocular pressure during the cardiac cycle, i.e. the “systolic IOP,” is obtained.

Q: *Should I correct my PASCAL IOP readings for corneal thickness; and which correction nomogram should I use?*

A: PASCAL IOP measurements are not influenced by corneal thickness and other variations in corneal properties. Therefore, no correction should be applied to your readings.

Q: *How can I check if the CANTILEVER is in proper position while measuring?*

A: The CANTILEVER is in correct position if you hear an uninterrupted oscillating sound synchronous with the patient's heartbeat. If the CANTILEVER excursion is too small, the oscillating sound will be broken and discontinuous. (This is the most common error in user technique, particularly if the user has been trained to take Goldmann applanation tonometry readings where minimal corneal contact pressure is preferable.) If the CANTILEVER excursion is too great, you will hear alerting beeps.

Q: *The sound I am hearing is interrupted or "broken up".*

A: You may be just barely touching the patient's eye, without sufficiently deflecting the CANTILEVER (see also question above).

Q: *How long should I stay on the eye to take data?*

A: The PASCAL software routine requires a minimum of three full, undisturbed heartbeat cycles for computing IOP and OPA reliably. To get a reliable result with an acceptable Q score ($Q \leq 3$), count at least five cycles of the sound wave before pulling off the eye.

Q: *Can I use PASCAL without disposable SENSORCAPS?*

A: Using SENSORTIPS without SENSORCAPS will cause the SENSORTIPS to deteriorate quickly, causing expensive replacement. Working with an unprotected SENSORTIP exposes the patient to risk of cross-contamination from previous patients.

Q: *Is it OK to clean and re-use SENSORCAPS?*

A: We have NOT TESTED, and we are not planning to test, the viability of SENSORCAPS after attempted cleaning with alcohol or any other means. We strictly discourage any such practice. We must assume that using alcohol to "clean" SENSORCAPS after use is NOT SAFE. Traces of alcohol remaining in the membrane material may in fact cause damage to the next patient's epithelium (epitheliolysis). Doctors planning to re-use SENSORCAPS will do so AT THEIR OWN RISK, irrespective of how they attempt to "clean" their used SENSORCAPS.

Q: *May the SENSORTIP be sterilized?*

A: Circuitry within the SENSORTIP does not tolerate autoclave sterilization. Attempts to sterilize the SENSORTIP will cause irreversible damage.

Q: *How should I protect my SENSORTIP when the PASCAL is not in use?*

A: In-between measurements, and overnight, keep the SENSORTIP on the tonometer and keep the last SENSORCAP used installed on the SENSORTIP to prevent it from collecting dust particles. For protection over prolonged periods of time, it is recommended to remove the SENSORTIP from the PASCAL unit, remove any SENSORCAP, and store the SENSORTIP in its storage container.

Q: *May I clean SENSORTIPS by immersing in Pantasept or a similar disinfectant?*

A: Exposure of electrical contacts, circuitry, and tip surface to disinfecting preparations or to bleach may cause irreversible damage and/or malfunction.

Q: *My results with PASCAL differ from the values I get with the Goldmann Tonometer.*

A: Applanation Tonometer measurements are subject to systematical errors if corneal thickness, radius, and rigidity deviate from values typical for a "standard cornea". IOP estimates from Applanation Tonometers are therefore likely to be different from Contour Tonometer measurements in most cases. Contour Tonometer readings are most likely a more accurate representation of true intra-ocular pressure.

Q: *Sometimes I cannot hear any sound during the measurement, although I am getting a result that looks plausible.*

A: You may be touching the eye before the LCD display screen has initially illuminated following activation of the PASCAL with the Blue Knob. During activation, the PASCAL performs a self-test and sets the current pressure reading to zero. If the SENSORTIP is already in contact with the eye at this point, no further pressure increase will be detected and no sound will be heard. Nevertheless, the PASCAL is acquiring data, and after the Interrupt Maneuver the software will usually be able to retrieve the correct IOP value from the data.

Q: *Can I have several printers operating simultaneously in my office?*

A: Yes. Upon initialization, each printer is assigned to its PASCAL unit, and once this has happened, each PASCAL will only talk to its assigned printer. To initialize the printing function of your PASCAL and to assign a specific printer to it, all other printers present must remain switched off during the initialization procedure.

Q: *Can I use one and the same printer for all PASCAL units in use in my office?*

A: Yes. The printer will print the results of all PASCAL units to which has been assigned, provided they are within range. Each printout will contain the serial number of the PASCAL unit which has sent that specific data set. Printing to the same printer from several devices may create a risk of data confusion. Therefore, be careful to properly identify each printout.

7.4.



Tips and Tricks

7.4.1. Optimizing patient cooperation

- Drop anesthetic in both eyes, to reduce patient's blinking urge.
- Keep the room lights on so the visual input from the opposite eye will distract the patient from the approach of the SENSORTIP towards the measured eye. Having the room lights on also helps with the patient's fixation.
- Suggest to the patient to fixate on fixating light (installed on some slit lamps), or on your earlobe, or on an object across the room. A steady eye will greatly improve the quality of the readings.
- Encourage the patient to listen to the sound generated by his/her heartbeat, and to try and make it sound "nice and regular",
- Avoid staying on the eye with the PASCAL device longer than necessary. Eventually patient will start blinking, and it will become increasingly difficult to terminate the measurement in an orderly fashion to achieve a high-quality Interrupt Maneuver. Three smooth continuous waveforms of sound (heartbeats) is minimal, six waveforms is optimal, more than ten waveforms is excessive,
- To avoid touching the patient's eyelashes (which will cause patient to blink), try approaching the eye with the SensorTip positioned slightly below the apex of the cornea. When moving forward after making the first contact with the cornea, the contact surface of the SensorTip will move up due to the movement arc of the cantilever, and with some minor corrections you will easily reach a properly centered position on the cornea for your measurement.

7.4.2. Working with SensorCap protective tip covers

- Never use the same SENSORCAP on more than one patient. Attempting to wipe the SENSORCAP may damage it and may cause instrument malfunction.
- It is usually considered safe to use the same SENSORCAP on both eyes of the same patient. This may help expedite your work with the patient and help avoid interruption in your patient session.
- If you are planning to leave your PASCAL unused for a prolonged period of time (i.e. more than 1-2 days), it is recommended to remove the last SENSORCAP from the SENSORTIP. If left on too long, SENSORCAPs may stick to the SENSORTIP surface, making them difficult to remove.

7.4.3. Working with SensorTips

- To insert or remove a SENSORTIP while PASCAL is mounted on the slit lamp, the tip carrier may be rotated 90° to either side. For correct operation, make sure the tip carrier is properly re-aligned with the microscope's optical axis after inserting a SENSORTIP.
- To clean your SENSORTIPS, use a soft tissue (e.g. Kleenex) soaked in water. If necessary, a few drops of clear household soap solution may be added. However, use alcohol sparingly and not too often. Wipe contact surface with a rotating motion. Alternatively, compressed clean air (e.g. "Dust-Off") may be used to remove any particles that may stick to the SENSORTIP surface. Avoid using any sharp or hard objects when cleaning the SENSORTIP.
- Should a SENSORTIP become contaminated, clean it immediately after use to prevent any deposits from drying on its surface. If you detect any salt crystals (e.g. dried tear fluid) adhering to the tip, rinse thoroughly with water to dissolve any residue. Salt crystals rubbed into the tip may severely damage the tip.
- Do not soak or submerge SENSORTIPS — the electrical contacts at the rear may get damaged.



7.4.4. Working with the wireless printer

- It is highly recommended to leave the printer always plugged in. This will help to avoid problems arising from a broken connection between PASCAL and its associated printer.

8. Appendix

8.1. Dynamic Contour Tonometry

8.1.1. Functioning principle of Contour Tonometry

The Contour Tonometer (Fig. 19) consists of a cylindrical tip with a surface contour which closely resembles the contour assumed by the cornea when pressure on both sides is equal. When held against the cornea with a constant, small appositional force F , cornea and tip will be in direct contact in a circular area with diameter d ("contact area" A_c). Within the contact area, the cornea thus assumes the above mentioned, matched contour. The distribution of external forces between tip and cornea matches the internal force generated by IOP. A change in the appositional force F will cause d to change, but will not affect the force distribution, provided the diameter of the tip is larger than d .

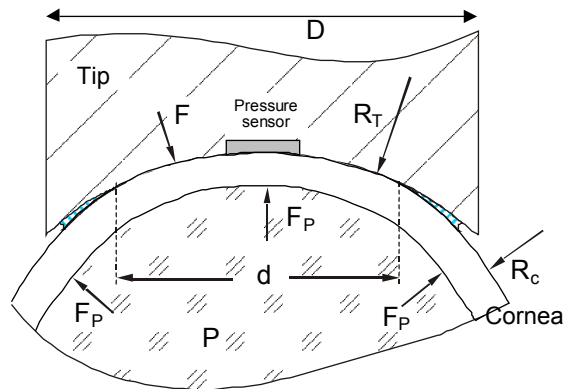


Fig. 19 Contour Tonometer. Schematic representation of cylindrical, contoured tip in contact with cornea ("Contour Match").

R_C	Radius of Cornea
R_T	Curvature Radius of Tonometer Tip
F	appositional force
F_P	internal force generated by IOP
d	diameter of contact area A_c
P	intra-ocular pressure (IOP)

The radius of curvature R_T used for the SENSORTIP is slightly larger than the curvature radius R_C of the cornea in its natural, unloaded state. The forces F_P exerted by intra-ocular pressure P generate tangential tensions in the cornea. Within the contact area, the same forces F act at both sides of the cornea and thus cancel. Hence, no tangential tensions are generated within A_c . Tangential tensions in the neighborhood of area A_c act along its rim to generate concentric forces pulling on the cornea and thus flattening the corneal contour across A_c ; i.e. the radius of curvature R_C will increase by a small amount ΔR relative to the normal, force-free situation and will become equal to R_T . Within contact area A_c , the contours of the tip and of the cornea thus ideally match. This condition shall be termed "**Contour Match**".

In the Contour Tonometer, the apposition force F is maintained at a constant value by the device's CANTILEVER mechanism. The diameter d of the contact area A_C will vary, depending on the conditions required to achieve contour match, and will not be relevant for the measurement. The Contour Match condition establishes itself irrespective of thickness or original shape (curvature) of the cornea, provided that the original corneal radius R_C is smaller than the tip curvature R_T . As the Contour Match condition is thus automatically fulfilled, *pressure on either side of the cornea will be equal*; i.e. the pressure measured by the pressure sensor built into the tip will correspond exactly to intra-ocular pressure. Therefore, the output from the pressure sensor provides a direct measurement of IOP.

8.1.2. Comparing with applanation tonometry data

An important consequence of the design characteristics discussed above is that the pressure measurement furnished by the Contour Tonometer is independent of corneal radius, corneal thickness, corneal rigidity, and hydration, as long as a few conditions are met:

- Corneal radius must be smaller than the curvature radius of the Tonometer Tip. The PASCAL SENSORTIP has been designed so as to ensure that this condition is met for all corneas with a radius of curvature not exceeding approximately 10.4 mm (i.e. keratometric diopter value should be larger than 32.5).
- The diameter of the contact area must be larger than the diameter of the pressure sensor area. With steeper corneas (small corneal radius), the contact area becomes smaller, posing a limit on corneal radii with which the Contour Match condition can be correctly established. From experiments and calculations, this lower limit for corneal radius is approximately 5 to 6 mm (55 to 65 keratometric diopters).
- Corneal thickness and rigidity must be such that the cornea can change its curvature, as dictated by the contour match condition, without any significant force being required. Experiments and theoretical calculations have demonstrated that this condition is met for corneal thicknesses ranging from 300 to 700 microns.

The Contour Tonometer will thus furnish correct pressure measurements from essentially all human corneas, with the possible exception of extremely flat or irregular corneas that may be encountered after keratoplasty, or as a result of scarring.

In contrast, the functioning principle of Applanation Tonometers (in particular the Goldmann Tonometer) is based on measuring the force required to achieve a specified deformation of the cornea. The Goldmann Tonometer is designed to furnish a correct pressure measurement when applied to a "standard cornea" with a thickness of 537 microns and a radius of 7.8 mm. The more a given cornea deviates from these values, the larger the systematic error inherent to the method. Many studies have demonstrated that corneal thickness has a particularly noticeable effect, and various correction nomograms have been proposed which claim to correct applanation tonometer readings for corneal thickness. However, the deformation characteristics of

individual corneas also vary significantly due to subtle differences in structural integrity which cannot be quantified. A particularly striking example is the profound effect of dissection or removal of Bowman's membrane resulting from corneal refractive surgery (LASIK or PRK). On such eyes, Goldmann Tonometers have been shown to furnish false low results by 5 mmHg or more.

Furthermore, as pointed out already by Hans Goldmann in his original work on Applanation Tonometry, the Goldmann Tonometer has a general systematic error of -1 mmHg, even on the standard cornea. The PASCAL Contour Tonometer has been calibrated to give a precise measurement of true intra-ocular pressure.

As a consequence of the fundamentally different measuring principles and the behavior described above, IOP readings from the two types of Tonometers will usually not agree. The Goldmann Tonometer (as well as any other Applanation Tonometer) is not a precise pressure measuring device and should therefore not be used as a standard against which to compare the precise measurements of the PASCAL Contour Tonometer.

8.1.3. "Unexpectedly different" results

Occasionally you will see PASCAL results that differ considerably (by several mmHg) from IOP estimates obtained with applanation tonometers. "Strange behavior" is primarily encountered with thicker than normal corneas, but may also be seen with other corneas.

Major differences are to be expected whenever the biomechanics (elasticity, rigidity, hydration, linking of stromal lamellae, etc) differ from the assumed properties of a hypothetical "standard cornea". These differences are largest, and easy to understand and accept, when we are dealing with a surgically altered cornea (e.g. by LASIK or LASEK or PRK; as described in several papers). But differences are also known to exist in corneas of people with ocular diseases (e.g. Glaucoma, Diabetes), or under the influence of certain drugs (e.g. some types of Glaucoma drops). Differences may also exist, and have been found, even in healthy subjects.

Variations in corneal thickness are well known to produce deviations in applanation IOP. However, different reports have proposed different numbers to be used for correction nomograms. Corneal thickness is easy to measure; therefore it is tempting to try and correct false IOP readings by pachymetry. This works best for homogeneous populations of healthy subjects (e.g. healthy, 30 yr old Caucasian men). In a typical, heterogeneous population of patients seen in a typical doctor's office, the correlation between CCT and applanation IOP will all but break down. For post-LASIK/PRK patients, pachymetry-based correction nomograms may even produce results with the wrong sign. This is due to the fact that the effect caused by biomechanics is often much larger than a CCT effect. Biomechanical properties are, for all practical purposes, not amenable to measurement.

As evidenced by the increasing number of studies published, Contour Tonometry is much less dependent on biomechanical variations than applanation tonometry. For all practical purposes, it seems to be safe to say the PASCAL measurement is factually independent of biomechanics, bulbus geometry, or refraction.

A careful study, performed with human cadaver eyes, has proven that DCT measurement agrees very closely (better than 1mmHg) with the true IOP measured manometrically inside the bulbus. And initial results (unpublished) from intra-cameral measurements on live eyes (performed during cataract surgery) seem to confirm these findings.

Therefore, if someone finds, for example, 15 mmHg with Goldmann and the same result with an air tonometer, but, say, 19 mmHg with the PASCAL, such a result is not at all "impossible" or "incredible" or "false". It may be hard to believe against a background of decades of experience with what is still referred to as a "Gold Standard". However, people should be reminded that it is a proven fact that applanation delivers false results in certain circumstances. What is less well known is just how large the error can often be.

Of course, any instrument may furnish faulty results under certain conditions. This can certainly also happen, and has been seen, with the PASCAL tonometer. Possible reasons may be:

- PASCAL tip not correctly centered on the eye.
- Extremely flat corneas which adhere to the entire tip surface.
- SensorCap not properly mounted -- air bubbles or wrinkles in the membrane.
- Physically damaged SENSORTIP, with an uneven surface (e.g. caused by partial delamination of the coating of the contact surface, or mechanical damage caused by attempted vigorous cleaning).
- Poor data quality (with a $Q > 3$), due to poor patient cooperation, or too short measurement time, or low OPA (< 1 mmHg).
- Poor lacrimation of patient's cornea; or excessive lacrimation. These two conditions can have a major effect on the quality of the data generated, and need to be managed carefully. This topic will be discussed in detail further below (see [section 8.1.4](#)).

It is therefore always a good practice to check your result (including the Q value shown on the LCD) and your instrument (whether it looks initially "believable" or not) and, when in doubt, to perform a second measurement. Most of the conditions which may give rise to errors can be seen and corrected when carefully observing the cornea – tip interface.

Only a minority of the potential causes for measurement errors listed above are patient-related. These deserve special discussion as they can be managed if their consequences are properly understood.

8.1.4. Dealing with lacrimation

Excessive lacrimation: If there is too much liquid on the cornea, the SENSORTIP may actually not touch the eye. It will "float" on the excessive liquid (this may happen more frequently with flat corneas than with steep corneas; Fig. 20). In this case you are likely to get very low IOP values and no real oscillation (irregular curve, irregular sound with no clear oscillation pattern; often poor Q value). Removing the excess liquid from the eye and from the SENSORTIP will help to get a correct measurement.

Poor lacrimation / dry eye: For PASCAL measurements it is important to have a complete tear film between cornea and SENSORTIP surface. If part of the interface is completely dry, this may cause the cornea to stick to the SENSORTIP. If that happens, you will notice that when moving the slit lamp, the contact area will not move freely, but the eye is pulled along with the SENSORTIP. It is easily seen that this will cause extreme distortion forces to occur in the cornea, leading to readings which may be up to 2x IOP. Another situation that may occur with poorly wetted corneas is that you do not see a complete circular contact area, but a contact area with irregular borders (this is most frequently seen on the top part which tends to run dry first due to gravity; Fig. 22). In this situation it may help to add some liquid (artificial tears, preferably a low viscosity variety; or more anesthetic drops). Incidentally, this situation may also occur in applanation tonometry. But if there is insufficient liquid, there will be insufficient Fluorescein and therefore no fluorescent ring, prompting the observer to almost automatically instill some more drops. Insufficient lacrimation also creates a risk of epithelial erosion from moving around with the tip (Goldmann or PASCAL) on the cornea.

Hence two important rules:

- Excessive lacrimation: low PASCAL readings. Remove excess liquid.
- Poor lacrimation: high PASCAL readings. Add drops.

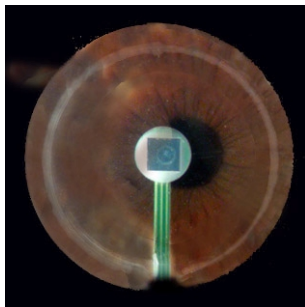


Fig. 20: excessive lacrimation: entire lens filled with tear fluid.

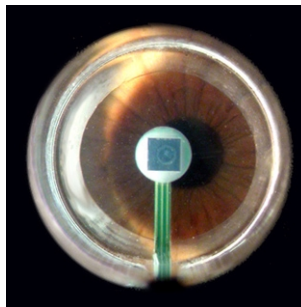


Fig. 21 regular pattern: contact area is circular and smaller than total lens diameter.

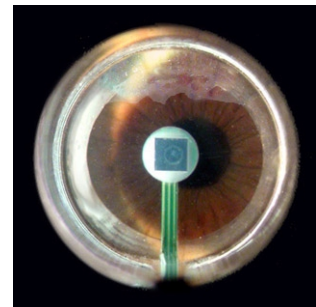


Fig. 22 poor lacrimation; tear-film breaks up from top.

All this is not fundamentally different from applanation tonometry. Experienced, careful observers will take those same precautions also with the Goldmann. But other observers may be satisfied doing a "quick and dirty" IOP with the Goldmann, touching the cornea merely for a few tenths of a second. Goldmann technique appears to be more "forgiving" (actually, deceptively forgiving - users think they are getting a good reading when they are, in reality, merely guessing at a result in an unstable situation).

8.1.5. Dynamic Tonometry vs. Static Tonometry

The pressure sensor of the PASCAL Tonometer has a very fast response to rapid pressure changes. It is capable of recording the pressure fluctuations originating from pulsatile ocular blood flow and other physiological effects in real-time. The signal processing software determines the lower (diastolic) and upper (systolic) limits of the intra-ocular pressure. The difference between the two is referred to as "Ocular Pulse Amplitude (OPA)" and is displayed along with the base (diastolic) IOP on the PASCAL's LCD display. The IOP may be regarded as the static component of intra-ocular pressure, while the OPA in addition provides elementary information about the dynamic component inherent to intra-ocular pressure.

Most Applanation Tonometers provide only an estimate of the static IOP component. Depending on individual technique, the static IOP estimate may be indicative of the lower or upper IOP limit, or to some in-between "pseudo-steady-state" value.

8.2. How does PASCAL compute IOP and OPA?

During a measurement, the pressure signal detected by the pressure sensor built into the SENSORTIP is digitized 100 times per second in real-time and stored in the unit's memory. Also, the signal is continuously converted into an audio signal to provide audio feedback to the user. The processing unit continuously monitors the signal level. When the level drops to zero after the tonometer is retracted from the eye, the processor will compute the zero level baseline signal and use this as a reference value for the subsequent calculation of IOP. At this point, data acquisition will stop and a double beep will sound.

As a next step, the system software will perform the RangeFinder routine, analyzing the entire pulse curve recorded and looking for sections that contain the characteristic oscillation typical for an ocular pulse curve. Sections containing excessive noise or glitches, or any other irregularities, will be ignored. Sections containing valid data are then compared and ranked according to their quality. The section ranking highest is then chosen as the range to be used for computational analysis.

The software finds the evenly spaced maxima and minima and generates a list containing their positions and intensities. The average of all minima found is computed and posted as IOP. The average of all differences between maxima and minima is computed and posted as OPA (Ocular Pulse Amplitude).

The reliability of the result thus obtained is assessed according to several criteria, and posted as a quality rating, or "Q score". Q = 1 denotes an optimum quality result; Q = 4 or 5 denotes an increasingly questionable result which should be taken with caution. It may be advisable to repeat a measurement if Q = 4 or 5.

If the software cannot find a valid range for performing the computation, or if the zero level baseline cannot be determined, no result will be posted.

Posted results for IOP, OPA, and Q are displayed on the built-in LCD, and written into a results list for later retrieval.

8.2.1. The Q score

Each time PASCAL computes and displays an IOP measurement result, the Quality of the result is assessed and a "Q score" is computed and displayed. Q = 1 stands for optimum quality; Q = 5 represents poor quality. A good Q score (Q = 3 or less) indicates that the result was computed from high quality data and therefore can be assumed to be reliable. If the Q score is poor (Q = 4 or 5), a possibility exists that the algorithms used for extracting minima and maxima from the ocular pulse pressure curve have been misled by artifacts in the data, possibly producing an erroneous result.

To compute the Q score, the data points collected are examined for characteristics such as noise level, spikes (singularities), drift, and continuity. The amount of data available (i.e. the number of diastoles and systoles (minima and maxima) found is also taken into consideration. The Q score obtained is a weighted composite of these components.

When a result with a Q score of 4 or 5 is obtained, the result may correspond to the correct IOP/OPA but it may also be in error as the computation routines may not be able to deal with the irregularities in the data correctly. Hence it is strongly advisable to discard any results with a Q higher than 3, and to repeat the measurement.

To obtain better (lower) Q scores, try the following:

- Obtain better patient cooperation, by advising patient to relax, keep the eye open and look straight ahead.
- Obtain a longer stream of data by keeping the SENSORTIP centered on the contact zone for a few seconds longer. While a result can be computed from as few as three pulse cycles, obtaining 5 to 6 pulse cycles will tend to furnish a more reliable result with a lower (better) Q score.

Occasionally, patients with cardiac arrhythmia are encountered. Depending on the specific characteristics and frequency of occurrence of the arrhythmia, such pulse curves can be a challenge for PASCAL's IOP/OPA algorithm. Such situations may easily be detected, and an IOP estimate obtained visually, by inspecting the actual pulse curve printout (available only on PASCAL WIRELESS systems equipped with a printer).

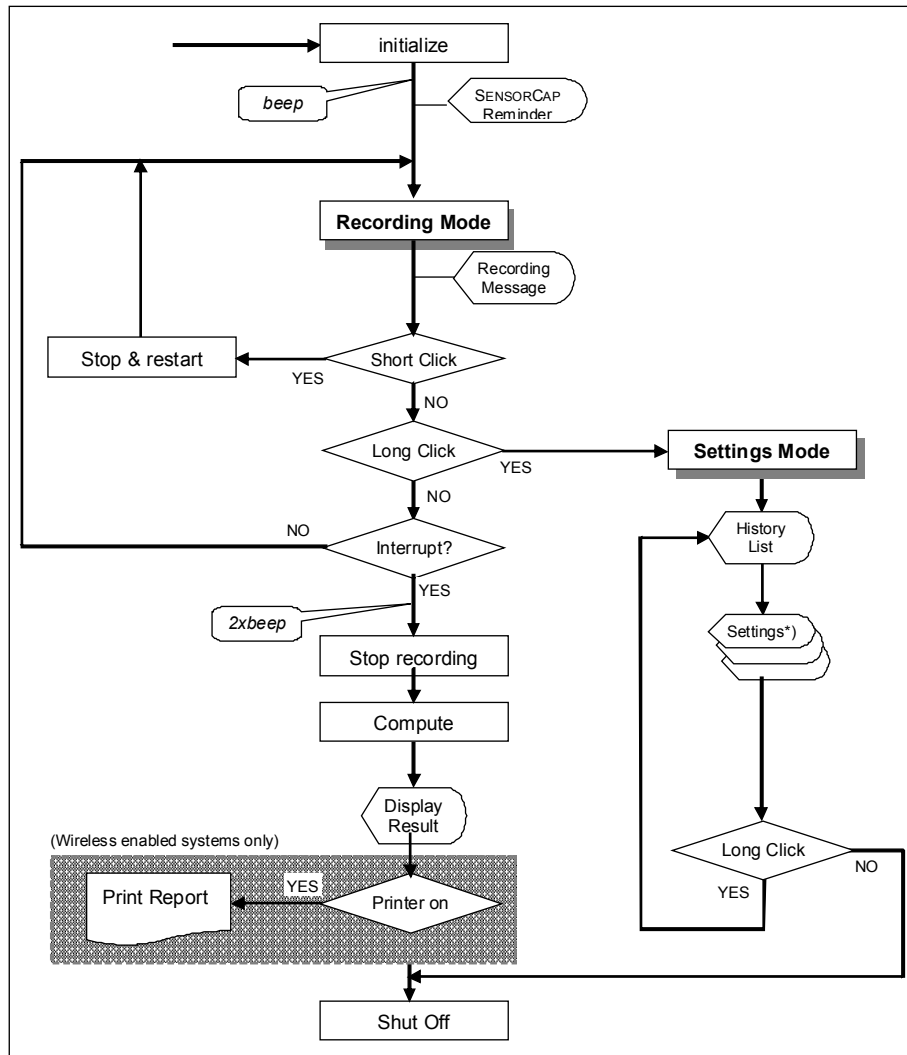
8.3. PASCAL Software Structure

The software controlling the internal microprocessor of the PASCAL Tonometer operates in two basic modes (additional remote-controlled modes used for servicing are not considered here). The interplay between the two modes is depicted in [Fig. 23](#).

Recording Mode (or “Active Mode”) is automatically activated when PASCAL is switched on with a short click of the Blue Knob. In this mode, the PASCAL takes data and detects when the user ends the measurement (i.e. pulls the tonometer away from the patient's eye). It analyzes the recorded data and computes and displays the result of the measurement. When finished, the PASCAL automatically shuts down. The entire process proceeds automatically. The only user input recognized by the software while in Recording Mode is the command to access the User Settings Menu (executed by performing a “long click”).

In **Settings Mode**, the user may view and, if desired, modify certain basic instrument settings within the User Settings Menu, or view a list of results from preceding measurements. In User **Settings Menu Mode**, the user may view, and modify, certain basic instrument settings, or view a list of results from preceding measurements.

Fig. 23 PASCAL Software Structure: Recording Mode and Settings Mode



*) for details on Settings Mode see Fig. 16

8.4. Technical Specifications

8.4.1. Tonometer System

Part Number: Standard PASCAL System:	311.001.001 or 311.001.002
PASCAL WIRELESS System:	311.011.001 or 311.011.002
Description:	Dynamic Contour Tonometer
Device Type:	Contact Tonometer
Trade Name:	PASCAL [®]
Safety design standards:	EN 60601-1:1990 + A1:1993 + A2:1995
Classification:	Class IIa Medical Device (MDD, 93/42/EWG)
Registration (Europe):	CE 0297 (CE-marked)
Registration (USA):	FDA 510(k) premarket notification K#032967
FCC labeling (PASCAL WIRELESS systems only):	PASCAL [®] Model No. 311.011.001 / 002 Contains FCC ID: POOWML-C10XX
IC labeling (Canada) (PASCAL WIRELESS systems only):	IC: 5508A-PASCAL (The term "IC" before the certification / Registration number only signifies that the Industry Canada technical specifications were met.)
IOP recording range:	5 to 200 mmHg
Minimum OPA detection limit	0.5 mmHg
A/D converter sampling rate:	100Hz at 12 bit dynamic range
Resolution:	± 0.10 mmHg
Precision:	± 2% or ± 0.2 mmHg, whichever is larger
Maximum recording time:	180 sec
Battery voltage range:	2.0 - 3.5 VDC
Transmission range (PASCAL WIRELESS systems only):	Up to 10 meters (30 feet) inside same room.
Dimensions:	170 mm (H) x 88 mm (W) x 40 mm (D)
Contact diameter of SENSORTIP:	7.0 mm
Curvature radius of SENSORTIP:	10.5 mm
Weight:	210 g
Shipping Weight:	2.400 kg
Main Unit Microprocessor:	Mitsubishi M30626 FHPFP.
Memory:	384kB Flash internal, 32kB SRAM internal, 512kB SRAM external, EEPROM Microwire 16kB external.
Ambient operating temperature:	+10°C to +45°C (50 to 115°F)
Storage temperature:	0°C to +55°C (30 to 130°F)

Ambient operating atmospheric pressure:	800 hPa to 1060 hPa
Storage atmospheric pressure:	700 hPa to 1060 hPa
Operating humidity:	20 – 75 % relative humidity
Storage humidity:	0 – 95 % relative humidity
Manufacturer:	SMT Swiss Microtechnology AG Allmendstrasse 11, CH-2562 Port (Switzerland) phone: +41 32 332 7070 e-mail: vision@smtag.ch website: www.smtag.ch


8.4.2. Printer Accessory

Part Number:	311.660.001
Model Number:	DPT-100-BT
Description:	Thermal printer, portable, battery operated. Equipped with a rechargeable battery pack and power supply.
Paper:	Thermal printer paper rolls, 58 mm wide.
Dimensions, Weight:	14.5 x 18.5 x 6.5 cm; 800 g (complete shipping weight)
Temperature:	0 – 50°C
Relative humidity:	10% - 85%
Power Supply: primary voltage: secondary voltage:	100 – 240 V AC \pm 10% 15 V DC; 600 mA
Outlet plug adapters:	Swiss, Euro, USA, UK, Australia
Manufacturer (Printer):	Custom Engineering SPA Str. Berettine 2, 43010 Fontevivo (Parma), Italy phone: +39 0521 680 163 www.custom.it
Manufacturer (Power Supply):	ANSMANN ENERGY GMBH Industriestr. 10, D-97959 Assamstadt, Germany phone: +49 6294 4204-0 www.ansmann.de

8.4.3. Rechargeable Battery Kit

Part Number:	311.660.001
Description:	Electronic battery charger
Power Supply Voltage:	100 – 240V AC $\pm 10\%$ 50/60Hz primary; 12V DC $\pm 10\%$, 800 mA secondary
Outlet plug adapters:	Swiss, Euro, USA, UK, Australia
Dimensions, Weight::	7.2 X 5.9 X 4.4 cm (with battery pack); 520 g
Temperature:	0 – 25°C
Manufacturer:	Hy-Line Power Components AG Gründenstrasse 62, CH-8247 Flurlingen, Switzerland Phone: +41 52 647 42 01 www.hy-line.ch

8.5. System Components

REF	Name	Description
	PASCAL systems must be ordered with either S1-type bracket (see Fig. 4, page 14) or S2-type bracket (see Fig. 5, page 14) as required if you plan to suspend the unit using its mounting bracket. (Appropriate part numbers are listed below). If mounting bracket is not used (device mounted using a footplate adapter), either a S1- or S2- type unit may be used.	
311.001.001 / 002	PASCAL System S1 / S2	Complete System, standard version, based on S1 or S2 Main Unit
311.101.001 / 002	Main Unit S1 / S2	Main Unit (standard version) with S1 / S2-type mounting bracket
311.011.001 / 002	PASCAL WIRELESS System S1 / S2	Complete System, wireless-enabled version, based on S1 or S2 Main Unit
311.111.001 / 002	Main Unit, WIRELESS	Main Unit (wireless-enabled version), with S1 / S2-type mounting bracket
311.640.001 / 002	Attachment Kit S1 / S2	Attachment screws and Torx wrench for S1/S2-type Main Units (System includes appropriate Attachment Kit)
311.510.102	SensorTip	(System includes one SensorTip)
311.751.102	Battery Pack	(System includes one installed battery plus a reserve battery)
311.701.205	AppliPack	(System comes with 24 SensorCaps in AppliPack packaging)
311.951.001	User Manual	(System comes with a User Manual in English; supplied in printed form or on CDROM)
311.951.101	Quick Reference Sheet	(System comes with a laminated Quick Reference Sheet in English Language).

8.6. Accessories and Consumables

REF	Name	description
Optional Accessories:		
311.660.001	PASCAL Printer	Wireless printer, battery operated. Compatible with PASCAL WIRELESS systems only. Uses standard AA disposable or rechargeable batteries and standard thermal printing paper (58mm wide roll paper). Note: Consumables for the printer may be obtained from any office supplies store (not available from PASCAL manufacturer / suppliers)
311.640.005	Adapter Kit	for mounting the PASCAL Main Unit on Haag-Streit-type slit lamps. Includes PASCAL FOOTPLATE and BASE PLATE. (Adapter Kits for other types of slit lamps are available on request)
311.510.002	SensorTip	Single SensorTip, as back-up or replacement for the one included with the basic system.
311.510.003	SensorTip-3	Package containing 3 SensorTips.
311.761.001	Rechargeable Battery Kit	Battery Charger Kit (110/220V), with two rechargeable batteries (to be used in lieu of disposable batteries included with System).
311.620.001	Test Kit	for performing pressure sensor calibration checks.
311.951.002	Other Language User Manuals	PASCAL [®] User Manual in foreign language versions; electronic version, PDF Format, on CDROM.
Consumables:		
311.751.002	Replacement Batteries, disposable	5 disposable batteries, as replacement for the 2 batteries included with system. NOT RECHARGEABLE.
311.761.105	Replacement Batteries, rechargeable	2 rechargeable batteries (Battery Charger p/n 311.761.001 is required).
311.701.201	SensorCaps-240	Box containing 240 sterile SensorCaps (sterile, disposable protective tip covers, each in an AppliPack for easy mounting).

8.7. Warranty Information

SMT AG guarantees the PASCAL Dynamic Contour Tonometer for 12 months from the date of purchase to be free of defects in parts and workmanship. This warranty is valid only to the original purchaser of the device, and only if all repairs, maintenance and adjustments were made by SMT or by a certified Service Center.

This warranty does not cover normal wear and tear or defects, malfunction or failure resulting from misuse, neglect, improper set-up or maintenance, modification, or alteration.

This warranty is exclusive and in lieu of all other warranties, either express or implied, including but not limited to warranties of merchantability or fitness for a particular purpose. This warranty represents SMT AG's sole liability or contract for the product.

SMT AG shall not be responsible for any direct, incidental consequential or exemplary damages suffered by any party, even if that party has been advised of the possibility of such damage. This warranty cannot be extended, broadened, or otherwise modified by any SMT AG representative.

8.8. Service and Support Information

For any support, service, or maintenance, please contact the Distributor from whom you have purchased your PASCAL Tonometer, or a SMT-authorized Service Center. A list of contacts for specific support situations is available from SMT's website at www.pascal-tonometer.com.

For all questions and problems relating to your PASCAL Dynamic Contour Tonometer, you may also contact the Central Customer Support facility of Ziemer Ophthalmic Systems Group:

e-mail: customer.service@ziemer-ophthalmics.com

website: www.ziemer-ophthalmics.com

Phone: +41 32 332 7070

Mail Address: Ziemer Ophthalmic Systems Group AG
Allmendstrasse 11
CH-2562 Port (Switzerland)

8.9. Declaration of Conformity

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY DECLARATION DE CONFORMITÉ / DICHIARAZIONE DI CONFORMITÀ	
Wir / We / Nous / Noi	
Name + Adresse der Firma:	SMT Swiss Microtechnology AG
Name and address of the firm:	Allmendstrasse 11
Nom + adresse de l'entreprise:	CH-2562 Port
Nome + indirizzo della ditta:	Switzerland
<p>erklären in alleiniger Verantwortung, dass declare in our own responsibility that déclarons sous notre propre responsabilité de dichiariamo sotto propria responsabilità che</p>	
das Medizinprodukt the medical device le dispositif medical il dispositivo medico	PASCAL[®] Dynamic Contour Tonometer
<p>allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht. meets all the provisions of the directive 93/42/EEC which apply to it. remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE. addempie a tutte le esigenze della direttiva 93/42/CEE che lo riguardano.</p>	
Angewandte harmonisierte Normen	EN 60601-1
Applied harmonized norms	EN 60601-1-2
Normes harmonisées appliquées	EN 60601-1-4
Norme armonizzate applicate	
Benannte Stelle	DQS GmbH
Notified body	
Organisme notifié	
Organo notificato	
Konformitätsbewertungsverfahren	93/42/EWG, Anhang II
Conformity assessment procedures	93/42/EEC, Appendix II
Procédure d'évaluation de la conformité	93/42/CEE, Appendice II
Procedimento d'evaluazione della conformità	93/42/CEE, Appendice II
Port, 14.10.2003	F. Ziemer, CEO 