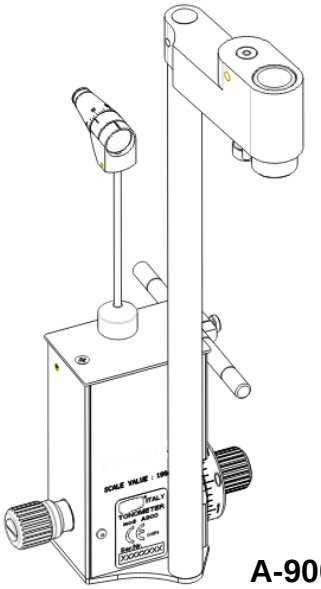
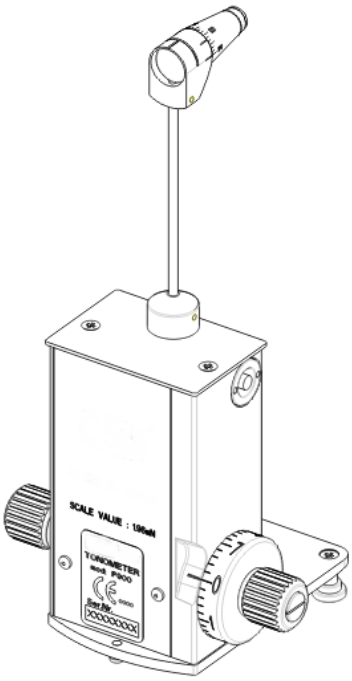
Instruction Manual

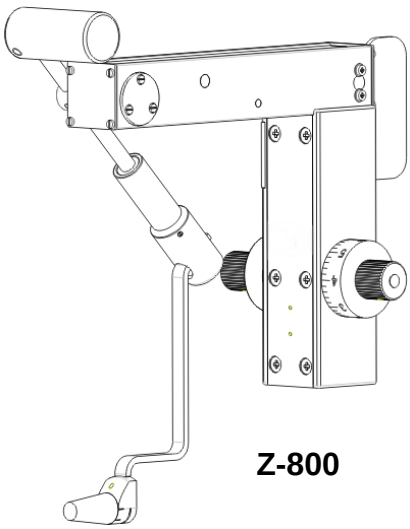
Applanation Tonometer



A-900



T-900



Z-800

GA bon T900_A900_Z800 Rev 1.2 E 09.02.09.doc

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bon Optic Vertriebsgesellschaft mbH – managing director: H. Jochen Kaber – HR Lübeck, HRB 3475 – VAT No. 161662634

1 Introduction

Dear customer

Thank you for choosing one of our applanation tonometers. Please read the operating instructions carefully before using the device. Keep this instruction manual safe for future use.
Please observe the safety instructions.
If you have any further questions, please contact our customer helpline.

Meaning of the symbols in the operating instructions

Caution! Please observe safety instructions with this symbol to prevent personal danger or damage to property.

Important! Indicates particularly important information to maintain the function of the device/system or to extend its life.

Note! Indicates information for correct use so that errors may be avoided.

2 Important Information

Manufacturer : bon Optic Vertriebsgesellschaft mbH · Stellmacherstr. 14 · D-23556 Lübeck

2.1 System Information

Device name : T-900 / A-900 / Z-800

2.2 Application and classification

The applanation tonometer is used for the measurement of the intraocular pressure of the eye and may only be operated by competent and accordingly briefed persons. The apparatus is operated in combination with a slit lamp.

The applanation tonometer T-900 / A-900 / Z-800 is a Class 1 non-invasive, active medical device in accordance with the classification regulations of Directive 93/42/EWG on medical devices (MDD).

2.3 Liability

The applanation tonometer is manufactured according to the current technical status and the recognized safety regulations and is tested in accordance with strict quality criteria.
bon Optic only accepts liability for the safety, reliability and performance of the device if

- assembly, changes or repairs have been carried out by a person by competent persons.
- the device is operated in accordance with these operating instructions.
- the operator complies to the Ordinance on the Operation of Medical Devices (MPBetreibV).

If the system is assembled, changed or repaired by an unauthorized person, if it is improperly maintained or not used as described in 2.2, the manufacturer is no longer liable.

2.4 Scope of delivery

T-900:

1 x Applanation Tonometer T-900
1 x Gauging Prism
1 x Retaining Plate
1 x Check Weight
1 x Allen Key
1 x Instruction manual

A-900:

1 x Applanation Tonometer A-900
1 x Gauging Prism
1 x Retainer
1 x Check Weight
1 x Allen Key
1 x Instruction manual

Z-800:

1 x Applanation Tonometer Z-800
1 x Gauging Prism
1 x Retainer
1 x Check Weight
1 x Allen Key
1 x Instruction manual

3 Safety Instructions

Please follow the legal requirements on accident prevention and observe the following safety instructions!

Setting-up and assembly:

- After receiving the device, leave it in the original packing, in order to ensure that the components reach ambient temperature and therefore prevent possible condensation.

Operating:

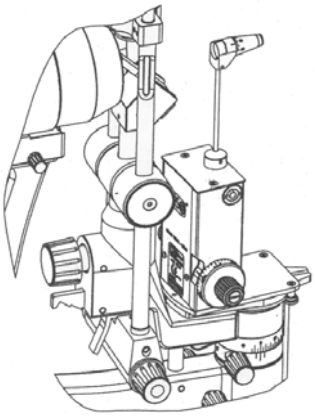
- Do not expose the device to extreme temperatures.
- Avoid dropping or splashing water on the device.
- The operating temperature is between +15° C and +30° C.
- Marginal values for barometric pressure: >=700hPa und <=1060hPa
- Marginal values for relative humidity: >=30% und <=75%
- Check the gauging prism for damages before every use, by the use of the slit lamp microscope for example.
  In the case of a cracking, disinfectant may infiltrate into the antrum of the gauging prism. If it comes into contact with the patient's eye, this may result in a chemical burn of the cornea.

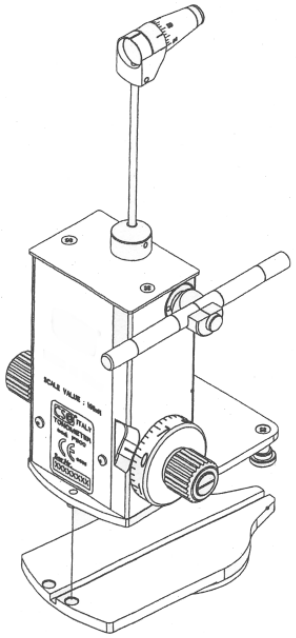
Other Information:

- Take notice of the cleaning information.
- Take notice of the relevant national regulations regarding the measuremental technical control.
- Avoid any shock or impact and do not expose the device to permanent vibrations.

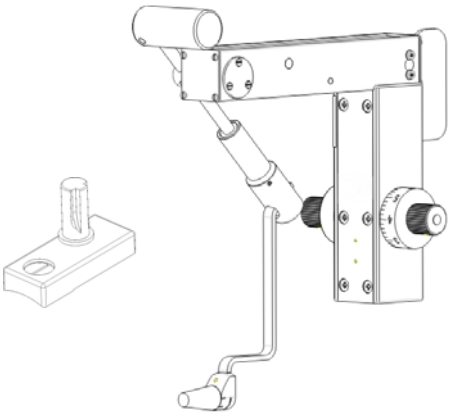
4 Assembly

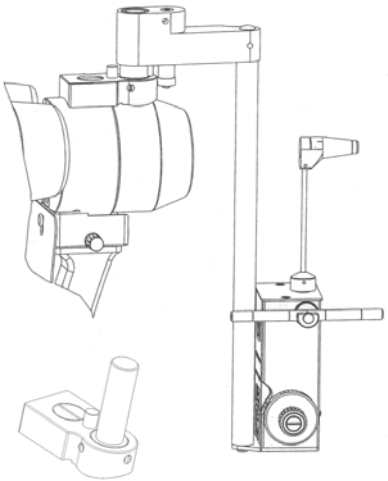
T-900:
Stick the pictured retaining plate into the slit lamp axis, using the connected pin.
If necessary, take of the cap on the axis.
Then place the applanation tonometer on the retainer plate.





A-900 / Z-800:
Screw the pictured retainer onto the magnification adjuster of the slit lamp. If necessary, remove the cap of the threaded hole. Then apply the applanation tonometer to the pin on the retainer.





5 Functional Principle

The applanation tonometer defines the intraocular pressure, by measuring the force required to flatten a defined surface of the cornea.

The cornea is applanated by a plexi-glas pressure-corpus, which is set in a ring-shaped retainer at the end of the pressure arm. The circular pressure surface has a diameter of 7,0 mm and is flat, featuring a rounded edge, whereby an injury of the cornea is made impossible.
The pressure corpus is brought into contact with the patient's eye by mowing the slit lamp forward. Then the pressure corpus is pushed onto the eye with increasing force, until an area with a diameter of 3.06 mm (this equals a circular area of 7,35 mm^2) is flattened.

The user accomplishes the precise optical measurement of the small flattening surface visualy, by using a factor 10 magnification on the slit lamp.
In the area of surface contact between cornea and pressure corpus the tear fluid is forced outward. It contains floureseine and shines green-yellow because of the blue light. The boundary between flattened and curved cornea appears clearly as a fine green-yellow band. The built-in doubling system within the pressure corpus splits the picture of the flattened circle and displaces the two halves by 3,06 mm to each other.

The rigidity of the cornea and the eye-ball (bulbus) is inconsiderable, due to the fact that the small area of flattening, of only 7,35mm^2, the shift in volume only amounts to a mere 0,56 mm^3. The intraocular pressure is only raised by approximately 2,5% through the measuring process. Repeated measurements do not decrease the intraocular pressure, because a massage-effect does not occur due to the low pressure increase.
The measured data is displayed directly in mmHg. All versions have high accuracy. The error of a single measurement averages at approximately $\pm$ 0,5 mmHg.

6 Accomplishment of a Pressure Measurement

6.1 Preparation of Slit Lamp and Applanation Tonometer

- Make sure that the applanation tonometer is properly mounted to the slot lamp.
- The measuring prism must be disinfected.
  Do not use alcoholic solutions for disinfections!
- Place the blue filter into the lighting-ray channel of the slot lamp.
- Place the green filter observation-ray channel in order to monitor the green fluorescence light.
- Turn the pressure head with the gauging prism towards the patient until it snaps in place.
- Turn the measuring drum to the scale line 1.
  Note: If the cornea is touched <u>without</u> pressure, the patient feels an unpleasant vibration.

6.2 Preparation of the Patient

- Use an appropriate anesthetic to numb the surface of the eye.
- Optionally use a liquid fluorescine or in form of paperstrips, for the precise observation of the eye-surface.
- Let the patient place his chin onto the chinrest and make sure that his forehead touches the brow-band.

6.3 Pressure Measurement Procedure

- Ask your patient to look straight.
- Bring the gauging prism to eye level, using the slit lamp.
- If fluoresceine was used, the patient should shortly close his eyes directly before the measurement. This way the cornea is sufficiently moistened with tear fluid.
- Slowly move the slit lamp forward, in order to bring the gauging prism into contact with the cornea (central – in the area of the pupil). When contact is made, the boundary of the cornea (limbus) shines bluish. This shining is best observed from the side (not through slit lamp microscope). Immediately stop the forward movement of the slit lamp, after contact with the cornea is established.

- Now look through the microscope of the slit lamp. If the two semicircular fluoresceine bands pulsate at a constant pace, the applanation tonometer is in the correct measuring position (diagr. 6.1). The fluoresceine bands may be of differing size, depending on the intraocular pressure. If necessary, correct the position of the applanation tonometer with the joystick of the slit lamp until you can see following picture in the observation field:

Diagram 6.1

Marginal movements of the slit lamp do not influence the size of the semi circles.

- Now, increase the pressure by turning the measuring drum, until the inner edges of the semi circles slightly touch each other. They should overlap at eye-pulsation:

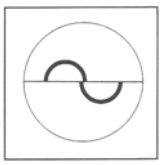


Diagram 6.2

The width of the fluoresceine band should amount approximately 1/10 of the diameter of the flattened surface, thus approx. 0,3 mm.
The scale reading on the measuring drum **multiplied by 10** equals the intraocular pressure in mmHg.

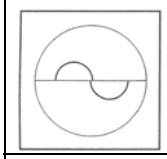
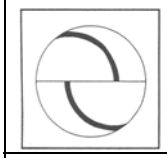
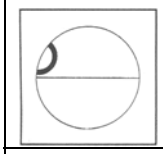
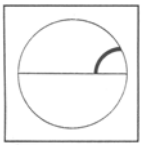
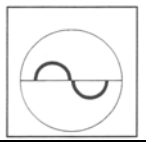
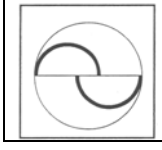
The use pressure measurement in mmHg in medicine has historical reasons (pressure measurement by utilizing a mercury column).

This equals:

1 mmHg = 0,00133 bar
1 bar = 750 mmHg

7 Failure Sources

The following shows up typical errors and/or maladjustments and how to avoid them.

Diagram	Cause	Solution
	**Fluoresceine band too wide:** The gauging prism was not dried properly after cleaning, or the eyelid came in contact with the gauging prism during the measurement. The reading will be higher than the true intraocular pressure.	Abort the measurement and dry-off the gauging prism.
	**Fluoresceine band too narrow:** The tear fluid dried out during the longer measurement. The reading will be lower than the true intraocular pressure.	Abort the measurement and let the patient close his eyes a few times in order to produce tear liquid.
	**Fluoresceine band too big:** a) The gauging prism is not touching the cornea correctly. b) The protection weight is squeezing the eye. The flattened area is too big.	Retract the slit lamp and re-apply the gauging prism until you can observe an even pulsation.
	**The two semi-circular surfaces are not positioned in the middle of the pupil area:** The position of the gauging prism is not correct.	Lift the slit lamp and move it to the left.
	**The two semi-circular surfaces are not positioned in the middle of the pupil area:** The position of the gauging prism is not correct.	Move the slit lamp to the right.
	**The two semi-circular surfaces are not positioned in the middle of the pupil area:** The position of the gauging prism is not correct and the pressure is too high. The pressure reading here is significantly higher than the true intraocular pressure.	Lower the slit lamp and decrease the pressure put onto the eye by the gauging prism.
	**The inner edges of the fluoresceine bands do not touch each other:** The measuring pressure is too low.	Increase the pressure with the measuring drum.
	**The inner edges of the fluoresceine bands do not touch each other:** The measuring pressure is too high.	Decrease the pressure with the measuring drum.

8 Informations regarding the Examination

8.1 General

Patients that are upset and/or frightened, usually have a higher intraocular pressure at the first measurement. Therefore a decrease of tension occurs within the first minute, because the patient realizes, that tonometry with the applanation tonometer is not connected to unpleasant sensations. At good anesthesia and well-opened eyes, the patient feels absolutely nothing. Therefore accomplish a test measurement on both eyes, of which you discard the results. Following that, three more measurements are achieved on each eye. The measured results are correct, when the pressure has stabilized. If the procedure is followed correctly, the variance between the results is ± 0,5 mmHg.

At long lasting measurement on one eye, more or less obvious signs dehydration of the corneapithel on both eyes occurs. A ring of small fluoresceine-positive dots appears on the contact area between the cornea and the pressure corpus of the eye, which is measured at the moment. Irregular „maplike“ fluoresceine-positive spots occur on the other eye, making a relevant measurement impossible.
Due to this fact only short but alternating measurements on both eyes should be accomplished. Obviously the visual acuity is influenced by these fine epithel defects. Therefore examinations regarding visual acuity and visual field should be accomplished before the tonometry.

8.2 Measurements involving Astigmatism

If the cornea is spherical, the examination can be done on any given meridian, most comfortably on the 0°-Meridian. On eyes with an astigmatism greater than 3 diopters, the chosen meridian is of greater importance, because the flattened surface is not circular anymore, but elliptic. Calculations show that at greater cornea-astigmatisms an area of 7,354 mm^2 (diameter 3,06 mm) is flattened, when the pressure corpus is positioned in an angle of 43° to the meridian of the greatest radius.

For Example:
If the astigmatism of the cornea is 6.5 mm/ 30° = 52.0 dpt/30° and
8.5 mm/120° = 40.0 dpt/120°

the 120°-mark of the scaling on the pressure corpus is set to the red 43°-mark on the prism retainer.

If on the other hand the following is measured 8.5 mm/ 30° = 40.0 dpt/30° und
6.5 mm/120° = 52.0 dpt/120°

the scale interval 30° is set to the red 43°-mark.

The axis angle of the greatest radius is simply set to the red 43°-mark here.

9 Controlling the Measurement Display

The pressing force of the pressure corpus is caused by a spring in the device. Because this can change through inappropriate use, but also through aging, the device should be checked on a regular basis. The check is accomplished in 3 drum positions:

9.1 T-900, A-900

a) Check at Drum Position 0

Insert the gauging prism.

Check-Position - 0.05:
Move the zero-mark of the measuring drum downward against the index, for the width of the mark (diagr. 9.1). If the pressure arm is brought into the area of free movement between the catches, it should autonomously move against the catch toward the examiner.

Check-Position + 0.05:
Move the zero-mark of the measuring drum upward against the index, for the width of the mark (diagr. 9.2). Analogical the pressure arm should move towards the catch on the patient's side.

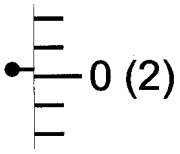


Diagram 9-1

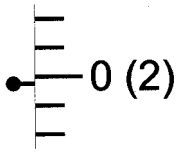


Diagram 9-2

b) Check at Drum Position 2

Herefore use the included check-weight, which has 5 engraved rings.
The ring in the middle equals the scale value 0, the two rings immediately left and right of it equal the scale value 2 and the two most outbound equal the scale value 6.

Now, adjust to the scale value 2, using the index mark on the retainer of the check weight, so that the longer part is showing towards the examiner. Insert the check weight into the sensing axis (see analog diagr. 9.3).

The pressure arm now must move, at drum position 1.95 / 2.05, out of the area of free movement to the appropriate catch. The check at scale value 2 is the most important, because the measurement of the intraocular pressure in this area has the most significant importance.

c) Check at Drum Position 6

Analogical the tonometer may be checked at scale value 6. The check values then are at 5.9 / 6.1. Move the scale mark on the measuring drum up or down against the index for 1/2 interval.

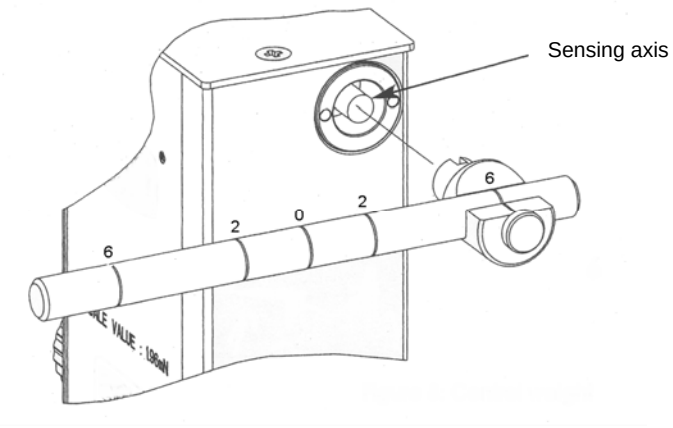


Diagram 9.3

9.2 Z-800

a) Check at Drum Position 0

Insert the gauging prism and set the measuring drum on the tonometer to scale value 0. The arm with the gauging prism should now swing freely between the catches.

b) Check at Drum Position 2

Herefore use the included check-weight, which has 5 engraved rings.
The ring in the middle equals the scale value 0, the two rings immediately left and right of it equal the scale value 2 and the two most outbound equal the scale value 6.

Now, adjust to the scale value 2, using the index mark on the retainer of the check weight, so that the shorter part is showing towards the examiner. Insert the check weight into the sensing axis (see analog diagr. 9.4).

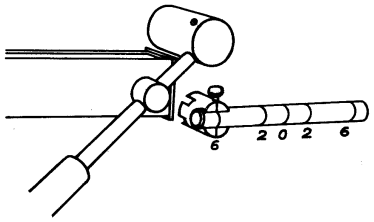


Diagram 9.4

Check-Position - 0.05:
Move the zero-mark of the measuring drum downward against the index, for the width of the mark (diagr. 9.5). If the pressure arm is brought into the area of free movement between the catches, it should autonomously move against the catch toward the examiner.

Check-Position + 0.05:
Move the zero-mark of the measuring drum upward against the index, for the width of the mark (diagr. 9.6). Analogical the pressure arm should move towards the catch on the patient's side.

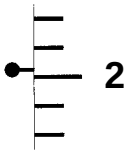


Diagram 9.5

Diagram 9.6

c) Check at Drum Position 6

Analogical the tonometer may be checked at scale value 6. The check values then are at 5.9 / 6.1. Move the scale mark on the measuring drum up or down against the index for 1/2 interval.

10 Maintenance and Care

10.1 Care

Clean the applanation tonometer with a clean and damp leather cloth. Do not use any scrubbing or aggressive cleaning aids!

Use an appropriate disinfectant for the gauging prism (Sekusept®, Gigasept® FF, Pantasept® - for example) and take note of the instruction manual.

Standard Disinfections of Gauging Prisms:

1. Clean the gauging prism under running cold water for 30-60 seconds.
2. Disinfect the gauging prism in accordance to the instruction manual of the disinfectant (Pantasept® - 10 minutes, 3 % aqueous solution, for example).
3. Rinse the gauging prism (min. 10 - max. 60 min.) under running cold water.
4. Dry the gauging prism with a clean and soft cloth.
5. Store the gauging prism in a clean and dry container.

10.2 Maintenance

Control the measurement display in 6-month intervals (see chapter 9).

Change the reusable gauging prism every 2 years at the latest, in order to provide optimum safety to your patients.

10.3 Measuremental Technical Control (MTK)

This device is subject to a, required by law, Measuremental Technical Control by an authorized test center (in 2 year intervals in Germany).

11 Guarantee

Should defects as the result of material or production errors occur within 24 months of purchase, we guarantee free-of-charge repair of the appanation tonometer or we will decide whether to offer you a free exchange, provided that:

- A receipt with the date of purchase can be provided.
- The device has been used properly and in accordance with the conditions of use.
- Repairs have not been carried out by anyone other than the bon Optic customer service team or persons authorized by bon Optic.

Guarantee services do not result in extension of the guarantee, nor do they represent the start of a new guarantee. The sales guarantee is not applicable to consumable products.

The terms and conditions of trade of bon Optic also apply.

12 Technical Data

Measuring Method:	Spring-loaded Weight
Measuring Range:	0 – 80 mmHg (0 – 10.64 kPo)
Backlash:	< 0.25 mN
Standard Deviation:	0.49 mN 3s 1.5% (measured value)
Operational Temperature:	15° - 30°C
Limit Values Ambient Pressure:	>=700hPa and <=1060hPa
Limit Values Relative Humidity:	>=30% und <=75%

Net weight A-900:	0.73 kg (without accessories)
Net weight T-900:	0.65 kg (without accessories)
Net weight Z-800:	0.85 kg (without accessories)

Correlation between the Setting of the Measuring Drum, Force and Pressure:

Position of the Meas. Drum	Force/ mN	Pressure	
		kPa	mmHg
1	9,81	1,33	10
2	19,62	2,66	20
3	29,43	3,99	30
4	39,24	5,32	40
5	49,05	6,65	50
6	58,86	7,98	60
7	68,67	9,31	70
8	78,48	10,64	80

Transport und Storage Instructions	
	Temperature: -10 °C to +60 °C (+14 °F to+140 °F)
	Barometric Pressure: 500 hPa to 1060 hPa
	Relative Humidity: 10% to 90%
Do not maintain the Maximum Conditions for more than 15 consecutive weeks!	

EU - KONFORMITÄTSERKLÄRUNG
EC – DECLARATION OF CONFORMITY

Hersteller-Adresse: (Manufacturer adress)	bon Optic Vertriebsgesellschaft mbH Stellmacherstraße 14 D-23556 Lübeck
Gerätetyp / UMDNS-CODE: (Device typ/ UMDNS-CODE)	Applanationstonometer / (10-168) Applanation tonometer / (10-168)
Gerätebezeichnung: (Device name)	**T-900 / A-900 / Z-800**
Klassifizierung: (Classification)	**1** (Richtlinie 93/42/EWG, Anhang IX, Regel 1) **1** (MDD 93/42/EEC, annex IX, rule 1)

Wir erklären hiermit die Übereinstimmung des vorgenannten Produkts mit der EU-Richtlinie 93/42/EWG über Medizinprodukte.

We declare the compliance of the device with the requirements of the Derective 93/42/EEC about medical devices.

Angewandete Normen: (Applicable standards)	DIN EN 60601-1 EN 46000 ISO 8612	(03/96)
Überwachungsbehörde/ ID-Nr.: (Notified body/ Identification number)	**IMQ / 0051**	

Das Gerät ist gekennzeichnet mit / The device is marked with CE 0051

(Das CE-Zeichen bestätigt die Übereinstimmung des Applanationstonometers mit der EU-Richtlinie 93/42/EWG einschl. I,VI,VII)
(The CE marking confirms the compliance of the Applanation Tonometer with directive 93/42/EEC enclose I, VI, VII)

Lübeck, den 01. Juni 2004

(H. Jochen Kaber, Geschäftsführer)