TONOMETER

# MANUAL

A-900


VIEWLIGHT
POWERED BY INNOVATION

Before use this instrument, be sure to read this manual

EN

# CONTENTS

**CAUTION: Federal laws restricts this device for sale by or on the order of a physician orpractitioner**

The **F900** and **A900 Applanation Tonometers** are an accessory for Slit Lamp SL 900(F900 and A900) and SL 980 (A900), 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.

Please read 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.

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 F900 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 microscopic 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.
- Sceral 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.

1) Control weight housing
2) Rotating knob with measurement drum
3) Measurement head
4) Sensor arm
5) CE data plate with serial number and date of manufacture
6) Assembly plate pin
7) Assembly plate holes
8) Tonometer pin
9) Screw to fix A900 plate
10) Bearing for A900
11) Fixing hole on A900 plate
12) Adjusting ROD

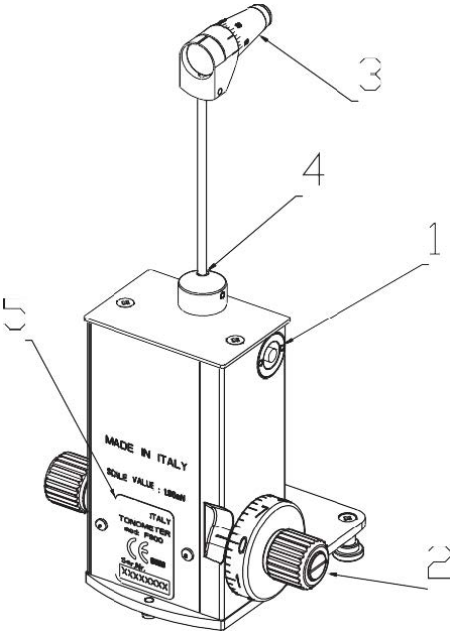
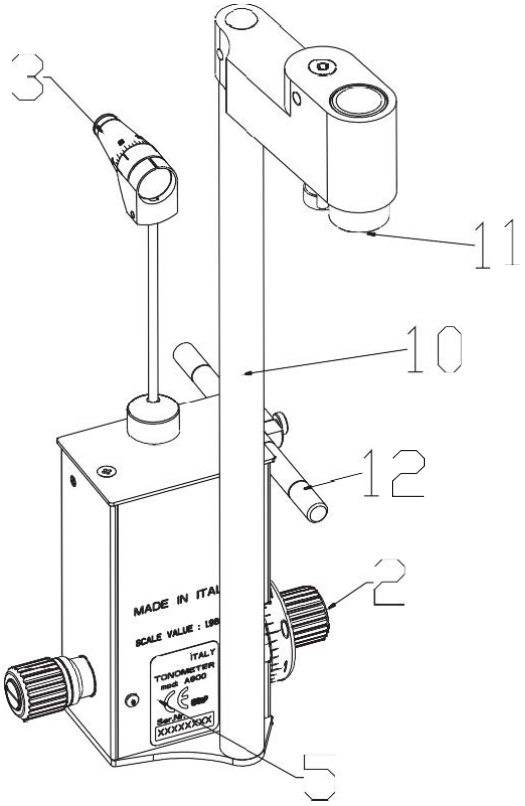



*Figure 1: F 900 Applanation Tonometer*

*Figure 1a: A 900 Applanation Tonometer*



**Applanation Tonometer F900**

*Adaptable for use with other manufacturers' slit lamps*

To assemble the lever-operated F900 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 F900 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.

**Applanation Tonometer A900 (on slit lamp SL 990 and SL 980)**

This instrument is being produced for those who wish the Tonometer to remain permanently on the slit lamp. It is mounted on a pivot on the microscope and for examination is swung forward in front of the microscope. A notch position ensures exact centering of the prism with the left objective, in fact the observation of the flattened area of The cornea is made through the left eye-piece only. When not in use the instrument is secured in a notch position to the right of the microscope.

## Accessories

The packing contains the following standard accessories:

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

## Assembly Plate

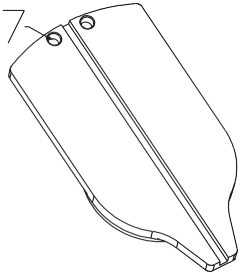



Plate Code 10.02.03.112 (for F900)

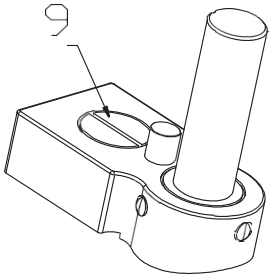
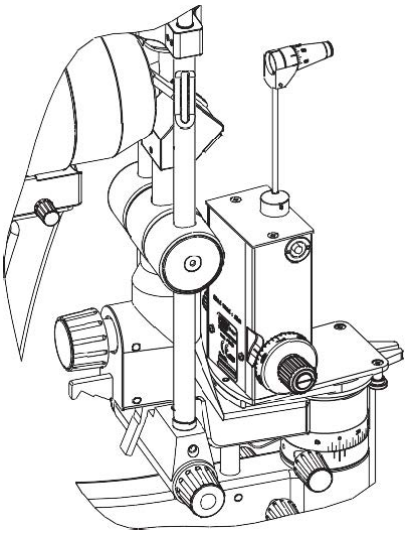


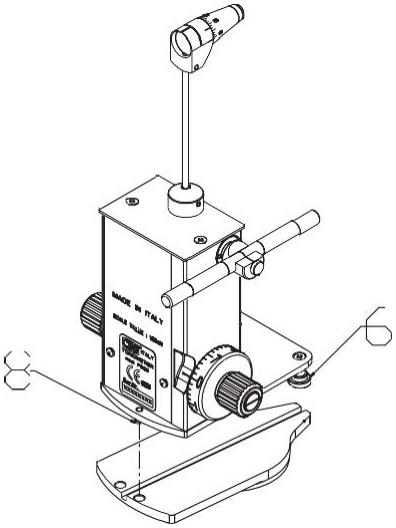

Plate Code 10.02.03.100 (for A900)

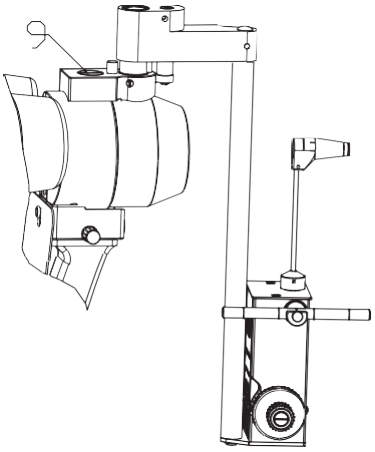
**IMPORTANT NOTE**
When assembling the tonometer on a device produced by another manufacturer, check that the reciprocal adaptation sizes of the various tonometer models are scrupulously observed.

## Tonometer F900

Once the support plate 10.02.03.112 has been positioned in the tonometer support hole on the slit lamp, assemble the lever-operated tonometer by inserting the pin (8) on its base into one of the openings (7) on the horizontal guide plate (according to which eye is to be examined) above the slit lamp axis.
The tonometer will slip easily onto the support plate; stability is assured by the locking pins (6).







## Tonometer A900

Mount the plate for tonometer 10.02.03.100 on the microscope, using to secure the screw (9), then mount the tonometer bearer (10) onto the peg in the fixing hole (11). At this point the tonometer is ready to be used.

**WARNING:**
USE THIS INSTRUMENT ONLY IN STRICT ACCORDANCE WITH THE INSTRUCTIONS CONTAINED IN THIS MANUAL.

## ELECTRICAL SAFETY, GENERAL PRECAUTIONS AND SAFETY WARNINGS

### Safety rules

- The Applanation Tonometer is designed and built in conformity with EC Directive **93/42/EEC** and the **ISO 9000** and **EN 46000** series quality standards.. For mechanical safety standards see also European Reference Standard EN 60601-1, Section 4.
- The Applanation Tonometer is a **Class I** device under EC Directive **93/42/EEC**. The instrument is designed to operate in a continuous service regime.
- The " CE " (European Community) mark attests that the Applanation Tonometer complies with the provisions of Annexes **I**, **VI**, and **VII** of EC Directive **93/42/EEC**. Furthermore, the instrument was designed and calibrated in conformity with **ISO 8612** "Ophthalmic Instruments – Tonometers." Production processes, testing, 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 original packing, it may be exposed to the environmental conditions below, during shipping and warehousing, for a maximum of 15 weeks, without suffering damage.
  **Temperature between -10 °C and +60 °C**
  **atmospheric pressure between 500 hPa and 1060 hPa**
  **relative humidity between 10% and 90%**
  The working ambient conditions, instead, are:
  **temperature between +15 °C and +30 °C**
  **atmospheric pressure between 700 hPa and 1060 hPa**
  **relative humidity between 30% and 75%**
  Upon receipt and before unpacking, allow the instrument to remain in its original packing for several hours in working ambient conditions (to eliminate any condensation and allow the components to reach optimal working temperature).
- When using the instrument, scrupulously observe all the relevant accident prevention measures established by law.

### Notes on Use

Observe the following prescriptions in order 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 accessories 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.

## 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 with the patient's eye by moving the slit lamp forward. Turn the measurement drum to increase the pressure on the eye until a continuous, uniform applanated surface 3.06 mm in diameter (7,354 $mm^2$ area) is obtained.

| Position of the measurement drum | Force | Pressure | |
|---|---|---|---|
| | mN | 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 |

*Figure 2: Relationship between the pressure of the measurement drum and the force and pressure on the applanated 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 international standard ISO 1000, the unit of force is the N (newton); mN (millinewton) is a submultiple of the newton; the unit of pressure is the Pa (pascal), equal to N/m2. The kPa (kilopascal) is a multiple of the pascal.
Conversion of the pressure values expressed in mmHg to may be converted to kPa using the comparative scale in Figure 3.

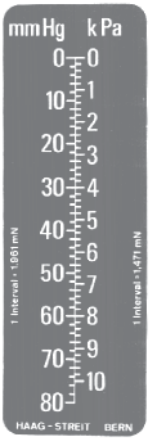



*Figure 3: Comparative Scale*

Measurement of the applanated surface is performed directly on the cornea. The duplication system incorporated in the measurement head divides the image and presents the two semicircular halves at 3.06 mm one from the other.
Before commencing measurement, anaesthetize the cornea locally, place a strip of fluorescein paper on the conjunctival sac, and insert the blue filter on the slit lamp.
The inner edge of the ring represents the line of demarcation between the cornea flattened by applanation and the non-flattened corneal surface.
The major advantage of applanation tonometry is the limited extent of eyeball deformation, which is equal to only 0,56 $mm^3$ surface area.
The values measured by this method of tonometry are only slightly influenced by scleral rigidity and the curvature radius of the cornea.
The principle underlying applanation tonometry is simple. Rigorous instrument construction criteria can guarantee god operation, reliability, and repeatability of results.
Despite the above, the instructions provided herein must be followed scrupulously if accurate results are to be obtained.

**WARNING**
Read Section 2 “Safe Use” before using the instrument. Observe all safety precautions.

## Preparing the Patient

1. For lengthy examinations, the patient’s eyes must always be anaesthetized to reduce lid movement.
2. Place a strip of fluorescein-soaked paper near the outside corner of the lids in the lower conjunctival sac, as for the Schirmer test. After a few seconds the lacrimal 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. Position the patient’s head with the chin on the chin rest.

## Preparing the instrument for examinations at 10 x magnification

Proceed as outlined below:

- Before beginning measurement, check that the eyepieces are correctly focused.
- Set the brightness control of the instrument to position 1.
- Insert the blue filter on the slit lamp beam path and fully open the slit diaphragm.
- Clean the measurement head with Pantasept fluid at between 0.5% and 3.0% concentration or with a similar disinfectant solution that is innocuous to organic glass (“plexiglass”). After cleaning, rinse the measurement heads in distilled water and allow to dry.
- Insert the sensor arm so that the measurement head and microscope axes are convergent.
- Rotate the measurement drum to position 1.

## F900 Applanation Tonometer

1. Rotate the pressure arm 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 diaphragm. The angle between the light source and the microscope should be about 60° in order 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 will always be observable and clearly focused during the examination.

## A900 Applanation Tonometer

1. Swing the illumination unit to the left. Bring the tonometer from the right in front of the microscope into the measuring position located by a notch. Swing the illumination unit to the left to touch the holder of the tonometer. This is the only position of the illumination unit permitting perfect tonometric examination of the left and right eye of the patient (there is no 60° angle between illumination and microscope).
2. Insert the blue filter in the slit lamp beam path and fully open the slit diaphragm. The angle between the light source and the microscope should be about 60° in order 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 will always be observable and clearly focused during the examination.

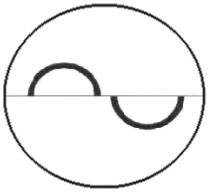
## Istruction to the Patient

1. The patient’s head must be firmly positioned on the chin rest and the forehead rest. If necessary, a band may be used to hold the head still.
2. Ask the patient to look straight ahead. If necessary, use the fixation target to keep the eyes still.
3. We recommend reminding the patient, at intervals during the examination, to keep his/her eyes wide open. If necessary, the examiner may use the tips of his fingers to hold the lids open, taking care not to exert pressure on the eye.
   In these cases, the angle between the microscope and the lighting unit must be reduced as required, to about 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

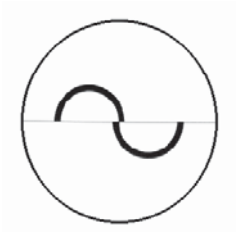
1. A few moments before measurement, ask the patient to close his/her eyes for a few seconds, in order to ensure that the cornea be sufficiently wetted by the lacrimal fluid containing the fluorescein solution.
2. Move the slit lamp forward to bring the measurement head into contact with the center of the cornea in the area above the pupil. The corneal limbus will be illuminated with a bluish light. The examiner will be able to better directly observe this phenomenon from the opposite side of the lighting unit. As soon as the corneal limbus is correctly illuminated, immediately stop all forward movement of the slit lamp.
3. After contact is established, observe the cornea through the microscope. With the measurement drum set to position 1, the two semicircular fluorescein rings (which will vary in size according to ocular pressure) will pulse rhythmically if the tonometer is in the correct position for measurement. Use the guide lever to make any corrections needed until the applanated surface is observed as two semicircular surfaces of equal area at the center of the field of vision. (Figure 4). Small adjustments downward made with the guide lever will have no effect on the sizes of the semicircular images.

*Figure 4: Semicircular images at the center of the field of vision.*



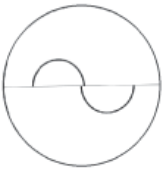
4. Increase ocular pressure by rotating the tonometer measurement drum until the margins of the fluorescein rings touch and the cross as the eye pulses (Figure 5). The width of the fluorescein rings around the contact position of the measurement head should be equal to about 1/10 of the diameter of the applanation surface (0,3 mm).
5. To read the scale, multiply the readings by a factor of ten (10). The result is the ocular pressure expressed in mmHg.

*Figure 5: Correct Final Position*



**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.*



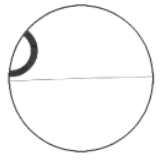
**Cause:**
The fluorescein half-rings are too narrow. The lacrimal fluid has dried during prolonged measurement. The pressure reading is lower than real ocular pressure.
***- Correction:***
*FAsk the patient to close his/her eyes once or twice, then repeat the measurement procedure.*

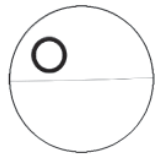
**2. The measurement prism does not touch the cornea or presses on the eye with the weight**

**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:**<br>The rings are too far to the right.<br>***- Correction:***<br>*Using the guide lever, move the slit lamp to the right.* |
|  | **Cause:**<br>The reading in this position is considerably higher than real ocular pressure.<br>***- Correction:***<br>*Using the height adjustment mechanism, lower the slit lamp until the two fluorescein half-rings are equal in size.* → *Measurement pressure will thus be reduced.* |
| **4. The inside margins of the fluorescein rings are not aligned and touching.** | |
|  | **Cause:**<br>The semicircular images are well centered. The outer margins are aligned but the inside margins are not, as is instead necessary for measurement.<br>***- Correction:***<br>*Increase pressure by rotating the measurement drum.* |
|  | **Cause:**<br>In this case, the inner margins of one semicircle are aligned with the outer margins of the other.<br>***- Correction:***<br>*Increase pressure by rotating the measurement drum.* |
|  | **Cause:**<br>Pressure has been increased excessively.<br>***- Correction:***<br>*Reduce pressure until the semicircular images come closer together and finally the inner margins align with each other, as shown in the last illustration.* |
|  | ***- Correct final position***<br>*The inner margins of the semicircular images are aligned 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 applanated; 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.

| | |
|---|---|
| Measurement force | generated by the spring |
| Installation<br>F900 (on slit lamp SL 990)<br><br>A900 (on slit lamps SL 980 and SL990) | assembled on the guide plate on the slit lamp arm<br><br>mountable on peg on microscope assembled on the guide plate on the slit lamp arm |
| Measurement range | 0 ÷ 80 mmHg (0 ÷ 10,64 kPa) |
| Approximation of the impact force on the measurement head for a 0 to 58,84 mN measurement range. | Standard divergence:<br>0,49 mN ≤ 3s ≤ 1,5 % of nominal value |
| Operating temperature range | from 15°C to 30°C |
| Measurement uncertainty | ≤ 0,49 mN |
| Net weight:<br>Tonometer F900<br>Tonometer A900 | <br>0,48 kg (without accessories)<br>0,82 kg (without accessories) |

## ROUTINE MAINTENANCE

## Check Procedures – 900 Series Tonometer (F900 and A900)

**Check procedure with the measurement drum set to 0**
Insert the measurement element.

Check Position – 0,05:
Rotate the measurement drum zero calibration downward by one space (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 move against the stop in the examiner's direction.
Check Position + 0,05:
Rotate the measurement drum zero calibration upward by one space (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 move against the stop in the patient's direction.

**Check procedure with measurement drum set to 2**

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

This check is made using the control weight (Figure 8). The load bar is engraved with 5 circles. The center circle corresponds to drum position 0, the two immediately to the left and right to position 2, and the outermost two to position 6. One of the position 2 marks on the weight is located exactly at the reference mark of the weight support. The weight 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.

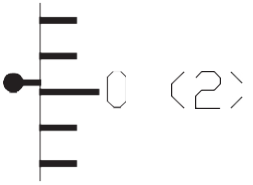


*Figure 6: Downward Movement*

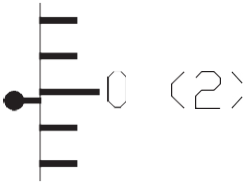


*Figure 7: Upward Movement*

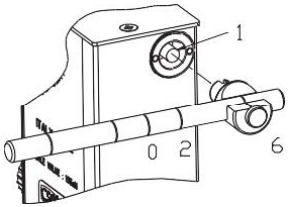



*Figure 8: Control weight*

**1.95 check position:**
Move the calibration mark 2 on the measurement drum downward with respect 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 direction as far as the stop.

**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 set to 6**
The tonometer check procedure with a scale 6 calibration is very similar to those described above The checkpoints are 5.9 and/or 6.1. Rotate the "6" calibration mark on the drum through ½ interval downward and/or upward, respectively, with respect to the index mark

**Cleaning the Measurement Heads**
- Always disinfect the tonometer measurement heads before use.
- We recommend using a solution of Pantasept disinfectant liquid at a 0,5% to 3,0% concentration.
- We recommend rinsing the measurement heads thoroughly in distilled water and drying immediately.
- Never use 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 for 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 responsible for ensuring safe operation must be perfectly fitted. Check that the connection screws are well tightened on all the accessory parts.

## DATA PLATE SYMBOLS

Read the instructions carefully


Mark attesting to compliance with standards and approval by the standards organization (no. 0051 - IMQ)

**1) Remove**

- Carefully measuring prism from holder

**2) Clean**

- 30-60 seconds;
- Running, cold water;
- Allowed mild soap.

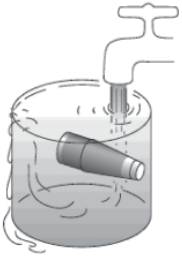
**3) Disinfect**

See to the following list of disinfectant allowed:

- Introducing the measuring prism in the disinfectant liquid:
- Leave it for 10 minutes

The use of the following products / procedures for disinfection will degrade the tip and cause it to fail:

- Alcohol
- Acetone
- UV radiation
- Sterilization
- Immersing in fluid for more than 1 hour
- Temperature above 60° C

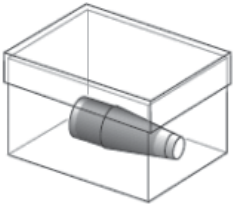


**4) Rinse**

- Min. 10 – max. 60 minutes
- Running cold drinking water

**5) Dry**

- With a one-way tissue
- clean
- soft



**6) Store**

- Place into container
- clean
- dry

| Disinfectant | Tested Concentration | Aldehyde - free | Containing Aldehyde | Comments |
|---|---|---|---|---|
| NaOCl Sodium Hypochlorite | **0.0525%** | **X** | | |
| NaOCl Sodium Hypochlorite | **2.5%** | **X** | | Max. 100 cycles of 1h |
| NaOH Sodium Hydroxide | **1M (1 mol/l)** | **X** | | Max. 100 cycles of 1h |
| H2O2 Peroxyde d'hydrogene | **3%** | **X** | | |
| Almyrol ® | **4%** | **X** | | |
| Anioxyde 1000 | **(*)** | **X** | | (*) Activated solution according to indication of manufacturer |
| Gigasept ® AF | **4%** | **X** | | |
| NU-CIDEX ® | | **X** | | (*) Activated solution according to indication of manufacturer |
| PeraSafe | | **X** | | (*) Activated solution according to indication of manufacturer |
| Perfektan TB | **4%** | **X** | | |
| Stabimed ® | **2%** | **X** | | |
| Sekusept ® PLUS | **4%** | **X** | | |
| Sekusept ® forte S | **3%** | | **X** | |
| Sporicidin ® (SSDS) | | | **X** | (*) Activated solution according to indication of manufacturer |
| Gigasept ® FF | **6%** | | **X** | |
| Pantasept ® | **3%** | | **X** | |

Viewlight nevertheless declines said responsibility if:

- installation and start-up are not performed in accordance with the instructions and precautions set forth in this manual.
- the instrument is used in ways not in accordance with the instructions and precautions set forth in this manual.
- accessories and/or spare parts not supplied or recommended by Viewlight are used.
- repairs and safety checks are performed by persons other than competent, qualified, and suitably-trained personnel authorized by Viewlight
- the electrical system of the installation site does not comply with CEI standards and the pertinent laws and regulations in force.

Viewklight. also declines any and all responsibility for direct or indirect consequences and/or injury/damage to persons and/or things deriving from improper use of the instrument and/or from erroneous clinical evaluation of information derived from its use.

## WARRANTY AND TECHNICAL ASSISTANCE

Viewlight guarantees this product for a period of 24 months from date of invoice. This warranty includes replacement, at authorized service center, of components and materials as well as relative labor. All shipping costs will be at the customer's expense.
Parts subject to wear and/or deterioration due to normal use and parts damaged by improper use or maintenance performed by persons not authorized by Viewlight are not covered by this warranty.

## CONDITIONS NOT INCLUDED UNDER WARRANTY

- Repair of damages caused by natural catastrophes, mechanical shock (dropping, crushing, etc.), defects in the user's electrical system, negligence, improper use, and/or maintenance/repairs performed using non-original materials and/or by persons not authorized by Viewlight
- Repair of damages attributable to any type of improper use or use not specifically intended by the manufacturer.

Viewlight declines responsibility for any interruption or inefficiency in service due to causes or circumstances beyond its control. The customer shall in no case have any right to compensation for damages suffered as a consequence of the unavailability of the equipment.

To request technical assistance with maintenance, contact a technical assistance center or directly contact:

**Viewlight**
8380 NW 64 St
Miami Fl, USA , 33166
Phone +305-406-3915 - Fax +305-938-5012

customerservice@viewlightusa.com
www.viewlightusa.com

TONOMETER

MODELS : F900, A900

that the aforementioned product is designed and built in compliance with the requirements contained in:
**Directive 93/42/EEC "medical devices" dated 14/06/1993,**
using the following norms:

- "CEI EN 60601-1 Standard for electromedical devices" (2nd edition - 1991 and subsequent modificationsthereto).
- "CEI EN 60601-1-2 (2nd edition -2001) collateral standards for electromedical devices" as the reference for the electromagnetic compatibility.
- The product is class I, as the Directive 93/42/EEC, and it'a a measurement device
- UNI EN ISO 8612:2001 Ophthalmic instruments: Tonometers
- It is put in market with mark CE 0051, including the code number of the notify body (IMQ) certificate n. 811/MDD.

The complete test reports performed on one model taken from the series production, and the rest of the technical, production and quality assurance documents (as called for in at- tachment VII to directive 93/42/EEC) are on file in the Viewlight company archives.

## REFERENCE STANDARDS

The following reference standards were applied in design, production, and testing of the product:

**EU Directives**

- **DIRECTIVE 93/42/EEC "MEDICAL DEVICES " of 14 JUNE 1993.**
- **DIRECTIVE 2002/96/EC "Waste Electrical and Electronic Equipment (WEEE)."**

**Standards concerning Quality Management Systems**

- **UNI EN ISO 9001:2000 "Quality Management Systems – Requirements."**
- **UNI EN ISO 13485:2004 "Medical Devices – Quality Management Systems - Clinical Requirements for Regulatory Compliance."**

**Technical Standards**

- **EN 60601-1 - "MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY." 1991 edition as amended.**
- **EN 60601-1-1 - "Medical Electrical Equipment – Collateral Standard: Safety Requirements for Medical Electrical Systems." 1994 edition as amended.**
- **EN 60601-1-2 - "Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility." 2001 edition.**
- **UNI EN ISO 15004 "Ophthalmologic Instruments – Basic Requirements and Verification Methods." 2000 edition.**
- **UNI EN ISO 14971:2004 "Risk Management for Medical Devices."**



## CERTIFICATIONS

CE 0051

CERTIFIED
QUALITY SYSTEM
ISO 9001:200
ISO 13485
CSQ
n° 9120 - CSQ1
n° 9124 - CSQ2

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