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OSafety

1) SAFETY CONSIDERATIONS

For safer and more effective use of the apparatus, the reader is asked to observe the following points:

General definition of safety symbols are indicated below.



Caution



Caution

When a wound occurs to the cornea contact surface of prism, please trade with a new prism. This is because the damage may be caused on cornea.

Please keep the prism clean with antiseptic solution to prevent the infection between patients.

It washes away the prism after the sterilization with clean water, and, please clean it.

Please do not perform sterilization by the following methods.

An autoclave, sterilization by boiling, sterilization with the highly-concentrated alcohol.

An electron beam, EO gas, the sterilization caused by the high frequency.

Please never break down the device.

It causes the trouble.



Caution

Don't sterilize a prism with alcohol. Cloudiness and the breaking are possible when I use it.



Caution

The use of sterilization of the prism is two years.

2) Indication

Name plate

The following matters are displayed on a nameplate.

- Product name
- Model No.
- Manufacturer & Distributer

- Serial No.

The following emblems are displayed.



Caution



Cf. instruction manual



The name of the maker and the location

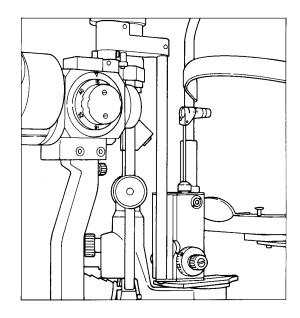


Manufacturer

If it is packing of the product shipment, this packing adapts to a transportation examination of EN ISO 15004.

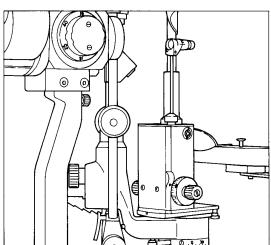
This product adapts to EN ISO 8612.

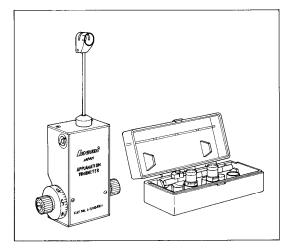
INAMI APPLANATION TONOMETER L-5110/L-5130



L-5110 INAMI Applanation Tonometer for the measurement of intraocular pressure is designed to be mounted on the microscope permanently.

When the tonometer is in use it can be swung forward just in front of the microscope and exact centering of the prism with the left eyepiece is engaged by notch. Illumination through the built-in cobalt filter projected to the plastic measuring prism for flattening the vertex of cornea gives reflection-free observation of split images.





Applanation Tonometer, prism set and calibration bar

Standard Set

Applanation tonometer1
Prism2
Calibration bar1
Mount for tonometer1

L-5130 INAMI Applanation Tonometer, same as L-5110 Applanation Tonometer, can be used with various INAMI Slit Lamps.

L-5130 can be placed on the guide plate in one of two possible positions. These positions are connected with the microscope, for observation can be made either through the right or the left eyepiece.

Specifications:

Measuring range: From 0 to 80mmHg in 2mmHg increments \pm 0.5mmHg

Diameter of the pneumatic face: 3.06mm

Measurement: 47mm wide \times 30mm deep \times 85mm high

Weight: 725gs.

Standard Set

Applanation tonometer1
Prism2
Calibration bar·····1

Optional Accessory

Special adaptor for compact slit lamps1 L-0329, L-0349, L-0399

I DESCRIPTION OF THE MEASURING PRINCIPLES

The cornea is flattened with a prism made of plastic. The anterior surface is flat, its diameter being 7.0 mm. The borders are rounded in order to avoid injuring the cornea.

The prism is brought into contact with the cornea by advancing the slit lamp (fig. 2). Then, by turning the measuring drum which regulates the force applied to the pressure arm, the tension on the eye is increased until a surface of known and constant size of 3.06 mm dia = 7.354 mm² is flattened (fig. 3).

The following table shows the relation between the position of the measuring drum, the force and pressure required for flattening an area of the above size.

Position of the measuring drum	Force	Pressure
1	1 Pond (1 Gram)	10 mm Hg
1	9.81 mN	1.33 kPa

The intraocular pressure in mm Hg is found by multiplying the drum reading by ten.

SI units according to standard ISO 1000

According to ISO 1000 the derived unit of force is the N (Newton) and its decimal sub-multiple the mN (milli Newton). They supersede the units kp (kilopond) and p (Pond):

$1p = 9.80665 \, mN$

Formerly forces were also expressed in kg (kilogram), g (gram) respectively. According to ISO 1000, kg and g are units of mass.

The scale shown in fig. 1 can be used for converting mm Hg into kPa (kilo Pascal) the SI unit for pressure.

A self-adhesive label with this conversion scale is available on request. The measurement of the flattened surface is made directly on the cornea. The optical system of the prism which doubles the image displaces the two halves of the image 3.06 mm from each other.

m	mHg	kPa	
	0 -	∓0	
	10-	主 主 2	
	20 -	₹ 3	
	30 -	- Լուժույժովավակակակակա 1 2 3 4 5 6 7 8 9	
1mN	40 -	± 5	ImN
Interval = 1.961mN	50 -	₹0 ₹7	Interval = 1.471mN
1 Inter	60 -	₹8	1 Inter
	70 -	₹9 ₹10	
	80 -] 10	

Fig. 1

Before measuring the pressure, the cornea must be superficially anaesthetised, a strip of fluorescein paper placed into the lower fornix and the blue filter inserted in the path of light. Where the prism touches the cornea, the fluid is pushed to the periphery of the contact zone and so forms a distinct yellow-green ring. The inner border of the ring represents the line of demarcation between the cornea flattened by applanation and the cornea not flattened.

The major advantage of applanation tonometry is the small bulbus deformation which amounts to only 0.56 mm³. The values found by this method of tonometry are only slightly influenced by scleral-rigidity and radius of corneal curvature.

The principle of applanation tonometry is simple. The careful construction of the apparatus is a guarantee of its continued correct performance. It is easily checked. Nevertheless, in order to obtain exact results, the method of use indicated must be strictly followed.

II PREPARING THE PATIENT

- 1. Anaesthetise both eyes with 2-3 drops of Novesine (Dorsacaine) 0.4% within half a minute. Both eyes must always be anaesthetised to prevent movements of the lids during prolonged examination.
- 2. Place a fluorescein paper strip near the external canthus in the lower conjunctival sac in the same manner as for the Schirmer test. After a few seconds the lacrimal fluid is sufficiently coloured and the paper can be removed. Fluorescein paper strips are preferable to solution, as the latter favours the growing of pathogenic germs, while the former can be sterilized.

When using drops, a solution of sodium fluorescein 0.5% is advisable. Should you wish to instill a solution of 1% or 2%, introduce a small amount of liquid into the conjunctival sac by means of a glass rod.

- 3. The patient is asked to put his head on the chin and forehead-rest of the Slit Lamp.
- 4. **Indications:** Practitioners licensed by law to perform tonometry may use the applanation tonometer to measure the intraocular pressure (I.O.P.).
- 5. **Contraindications:** Use is contraindicated in patients with known hypersensitivity to topical anesthetics such as tetracaine hydrochloride, and proparacaine hydrochloride.
- 6. **Warning:** An abnormal cornea can affect measurement accuracy. Measurements derived from an eye with a corneal scar, corneal ulcer, keratoconus, and irregular astigmatism are prone to error. Lid squeezing and forceful retraction of the lids will cause measurement variation, and increase the incidence of false positive findings.
- 7. **Precautions:** Prolonged use of a topical anesthetic may produce permanent corneal erosions with accompanying loss of vision. Protection of the eye from irritating chemicals, foreign bodies, and rubbing during the period of anesthesia is important. Patients should be advised to avoid touching the eye until anesthesia has worn off.

III PREPARING THE SLIT LAMP AND THE APPLANATION TONOMETER L-5110, L-5130

- 1. Before measuring, make sure that the eye-pieces are correctly focused.
- 2. Bring the blue filter into the beam of the Slit Lamp and open the slit diaphragm completely.
- 3. With the **model L-5110**, the angle between illumination and microscope should be about 60° so that the image appears bright and free of reflection. Turn the transformer switch to 6 volts. Take the Tonometer out of the accessory box and insert the pin in its base into one of the two holes in the horizontal guideplate on the Slit Lamps axis. The instrument can be used in two positions. Observation is always monocular, either with the right or with the left microscope.
- 4. When using the L-5130 Applanation Tonometer the fixation base has to be mounted first. Remove the screw on top of the cylindrical body of the microscope, the spring should remain in place. The fixation base is now mounted and firmly screwed down. It can be left on the microscope permanently, it does not interfere with the normal usage of the slit lamp. With the model L-5130, an angle of 60° between microscope and illumination device is not really practical. Therefore it is recommended to proceed as follows to measure the intraocular pressure. Swing the illumination device to the left. Bring the tonometer L-5130 from the right in front of the microscope where a notch position ensures the exact centring. Swing the illumination device from the left to touch the holder of the tonometer. This position facilitates the opening of the lids of the patient by the examiner where this procedure is necessary for measurement. The illumination of the flattened area is effected through the measuring prism with hardly any reflection. Observation of the flattened area of the cornea is made through the left eye-piece only.
- 5. Clean the measuring prism with an aqueous solution of Pantasept 0.5% or a similar disinfectant that does not damage perspex (no alcoholic solutions). Afterwards rinse in distilled water and dry with cotton wool.
- 6. Bring the pressure arm into the notch position so that the axis of the measuring prism and the microscope coincide.
- 7. Set the measuring drum at 1. If the prism touches the cornea without any force being applied, the pressure arm will vibrate and this may be disturbing to the patient.

IV INSTRUCTIONS TO THE PATIENT

- 1. The patient's head should be pressed firmly against the chin and forehead rest. If necessary use a head-rest band.
- 2. Instruct the patient to look straight ahead. If necessary use the fixation target to steady the eyes.
- 3. It is recommended that the patient is repeatedly asked to keep his eyes wide open during the examination. If need be the examiner may hold open the lids of the examined eye with his fingers provided that no pressure is applied to the eyeball. In this case reduce also with the model **L-5130** to 10° the angle between illumination device and microscope of observation so that the light traverses the prism.

V MEASUREMENT

- 1. Immediately before measurement the patient is asked to blink so that the cornea is well moistened with lacrimal fluid and fluorescein.
- 2. By moving the Slit Lamp forward the measuring prism is brought into contact in the centre of the cornea on the pupillary area. On contact, the limbus of the cornea shines with a bluish light. This is best observed by the naked eye from the side opposite to the illumination. As soon as the limbus lights up, stop moving the Slit Lamp.
- 3. Only after contact is the microscope used. The steady pulsation of the two fluorescein semi-circles, the size of which, with the measuring drum set at 1, will depend on the intraocular tension, indicate that the instrument is in the correct position for measurement, fig. 2. Any necessary correction has to be made by the control lever or the height adjustment control of the Slit Lamp, until the flattened area is seen as 2 semi-circles of equal size in the middle of the field of view, see fig. 2. (Should this not be the case, observe proceedings in chapter VI, Sources of error). Small movements with the control lever should not alter the size of the semi-circles.

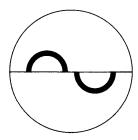


Fig. 2

4. The pressure on the eye is then increased by turning the measuring drum on the tonometer until the inner borders of the two fluorescein rings just touch each other, in other words when they overlap with each pulsation of the eye, fig. 3. The width of the fluorescein band around the point of contact of the measuring prism should be about one tenth of the diameter of flattening (0.3 mm).

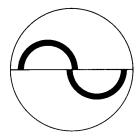


Fig. 3

5. Now read on the measuring drum, the amount of pressure applied. By multiplying this reading by ten, the intraocular pressure in mm Hg is found.

VI SOURCES OF ERROR

Errors will be introduced under the following conditions:

- 1 The fluorescein ring is too wide or too narrow.
- **2** The measuring prism does not touch the cornea, or presses with the protection weight on the eye.
- 3 The two semi-circles are not in the middle of the field of view.
- **4** The inner borders of the fluorescein rings do not touch each other.

Condition 1

Fig. 4: The fluorescein band is too wide. Either the measuring prism was not dried after cleaning or the lids have come into contact with the prism during measurement. The pressure read from the drum will be higher than the real intraocular pressure. For correction the Slit Lamp has to be drawn back and the prism must be cleaned and dried with a piece of cotton wool.

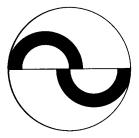


Fig. 4

Fig. 5: The fluorescein rings are too narrow. The lacrimal fluid has dried out during a protracted measurement. The reading on the drum is lower than the actual intraocular pressure. After the patient has opened and closed his eyes several times, the measurement may be repeated.

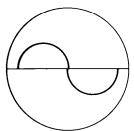
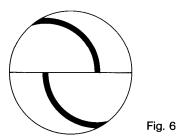


Fig. 5

Condition 2

If the patient retreats slightly there will be irregular pulsation, because the measuring prism only temporarily touches the eye. If the patient retreats still further, the fluorescein ring will disappear completely. Under these circumstances the use of a head-rest band might be an advantage.

Fig. 6: If the Slit Lamp is moved too far forward towards the patient or the patient moves, during measurement, towards the Slit Lamp, the pressure arm will push against a spring which will press against the eye with a low inoffensive force. The flattened area will be too large. Turning the measuring drum scarcely changes the picture. Draw the Slit Lamp back until regular pulsation of a correspondingly smaller surface is seen in the correct measuring position and the change of pressure will immediately alter the size of the flattened area.



Condition 3

Fig. 7 and 8: The Slit Lamp has to be elevated and moved with the control lever to the left.

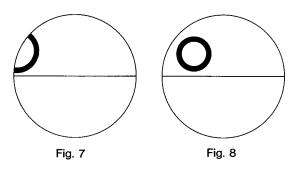


Fig. 9: The rings are too far to the right. Move the Slit Lamp by means of the control lever to the right.

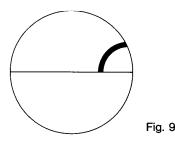
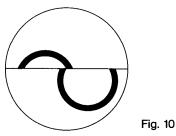


Fig. 10: The value indicated on the drum when the 2 fluorescein rings are in this position is considerably greater than the real intraocular pressure. Lower the Slit Lamp until true semi-circles are seen and reduce the pressure.



Condition 4

Fig. 11: Here the outer borders of the fluorescein rings touch. The inner borders, which are required to touch, do not in fact do so. Increase the pressure by turning the measuring drum.

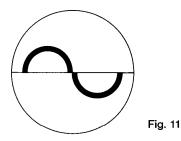


Fig. 12: Here the inner border of one semi-circle touches the outer border of the other. Increas the pressure still more.

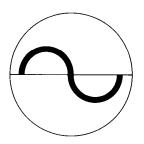


Fig. 13: The pressure has been increased too much. By reducing the pressure the circles will come together so that they touch each other correctly as in fig. 14.

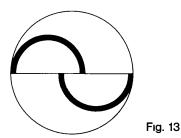


Fig. 14: Correct final position (like fig. 3).

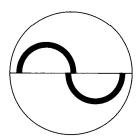


Fig. 14

Fig. 12

VII GENERALITIES CONCERNING THE MEASUREMENT

Measurements can be repeated frequently. At first, excited or nervous patients produce higher readings than normal. When the patient is aware that the procedure is not at all uncomfortable, however, the tension falls to the true value after a certain lapse of time. With the eyes wide open and a good anaesthesia the patient does not feel anything at all. Trial measurements should therefore be made on both eyes, the results of which will be ignored. Three further measurements should then be made and the values obtained are correct if they remain within a range of ± 0.5 mm Hg. When measuring an eye for a prolonged period of time desiccation of the corneal epithelium may appear on both eyes. In the examined eye a ring shaped lesion appears which takes the fluorescein colouration around the zone of contact. This lesion does not disturb the patient. The other, unexamined eye, may show dried out patches in the epithelium which are stained with fluorescein and which make useful measurements of the intraocular tension impossible by means of applanation tonometry. To avoid this condition, measurements should be made as rapidly as possible on each eye alternately. The above mentioned staining is of no consequence and disappears without treatment. The visual acuity, however, is evidently diminished temporarily by these lesions. Measurement of the visual acuity and the examination of visual fields should, therefore, be made before applanation tonometry.

VIII ASTIGMATISM

If the cornea is spherical, measurements can be made on any meridian, but it is most convenient to do it on the 0° meridian. This is not so when eyes with higher corneal astigmatism than 3 dioptres are examined, as the flattened areas are not circular but elliptic. It has been found that in cases of high astigmatism, measurements made in a direction of 43° to the meridian of the lower power ensure a flattened area of 7.352 mm² (dia. 3.06 mm).

For example:

If the corneal astigmatism amounts to

 $6.5 \text{ mm} / 30^{\circ} = 52.0 \text{ dioptres} / 30^{\circ} \text{ and}$ $9.5 \text{ mm} / 120^{\circ} = 40.0 \text{ dioptres} / 120^{\circ}$

the graduation value 120° of the prism is set at the red 43° mark of the prism holder.

If there is a corneal astigmatism of

 $9.5 \text{ mm}/\ 30^{\circ} = 40.0 \text{ dioptres}/\ 30^{\circ} \text{ and}$ $6.5 \text{ mm}/120^{\circ} = 52.0 \text{ dioptres}/120^{\circ}$

the graduation value 30° is set at the 43° mark. In other words, set the axial position of the greater radius, that is the axis of a minus cylinder, on the prism graduation at the red mark on the prism holder.

IX CHECKING THE INSTRUMENT

a) Checking at drum position 0 (zero)

Insert the measuring prism.

Measuring position -0.05:

The zero mark on the measuring drum is set one line width below the index (fig. 16).

When the pressure arm — with prism in position — is gently pushed it should move freely between the two stops and return towards the stop on the examiner's side.

Measuring Position +0.05:

The zero mark on the measuring drum is set one line width above the index (fig. 16). When following the same procedure as above the pressure arm should move towards the patient's side.

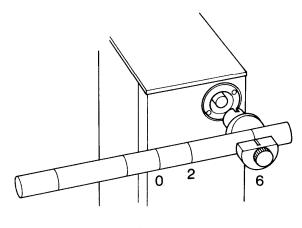


Fig. 15

b) Checking at drum position 2

For this check the control weight is used (Fig. 15). Five circles are engraved on the weight bar. The middle one corresponds to drum position 0, the two immediately to the left and right to position 2 and the outer ones to position 6.

One of the marks on the weight corresponding to drum position 2 is set precisely on the index mark of the weight holder. Holder and weight are then fitted over the axis of the tonometer so that the longer part of the weight points towards the examiner.

At drum position 1.95, 2.05 respectively (graduation mark 2 on measuring drum set one line width below/above the index respectively, as shown in fig. 16) the pressure arm should return from the area of free movement to the corresponding stop.

The check at drum position 2 is the most important and should be carried out frequently, as the measurement of intraocular pressure in this range is of particular importance.

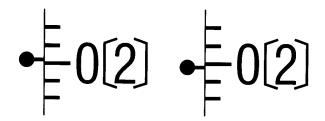


Fig. 16

c) Checking at drum position 6

In the same manner the tonometer should be checked at drum position 6. The corresponding checking points are 5.9 and 6.1. The graduation mark 6 on the drum is offset by half an interval below or above the index.

X THE 11 GLAUCOMA RULES

- 1. All patients aged 40 or more, and all myopes (over -3 D.S.) aged 20 or more should be examined with the Applanation Tonometer. This should be performed at least once a year in patients who are frequently seen.
- 2. If the ocular pressure is 21 mm Hg or higher, a visual field examination should be performed at a subsequent visit.
- 3. If perimetry is performed because of suspicion of glaucoma, this should be followed by measurement of the intraocular pressure.
- 4. When the intraocular pressure is between 21.0 and 22.5 mm Hg, and the visual fields are normal, repeat the perimetric examination and the tonometry in one year.
- 5. If the intraocular pressure is higher than 22.5 mm Hg and the visual fields are normal, the intraocular pressure should be checked in one week, and a perimetric examination should be repeated in 6 months.
- 6. If intraocular pressures higher than 22.5 mm Hg are repeatedly recorded, or if the intraocular pressure at one measurement be higher than 22 mm Hg, or if typical perimetric changes associated with glaucoma are found, the following examinations should be performed: charting of the intraocular pressure changes 2 measurements by applanation and a measurement of the morning pressure in a darkened room with the Schiötz-Tonometer, gonioscopy, determination of the ocular rigidity, perimetric examination, examination of the optic disc with the contact lens and Slit Lamp.
- The patient should persue his normal pattern of life and out-patient treatment is preferable, therefore, to in-patient treatment.
- 7. If during the plotting of the intraocular pressure curve several readings above 22.5 mm Hg are taken, medical treatment should be instituted, commencing with pilocarpine drops at night. The pressure should become normal during the whole day (the tension should remain below 20 mm Hg for 2 successive days), then checked after one week and again in two-weeks.
- 8. Deteriorations of the visual fields with an intraocular pressure below 22.5 mm Hg indicates the need for medical treatment.
- 9. If, despite careful medical treatment, intraocular pressures above 22.5 mm Hg are obtained, or if, despite a «normal» tension (not higher than 22.5 mm Hg) the visual field continues to deteriorate, treatment has to be changed. After the change of medication, the tension checked during a pressure curve should fall by a minimum of 2 mm Hg.

- 10. If despite optimal medication, the intraocular pressure remains between 22.5 and 26 mm Hg, the visual field must be rechecked every 2 months. Surgery would be advised if the visual field undergoes modification, or if despite optimal treatment the intraocular pressure remains above 26 mm Hg.
- 11. In the case of intraocular pressure becoming stabilized below 20 mm Hg the visual field should be checked every 4 months. If the tension is stabilized between 20 and 22.5 mm Hg the field should be examined every month.

Applanation Tonometry: Make a trial measurement first, then take 3 more measurements and calculate the mean value.

First examination of the visual field: Examine the whole field (4 isopters and blind spot).

Checking the visual field: Examine the central field of vision (2 or 3 isopters and blind spot).

XI DISINFECTION METHODS

We recommend the following disinfection for L-5112 Cone Prism.

A. Disinfection solution

0.05% Chiorhexidine digluconate

B. Disinfection methods

(1) Regular disinfection method

Soak L-5112 Cone prism in a fresh solution of 0.05% Chlorhexidine digluconate for 5 to 10 minutes. *If the cone prism is soaked in a fresh solution of 0.05% Chlorhexidine digluconate for 5 to 10 minutes. Then, rinse the solution out of the cone prism with distilled water, and wipe the cone prism softy with an absorbent cotton. And lastly, wipe it with a soft paper.

(2) If a serious infection is confirmed, please change the cone prism.

(3) After use

After use the equipment, keep clean and wipe with soft cloth. The portion which touches a patient and operator should be disinfected by the 70% of ethanol solution for disinfection of the equipment.

XII ENVIRONMENT OF USAGE

- (1)Don't get a device wet.
- (2) Please use the device in environment without sunlight, dust and the salt.
- (3) Please use it at a place without vibration and the shock.
- (4)Please use it at the place where harmful gas is not generated.
- (5)Please use room temperature and the humidity in the following ranges.

Room temperature: +10 \sim +30 $^{\circ}$ C

Humidity: Less than 85%



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