TONOMETER

MANUAL

Z-800

VIEWLIGHT
POWERED BY INNOVATION

Before use this instrument, be sure to read this manual

EN

CONTENTS

The **Z800 Applanation Tonometer** is an accessory for the Slit Lamp, used for measuring ocular pressure. Thanks to its versatility, the **Applanation Tonometer** can also be assembled on and used with other instruments; it can also be used as an accessory for slit lamps produced by other manufacturers.
Pleaseread this instruction manual and appendices carefully before using the Applanation Tonometer for the first time.
The **Applanation Tonometer** should be used only by suitably trained and authorized personnel. Only properly trained and authorized person should operate the applanation tonometer.
The manufacturer declines any and all responsibility and warranty coverage should the instrument be tampered with in any manner or should routine maintenance be omitted or performed in manners not in accordance with the manufacturer's instructions as set forth herein.

Brief Description of the Instrument

The Z800 Applanation Tonometer operates according to the " Goldmann method." In other words, it measures the pressure required for maintaining uniform applanation of the corneal surface. Precise measurement of the small flattened area is made using a slit lamp at 10x magnification.

Advantages:

- Measurement of the patient 's ocular pressure is made using a slit lamp, together with other routine microscopie measurements.
- Measurement accuracy is extremely high; the standard deviation among single measurements is approximately ± 0,5 mmHg.
- The value is expressed in mmHg and is read directly on the instrument.
- Scerai rigidity need not be taken into consideration because the small volume moved (0,56 mm3) increases intra-ocular pressure by only about 2.5%.
- Repetition of the measurement procedure does not reduce ocular pressure since no "massage effect" has been reported.
- There are no difficulties as regard standardization and calibration.

WARNING
Use this instrument only in strict accordance with the instructions contained in this manual.

Safety rules

The Applanation Tonometer is designed and built in conformity w ith **EC Directive 93/42/ EEC and s.m.i.**

The Applanation Tonometer is a **Class** I measurement f unction device under EC Directive 93/42/EEC and s.m.i.
The instrument is designed to operate in a continuous service regime.

The " (E>' (Eur op ean Community) mark attests that the Applanatio n Tonometer complies w ith the provisions of Annexes I, VI, and VII of EC Directive 93/42/EEC and s.m.i.. Furt he r- more, the instr ument was designed and calibrate ci in conformity with ISO 8612 "Op hthal- mic Instruments - Tonometers."
Production processes, te sting, start -up, maintenance, and repairs are conducted in strict conformity with the applicable laws and international reference standards .

As long as the Applanation Tonometer remains in its or igin ai packing , it may be exposed to the environmental conditions below, during shippin g and warehousing, fora maximum of 15 weeks, w ithout suff ering damage.

- temperature between **-1**O °C and +60 °C;
- atmospheric pressure between 500 hPa and 1060 hPa;
- relative humidity between 10% and 90%.

The w ork ing ambient conditions, instead, are:

- temp eratur e between +15 °C and +30 °C;
- atmospheric pressure between 700 hPa and 1060 hPa
- relative humidit y between 30% and 75%.

Upon receipt and before unpacking, allow the inst rum ent to rema in in its or igin ai packing for several hours in working ambient conditions (to eliminate any condensation and allow the components to reach op timal working temperature).

When using the instrum ent, scrupu lously observe **ali** th e relevant accident prevention me- asures established by law.

Notes on Use

Observe the following prescriptions in arder to ensure safe operation of the instrument.

Never use the instrument if the ambient temperature, atmospheric pressure, and/or relative humidity are outside the limits given above.

Use only cloths dampened with water to clean the Applanation Tonometer. Do not use corrosive products or alcohol.

When cleaning the measurement heads, observe the prescriptions set forth in the "Maintenance" section herein.

The relevant national reference standards for calibration of measurement instruments must always be complied with.

Clean only the exterior surfaces of the instrument following the instructions contained herein.

Repairs and modifications to the instrument must be made only by the specialized technicians of the manufacturer's Technical Service Center or by personnel trained and authorized by the manufacturer. The manufacturer declines any and all responsibility for loss and/or damages resulting from unauthorized repairs; furthermore, any such actions will invalidate the warranty.

Should the instrument suffer shocks (for example, should it accidentally fall), follow the check procedure outlined in the "Calibrations" section below; if necessary, return the instrument to the manufacturer for repair.

Use only the listed accessoires in conjunction with the instrument; use said accessories only in accordance with the procedures set forth in the instruction manuals.

Always carefully observe the safety rules and other precautions published herein.

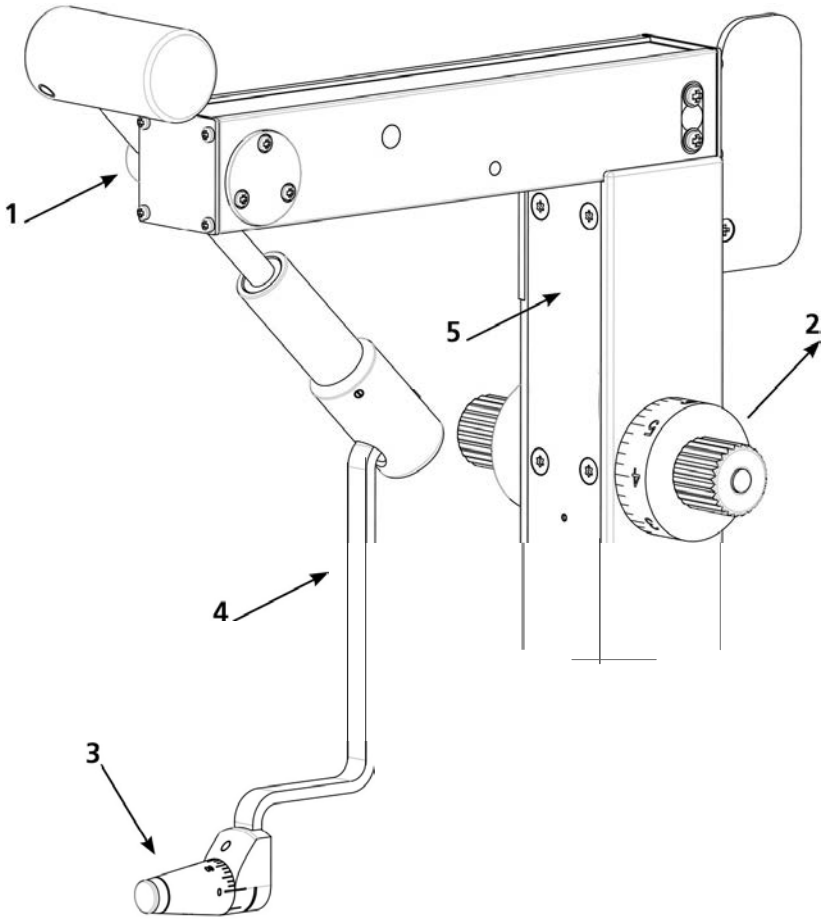
The instrument should be used only by qualified and specially trained personnel.

The owner of the instrument is responsible for training personnel in its correct use.

The year of manufacture and the instrument serial number are printed on the data plate.

LEGENDA

1) Contrai weight housing
2) Rotating knob with measurement drum
3) Measurement head
4) Sensor arm
s) **CE** data plate with serial number and date ot manutacture



Figur e 1: Z800 App!anation Tonomete r

Z800 Applanation Tonometer

Adaptable for use with other manufacturers' slit lamps

To assemble the lever-operated Z800 Applanation Tonometer, insert the assembly plate pin in the hole on the base of the microscope arm of the slit lamp. The instrument is now ready for use. When examining with the Z800 Applanation Tonometer, the angle between the lighting unit and the microscope in the left or right eyepiece should be about 60°. Adjust until the image is bright and without reflections.

Accessories

The packing contains the following standard accessoires:

1) Measurement head (pressure cone) code 10.20.01.100
2) Contra i and calibration lever
3) 2 mm Allen wrench
4) Assembly plate

Assembly Plate

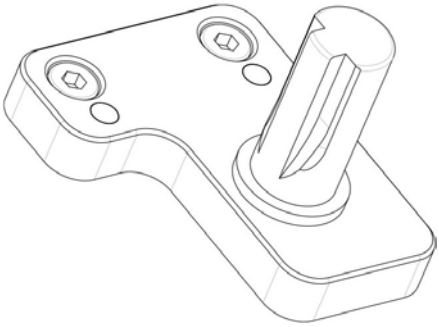


Plate Code 10.02.03.112

Not included in the standard accessory, basic but for what concerns mounting the tonometer on slit lamp, there are the assembly plates. Due to this fact, that type of tonometer is mounted on the top of the microscope of the slit lamp, the assembly plate will change depending on the type of microscope present.

SLIT LAMP WITH 2 MAGNIFICATION MICROSCOPE
Assembly plate cod. 10.02.02.101

SLIT LAMP WITH 3/5 MAGNIFICATION (GALILEIAN SYSTEM)
Assembly plate cod. 10.02.03.101 (Old style)
Assembly plate cod. 10.02.50.302 (New Style)

SLIT LAMP WITH ZOOM MICROSCOPE
Assembly plate cod. 10.02.16.608

Measuring ocular pressure

The cornea is flattened by an organic glass measurement head on a ring support at the end of the sensor arm assembly.The pressure surface of the measurement head is 7.0 mm in diameter. It is flat with rounded margins to avoid any damage to the cornea.

The measurement head is brought into contact w ith the patient's eye by moving the slit lamp forward. Turn the measurement drum to increase the pre ssure on the eye until a continuous, uniform appianateci surface 3.06 mm in diameter (7,354 mm^2 area) is obtained .

Position of the measurement drum	Force mN	Pressure kPa	mmHg
1	9,81	1,33	10
2	19,62	2,66	20
3	29,43	39,9	30
4	39,24	53,2	40
5	49,05	66, 5	50
6	58,86	79,8	60
7	68,67	93,1	70
8	78,48	10,64	80

Fig. 2: Relatio nship between the pressure of the measurement drum and the farce and pressure on the app lanated surface.

The intra-ocular pressure, expressed in mmHg, is calculated by multiplying the drum measurement by ten.

SI Units as per ISO 1000 standard

According to internationa l st and ard ISO 1 000, th e unit of farce is the N (newton); mN (millinewton) is a submultiple of the newton; the unit of pressur e is the Pa (pas cal), equal to N/m2. The kPa (kilopascal) is a multipl e of the pascal.

Conversion of the pressure values expressed in mmHg to may be converted to kPa using the comparative scale in figure 3.

Figu re 3: Comparative Scale

Measurement of the appianateci surface is performed directly on the cornea. The dupli catio n system incorporateci in t h e measurement head divides the im age and presents th e two semicircular halvesat 3.06 mm one fro m the other. Before commencingmeasurement, anaesthetize the cornea locally, piace a strip of fluorescein paper on the conjunctival sac, and insert the blue filt er on the slit lamp. The inner edge of th e ring represents th e line of demarcation between the cornea flatt ened by applanation and the nonflatt ene d corneal surface. The major advantage of applanation tonomet ry is th e limited extent of eyeball deformation , w hich isequal to only 0,56 mm3 surfa ce area. The values measured by this method of tonometry are only slightl y influenced by scierai rigidity and the curvatu re radius of th e cornea.The principle und erlying app lanation tonometry is simple. Rigoro us instrum ent construcli on criteria can guarant ee god operat ion, reliability, and repeatability of results.
Despite the above, th e instru ctions p ro vided herein must be followed scrupulously if accurate results are to be obta ined.

USING THE INSTRUMENT

WARNING
Read Section 2 "Safe Use" before using the instrument. Observe all safety precautions.

Preparing the Patient

1. For lengt hy examinations, the patient 's eyes must always be anaesthetizedto reduce lid movement.
2. Piace a st rip of fluorescein-so aked paper near th e outside corner of the lids in the lower conjunctival sac, as for the Schirmer test. After a fe w seconds the lacrimai fluid will be colored and the paper may be removed. When using drops, we recommend a 0.5 % solution of fluorescein sodium . If using a 1 % or 2% solution, use a glass rod to introduce a small quantity of liquid into the conjunctival sac.
3. Po siti o n the pati ent's head wit h the chin on the chin rest.

Preparing the instrument for examinations at 10 x magnification

Proceed as o utlined below:

- Before beginning measurement, check that the eyepiecesare correctly fo cused.
- Set the brightness contrai of the instrument to position 1.
- Insert the blue filt er on the slit lamp beam path and fully open the slit diaphr agm.
- Clean the measurement head w ith Pantasept fluid at between 0.5% and 3.0% concentrat ion o r with a similar disin fectant soluti o n that is innocuous to o rganic glass (" plexiglass"). Aft er cleaning, rinse the measur ement heads in distilled water and allow t o dry.
- Insert the sensor arm so that th e measur ement head and microscope axes are convergent.
- Rot ate the measu rement drum to positi on 1.

Applanation tonometer 2800

1. Ro tat e the pressurearm with the prism attached through the slit lamp beam along the observation axis of the right microscope.
2. Insert the blue filter in the slit lamp beam path and fully open the slit diap hragm. The angle between t he light source and the microscope should be about 60° in arder to obtain a clear image without reflections.
3. Adjust the microscope before and during the examination as needed to best adapt it to the eyes of the examiner, in such a manner that the fluorescein rings w ill always be observable and clearly focused during the examination.

Instructions to the Patient

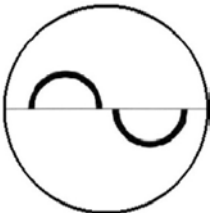
1. The patient's head must be firmly positi oned on the chin rest and t he forehead rest. If necessary,a band may be used to hold the head stili.
2. Ask the patient to look str aight ahead. If necessary, use the fixation target to keep the eyes stili.
3. We recommend reminding the pat ient, at intervals d uring the examination, to keep his/her eyes w ide op en. If necessary, the examiner may use th e tips of his f ingers to hold the lids open, taking care not to exert pressure on the eye.

   In thesecases, the angle between the microscope an d t he lighting unit must be reduced as required, to abo ut 10°, so that the light beam passes through the body of the prism.

   In this manner it should be possible to obtain an image with no reflections.

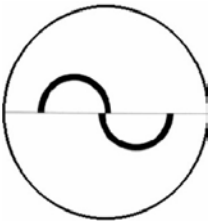
Measurement

1. A few moments before measurement, ask the patient to close his/her eyes fo r a few seconds, in arder to ensure that the cornea be sufficiently w etted by the lacrimai fluid containing the fluorescein soluti on.
2. Move the slit lamp forward to bring the measurementhead into contact w it h the center of the cornea in thearea above the pupil. The corneal limb us wi ll be illuminated wit h a bluish light. The examiner will be able to bett er directly observe thi s phenomenon from the apposit e sid e of the lighting unit. As soon as the corneallimbus is correctly illuminated, immediately stop ali forward movement of the slit lamp.
3. After contact is established , observe the cornea thr ough the microscope. With the measurement drum set to position 1, the two semicircular fluorescein rings (w hich will vary in size according to ocular pressure) will pulse rhythmically if the t onome ter is in the correct position for measurement. Use the guide lever to make any corrections needed until the applanated surface is observed as two semicircularsurfaces o f equal areaat the center of the field of vision. (Figure4).
4. Small adjustments dow nward made with the guide lever will have no effect on the sizes of the semicircular images.



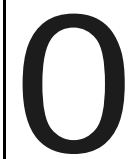
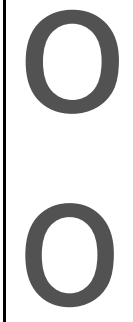
Figu re 4: Semicircular images at the center of the field of vision.

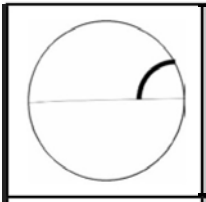
5. Increase ocular pressure by rotating the tonometer measurement drum until the margins o f the fluorescein rings to uch and the cross as the eye pulses(Fig ure 5). The w idth of the fluorescein rings around the contact positi o n of the measurement head should be equal to about 1/1O of the diameter of the app lanati o n surface (0,3 mm).
6. To read t he scale, multiply the readings by a factor of ten (1O). The resul t is th e ocular pressure expressed in mmHg.



Figur e 5: Correct Fina! Position

Sources of Errors

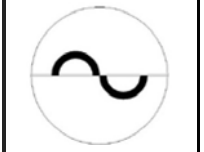
1 The fluorescein ring is too wide or too narrow	
	Cause The fluorescein half-rings are too wide. The measurement head was not dried after cleaning, or the eyelids came into contact with the measurement head during measurement. The pressure reading is higher than the real ocular pressure. ***Correction*** *Move the slit lamp back and dry the measurement head with a wad of cotton wool.*
	**Cause** The fluorescein half-rings are too narrow. The lacrimal fluid has dried during prolonged measurement. The pressure reading is lower than real ocular pressure. ***Correction*** *Ask the patient to close his/her eyes once or twice, then repeat the measurement procedure.*
2. The measurement prism does not touch the cornea or presses on the eye with the weight	
	**Cause** If the patient pulls his/her head back even slightly, the pulses will become irregular and measurement head contact with the eye will become intermittent. If the patient pulls his/her head even further back, the fluorescein half-rings will completely disappear. ***Correction*** *If possible, use a band to hold the patient's head in place.* **Cause** If during measurement the slit lamp is moved forward toward the patient or the patient moves toward the slit lamp, the sensor arm will be pushed into contact with a stop spring. The applanation surface is too large. The image will not change when the measurement drum is rotated. ***Correction*** *Back the slit lamp until regular pulses and a correspondingly smaller applanation surface are obtained. This is the correct measurement position, in which variations in pressure will not cause immediate variations in the applanation surface.*
3. The two semicircles are not centered in the field of vision	
	***Correction*** *Using the guide lever, move the slit lamp up and to the left.*



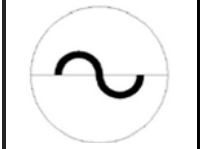
Cause
The rings are too far to the right.
Correction
Using the guide /e ver, move the s/it /amp to the right .

Cause
The reading in t his position is considerably higher t han real ocular pressure.
Correction
Using the height adjustment mechanism, /ower the s/it /amp unti/ the two f /uores- cein half - ring s are equa/ in size. Measurement pressure wi /l t h us be reduced.

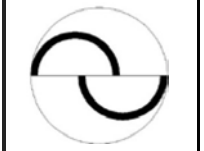
4. The inside margins of the fluorescein rings are not aligned and touching.



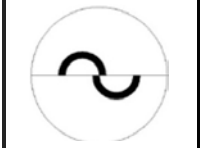
Cause
The semicircular images are well cente red. The outer marg ins are aligned but the inside margins are not , as is instead necessaryfor measuremen t.
Correction
Increase pressure by rotating the measurement drum.



Cause
In this case, the inner margins o f one semicircle are aligned with the outer margins of t he other.
Correction
Increase pressure by rotating the measurement drum.



Cause
Pressure has been increased excessively.
Correction
Red uce pressure unti/ the semicircular images come c/oser toge ther and finally the inner marg ins a/ign w it h each other, as shown in the fast illustration .



Correct fin al position
The inner margins of the semicircular images are a/i gn ed and touching one another.

IMPORTANT NOTE
Measurement must be performed in the least time possible on each eye. Should drying phenomena be observed on the corneal epithelium. check first of all the view and the field of vision.

The measurement procedure may be repeated several times. Nervous and anxious patients often have higher ocular pressure during the first measurement procedure.
It has been found that pressure decreases during the first few minutes of the procedure, when the patient realizes that the tonometric examination does not cause unpleasant effects. When correctly anaesthetized and with their eyes fully open, the patient feels absolutely nothing. Thus we recommend running a preliminary measurement procedure on each eye, the results of which need not be taken into consideration. After completing the preliminary procedure, run three measurement procedures on each eye.
These readings will be correct if pressure has stabilized. When the measurement procedures are performed correctly, the results of the various measurements will *vary* by only about ± 0,5 mmHg.
When the measurement procedure for one eye is prolonged excessively, drying phenomena will occur on the corneal epithelium of both eyes.
A ring of fluorescent deposits will form around the cornea contact surface and around the measurement head on the eye being examined.
The other eye will show fluorescent dry areas, resembling a map, which will hinder measurement, and in this case measurement will no longer be reliable.
The phenomena associated with extensive dryness will disappear in a short time with no need for treatment. Minimal defects in the epithelium will influence eye focusing.

Astigmatism

If the cornea is spherical, measurements may be made along any meridian, but it is convenient to measure along the 0° meridian.
This is not the case when measurements are made on eyes affected by corneal astigmatism greater than 3 diopters, since the flattened areas are not circular but elliptical.
It has been calculated that in cases of more severe corneal astigmatism a surface area of 7,354 mm^2 (ø 3,06 mm) must be appianated; in this case the measurement head forms an angle of 43° to the meridian of maximum radius.

For example:

with corneal astigmatism of:
6,5 mm/ 30° = 52,0 diopters / 30°, and 8,5 mm / 120° = 40,0 diopters / 120°

the 120° prism value will be aligned with the red 43° mark on the prism support.

with corneal astigmatism of:
8,5 mm/ 30° = 40,0 diopters / 30° and 6,5 mm/ 120° = 52 diopters / 120°

the 30° prism value will be aligned with the 43° mark. In other words, align the axial position of the major radius (that is, the axis of a negative cylinder) with the prism value at the red mark on the prism support.

Instaling the instrument

IMPORTANT NOTE
When assembling the tonometer on a device produced by another manufacturer, check that the reciprocai adaptation sizes of the various tonometer models are scrupulously observed.

To mount the tonometer assure to have the assembl y plate, suitable to holding the micro-scope on the slit lamp (see chapter ACCESSORY). Once the assembly plate has been fixed on the microscope, tighten the screw. The tonometer will slip easily onto this assembly plate.

Mantainance

Check Procedures - 2800 Tonometer

Check procedure with the measurement drum setto O
Check Positio n - 0,05:
Rotate the measurement drum zero calibration downward by one spa ce (equal to the width of one calibration mark) with respect to the reference index (Figure 6). When the sensor arm is in the free movement area, it should moveagainst t h e stop in the examiner's direction.
Check Pos ition + 0,05:
Rotate the measurementdrum zero calibration upward by one space (equal to th e w idth of one calibration mark) with respect to the reference index (Figure 6). When the sensor arm is in the free movement area,it should moveagainst th e stop in the pati ent 's di rection.

Check procedure with measurement drum setto 2

> **ATTENTION**
> **This is the most important check procedure, since measurement of ocu-lar pressure in this area is highly significant. We recommend running this check at least twice a year.**

This check is made using the contrai weight (Figure 8). The load bar is engraved w ith 5 circles. The center circle correspon ds to drum position O, the two immediately to t he left and right to position 2, and the outermost two to positi o n 6. One of the positi on 2 marks on the weight is locateci exactly at the reference mark of the weight support The we ight and the support are thus adapted by means of the tonometer shaft in such a manner that the longer portion of the weight is facing the examiner.

When the drum position is 1.95 and/or 2.05 , the sensor arm should move from the free movement area to the corresponding stop.

1.95 check position

Move the calibration mark 2 on the measurement drum downward with resp ect to the index mark, by a distance equal to the width of the mark itself (Figure 6).

When the sensor arm is moved slightly in the direction of the free movement area, it should move independently in the examiner 's directionas far as the stop.

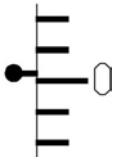


Figure 6: Downward Movement

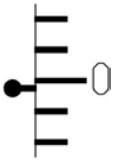


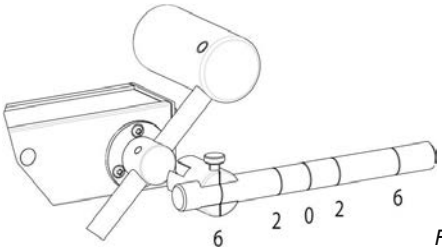
Figure 7: Upward Movement

2.05 check position

Move the calibration mark 2 on the measurement drum upward with respect to the index mark, by a distance equal to the width of the mark itself (Figure 7). The sensor should move until it touches the stop on the patient's side.

Check procedure with the measurement drum setto 6

The tonometer check procedure w ith a scale 6 calibration is very similar to those described above The checkpoints are 5.9 and/or 6.1. Rot at e the " 6 " calib ration mark on the drum through ½ interval downward and/or upward, respectively,with respect to t he index mark



Figu re 8: Contro/ weight

Cleaning the Measurement Heads

- Always disinfect the tonometer measurementheads be fore use.
- We recommend using *a* solutio n of Pantasept disinfectant liquid at *a* 0,5 % to 3,0% concentration.
- We recommend rinsin g the measu rement heads thorough ly in disti lled water and drying immediately.
- Neveruse alcohol to clean the organic glass ("plexiglass") measurement heads.
- We do not recommend disinfecting with UV.
- The measurement heads must not be immersed in liquids fo r long periods of time or exposed to high temperatures (70°C maximum).

Maintenance Notes

Those parts used for connection/assembly of the instrument that are respo nsibl e for ensuring safe operation must be perfectly fitted. Check that t he connection screws are well tightened on ali the accessory pa rts.

Technical

Measurement force	by leverage w eight
Installation	assembled on the guid e plate on the slit lamp arm
Measurement range	O + 80 mmHg (O + 10,64 kPa)
Approxim ation of the impact force on the measurement head fora O t o 58,84 mN measurement range.	Standard divergence : 0,49 mN .:5 3 s .:5 1,5 % of nominai value
Operating temperature range	from 15° to 30°C
Measurement uncertainty	.:5 0,25 mN
Net weight	0,850 kg (without accessorie)s

Data Plate Symbols

	Rea d th e instru ctions carefully
CE 0051	Mark attestin g to compliance with standard s and approvai by the standard s org anizatio n (no . 0051 - IMO)