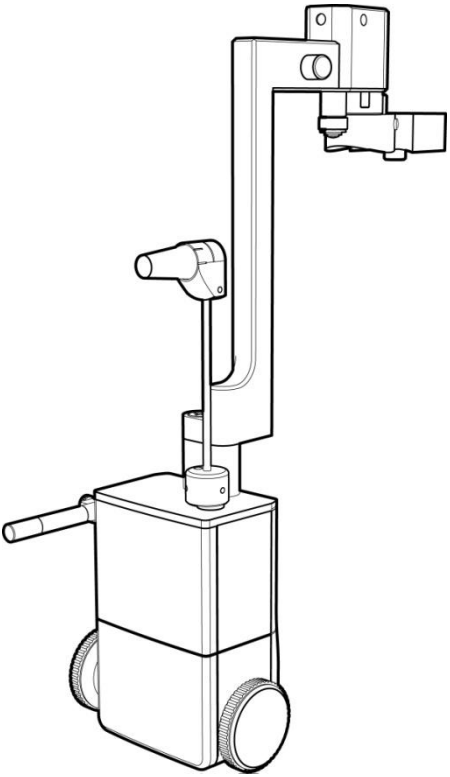
User's Manual

Applanation Tonometer HT-5000



Huvitz

Pacing Progress toward People

IMPORT NOTICE

This product may malfunction due to electromagnetic waves caused by portable personal telephones, transceivers, radio-controlled toys, etc. Be sure to avoid having objects such as, which affect this product, brought near the product.

The information in this publication has been carefully checked and is believed to be entirely accurate at the time of publication. HUVITZ assumes no responsibility, however, for possible errors or omissions, or for any consequences resulting from the use of the information contained herein.

HUVITZ reserves the right to make changes in its products or product specifications at any time and without prior notice, and is not required to update this documentation to reflect such changes..

CE 0197

Ver 1.0

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Contents

1. Safety Information

1.1 Introduction

Safety is everyone's responsibility. The safe use of this equipment is largely dependent upon the installer, user, operator, and maintainer. It is imperative that personnel study and become familiar with this entire manual before attempting to install use, clean, service or adjust this equipment and any associated accessories. It is paramount that the instructions contained in this manual are fully understood and followed to enhance safety to the patient and the user/operator. It is for this reason that the following safety notices have been placed appropriately within the text of this manual to highlight safety related information or information requiring special emphasis. All users, operators, and maintainers must be familiar with and pay particular attention to Cautions incorporated herein.

1. CAUTION

⚠ CAUTION
Please pay attention to this word.

2. Product Classification

※ This product is medical device

1) CE- *Regulatin MDD 93/42/EEC* ; Class Im (measuring functions)

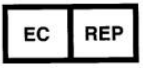
2) FDA – Class II

3) KFDA – Class II

3. Intended Use: Use for glaucoma diagnosis.

1.2 Safety Symbols

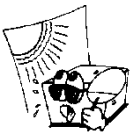
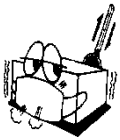
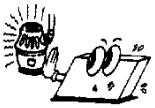
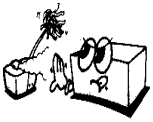
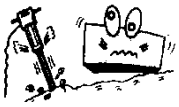
The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warn of any potential hazards. The classifications and symbols are shown below.

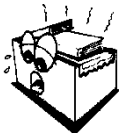
	Type B Isolated patient connection.
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate User's or Service Manual.
	It indicates the year of manufacture and the manufacturer.
	Manufacturer
	Authorised Representative in the European Community
	Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class I equipment for safety purposes.

	Temperature Limitation
	Keep DRY
 UL60601-1 CAN/CSA C22.2 NO.601.1	 MEDICAL EUIPMENT WITH RESPECT TO ELECTRIC SHOCK FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, AND CAN/CSA C22.2 NO.601.1
	Disposal of your old appliance When this crossed-out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health. 4. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.

1.3 Environmental Considerations

Please avoid the environment below for the operation and storage of the equipment.

	Where the equipment is exposed to water vapor. Don't operate the equipment with wet hands.
	Where the machine is exposed directly to the sunlight.
	Where the temperature changes frequently (Normal temperature for operation of the machine is at the range of 10°C ~ 40°C, and the humidity is at the range of 30%~75%.
	Where any heaters are at the close distance to the machine.
	Where the humidity is high and there are problems to the heat dissipation and/or ventilation.
	Where the equipment is subject to excessive shocks or Vibrations.

	Where the machine can be exposed to the chemical or flammable substances.
	Please keep the equipment out of dust and do not let inserted any metal parts such as coins, clips, etc.
	Do not disassemble or open the machine. The manufacture shall have no responsibility for any problems caused by these.
	Do not close the thermal ventilation outlet.

1.4 Safety (Note for Use)

1. This product can use only glaucoma diagnosis.
2. Applanation Tonometer must be used only through people to a medical treatment relation occupation.
3. Applanation Tonometer could be Transfortation / Storage / Operation from this environment.
4. Ambient condition

Transportation	Temperature : −40 °C ~ +70 °C Air Pressure : 500 hPa ~ 1060 hPa Humidity : 10% ~ 95%
Storage	Temperature : −10 °C ~ +55 °C Air Pressure : 700 hPa ~ 1060 hPa Humidity : 10% ~ 95%
Operation	Temperature : +10 °C ~ +40 °C Air Pressure : 800 hPa ~1060 hPa Humidity : 30% ~ 90%

5. Installation, Dispatch
   - To avoid condensation, allow the instrument to adjust to roomtemperature several hours before unpacking.
   - The Applanation Tonometer should be verified for damage after unpacking.
   - The maintenance according to “After use custody and

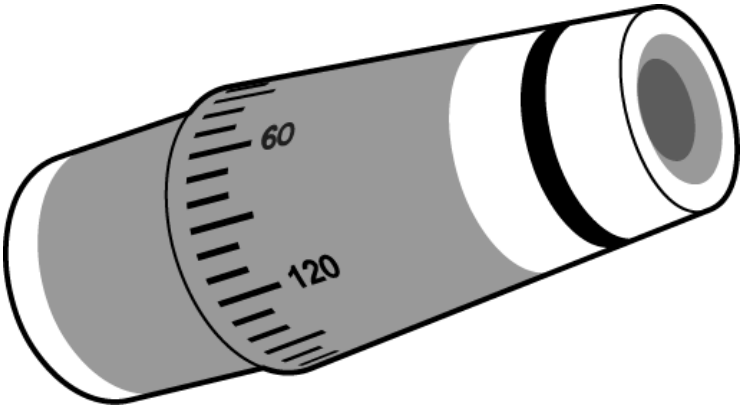
management method".

- Check : do the connection pieces fit (tonometer on slit lamp, measuring prism).
- Defective equipment should always be returned in an appropriate packaging.

6. Operation, Environment
   - The instrument may be operated by qualified and trained staff. Training is the responsibility of the user.
   - Only HUVITZ accessories may be used.
   - Must be satisfied with operational condition of using environment.
7. Cleaning body
   - Use only a cloth that has been moistened slightly and if necessary a little soap.
   - No fluids, abrasive mediums or caustic substances may be used.
   - The instrument is not to be sprayed.
8. Guareantee and third-party product liability
   - Instrument and accessories are produced from high-quality materials using the most modern methods. They have left our factory in a faultless condition. Nevertheless, if you should have any complaints, please consult your representative.
   - The manufacturer grants a guarantee on the instrument. For information regarding guarantee conditions, please refer to your local huvitz representative. The manufacturer guarantee covers breakdowns and defects that are caused by materials and design. Breakdowns and defects that are caused by improper use or outside influences are excluded from the guarantee.
   - Should non-authorised persons handle the instrument then all guarantee liabilities are null and void. Should the instrument be

used although damaged through incorrect use then this can lead to injury to persons. In this case the manufacturer rejects all liability.

9. Do not examine in case of eye infections or injured corneas.
   - There is no contraindication for performing tonometry. Medical assessment is necessary and due care is to be exercised.
10. Do not use damaged measuring prisms.
   - Prior to each use, the contact surface of the measuring prism must be checked for contamination or damage (scratches, cracks or sharp edges.) This must be carried out using the slit lamp microscope at a 10 to 16 x magnification. When found to be damaged, the measuring prism may no longer be used to avoid damage to the patient's cornea.
   - Disinfectant can penetrate into cracks in the measuring prism and lead to chemical burns on the patient's eye during tonometry.
11. Period of use
   - Due to the large number of variables to be taken into account (type and concentration of the disinfectants used, number of patients, handling etc.) it is practically impossible to make a statement as to how often and/or how long a measuring prism can be safely used. HUVITZ measuring prism recommends a maximum service life of two years before the expiry date. This service life applies subject to normal conditions of use, i.e., in compliance with the instructions contained in this manual for use. The period of use begins with the first application. The given time periods are not valid for damaged measuring prisms, they must be immediately replaced.


60
120

2 Product Description

2.1 Introduction

Applanation Tonometer HT-5000 is made for measuring intraocular pressure and It can assemble to HUVITZ Slit lamp(HS-5000). Applanation Tonometer HT-5000 can assemble another slit lamp. Must be used only through people to a medical treatment relation occupation.

2.2 Pressure Measurement Method

The Applanation Tonometer functions according to the 'Goldmann method'.

The measuring of the pressure required to maintain a uniform applanation of the surface of the cornea.

The Corneal is applanated by feeler arm with measuring prism. The diameter of contact surface diameter of measuring prism is 7.0 mm. The corner of the measuring prism is made roundly.

Measuring prism is contacted to patient's eyes according to forward movement of slit lamp.

Increase measurement knob until prism applanation surface becomes ø = 3.06 mm (area = 7.354 mm^2)

According to ISO 1000, pressure is N(Newton), mN(milli Newton)

Display value	Force	Pressure
10	**9.81mN**	**1.33kPa≒10mmHg**

The measurement of the flattened surface is made directly on the cornea. The

built-in duplication system in the measuring prism divides the image and displaces the two semi circular halves from each other by 3.06 mm.

Before measuring, it will be necessary to anesthetise the cornea locally, to place a strip of fluorescein paper in the conjunctival sac and switch on the blue filter of the slit lamp. The inner border of the ring represents the line of demarcation between the cornea flattened by applanation and the cornea not flattened.

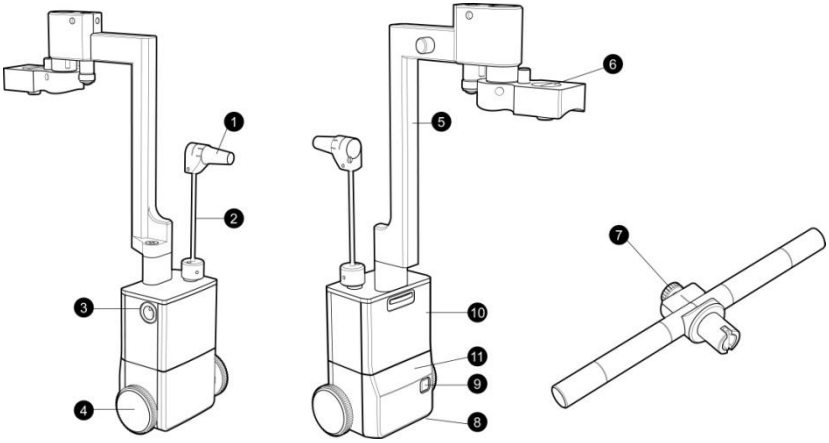
The major advantage of applanation tonometry is the small bulbus deformation which amounts to only 0.56 mm^3. The values found by this method of tonometry are only slightly influenced by scleral-rigidity and radius of corneal curvature, the intraocular tension increases by about 2.5% only.

The principle of applanation tonometry is simple. The careful construction of the apparatus is a guarantee of its continued correct performance. Nevertheless, in order to obtain exact results, the method of use indicated must be strictly followed. The readings obtained are based on the assumption that a cornea with a 'normal' thickness is being measured, alteration of the corneal thickness leads to changes in the measured IOP. A 'normal' corneal thickness is considered to be within the area of 530 to 560 microns.

2.3 Operation and Storage Condition

1. Storage
   - Temperature : −10˚C ~ +55˚C
   - Air Pressure : 700 hPa ~ 1060 hPa
   - Humidity : 10% ~ 95%
2. Operation Condition
   - Temperature : +10˚C ~ +40˚C
   - Air Pressure : 800 hPa ~ 1060 hPa
   - Humidity : 30% ~ 90%

2.4 Configuration

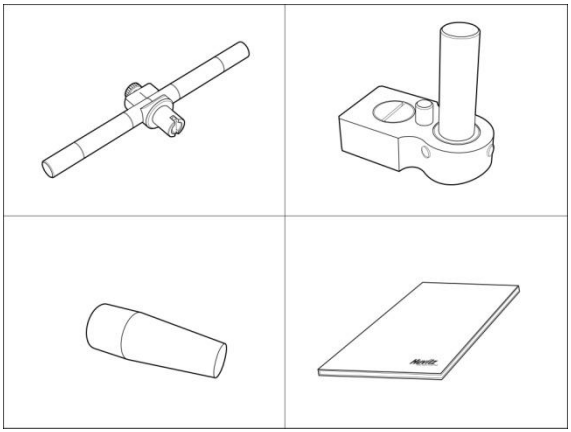


1. Measuring prism : Part for contacting to patient's cornea
2. Feeler arm : Part for locking up the measuring prism
3. Control weight insertion : Part for connecting the weight bar
4. Control drum : The IOP is measured by rotating control drum
5. Connection arm : Part for installing the tonometer to slit ramp
6. Adapter : Part for fixing the tonometer to slit ramp
7. Weight bar : For verification of equitment, the mark is indicated to 0, 20, 60 mmHg position
8. Manufacturing label
9. Function button : Function button is used for power on / off or function control
10. Battery cover : The alkaline battery is stored inside the battery cover (1.5V x 4)
11. Digital display(FND) : The IOP is displayed.

2.5 Basic Unit

This product supplied in the condition which is packed packing. Take out a product from packing and must check the next parts.

- Applanation Tonometer HT-5000 body
- Connection arm
- Weight bar
- Measuring prism (2EA)
- User's manual



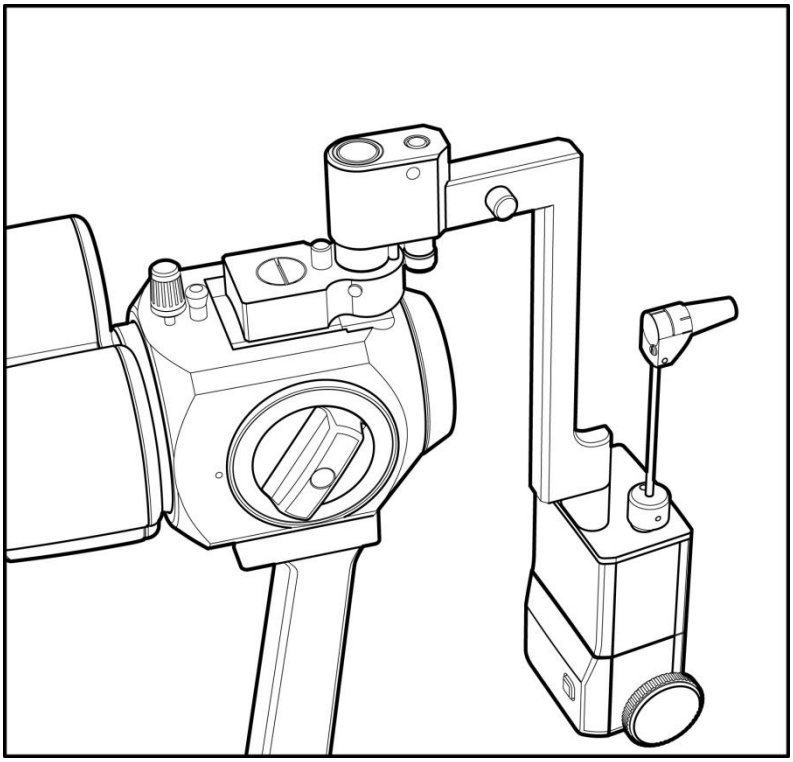
3 Installation

⚠ CAUTION

This product be supplied packing condition which be stand various transportation and standard storage condition. If product be defected, must be called immediately to the HUVITZ.

3.1 Product Installation

1. When install on the slit lamp of another company product, must confirm the part which is assembled of equipment.
2. When assembles Applanation Tonometer, need the mount adapter with screw.
   - ① Unscrew the set screw to be found above and in the middle of the cylinder body of the microscope.
   - ② Position the mounting base for the tonometer and tighten the set screw.
   - ③ When don't use this product, please turn rightward.



4 Operating the Equipment

4.1 Preparation before Using

⚠ CAUTION

Only to use 'HUVITZ' measuring prisms can guarantee trouble-free function. Stenilised Fluorescein paper should always be used because pathogenic excciters thrive well in Flrourescein solutions.

Should the measuring prism come into contact with the cornea without the pressure having previously been correctly set, sone vibrations can occur in the feeler arm that will produce unpleasant fellings for the patient.

1. Patient preparation
   - ① Anaesthetize both eyes with each e.g. 2-3 drops of an anaesthetic within half a minute. Always anaesthetize both eyes as otherwise blinking is unavoidable.
   - ② Place a fluorescein paper strip in the outer external canthus in the lower conjunctival sac. After a couple of seconds the tear fluid has taken on enough sufficient fluorescein. The paper strip can be removed.
   - ③ When using drops, a 0.25 % to 0.5 % sodium fluorescein solution is recommended. Should a 1 % or a 2 % fluorescein solution be instilled, a small drop is introduced to the conjunctival sac using a glass rod.
   - ④ The correct eye height of the patient can be set at the chin rest.
2. For Huvitz Slit lamp and HT-5000
   - ① The focus of the eyepiece is to be checked before the examination.

② Set the magnification to 10x.

③ Set the equipment power supply / the control drum to the lowest setting.

④ The illumination device of the slit lamp set position of the blue filter and open the slit diaphragm fully.

⑤ Feeler arm into place so that the axis of the measuring device and the microscope coincide.

⑥ Turn the tonometer on and adjust it to a value between 5 and 10.

⑦ Bring the illumination device from the left into contact with the tonometer bearer arm. This is the only illumination position in which both the patient's left and right eye can be examined (no 60° position). This arrangement simplifies the splaying of the patient's eyelids should this be necessary to make measurements. The illumination of the applanated surface through the prism head is generally reflection-free.

3. Patient instructions

① Press the head firmly on the chin rest and forehead support. If necessary use a holding band to fix the head's position.

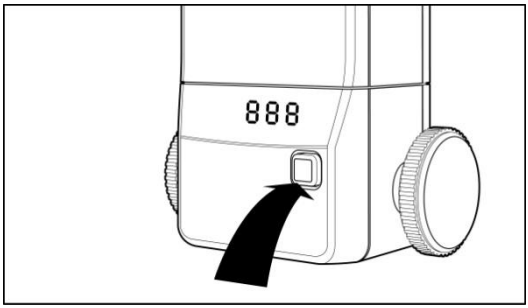
② The patient must look straight forward. If necessary, the small fixing light can be used to steady the eyes.

③ It is recommended that the patient should be repeatedly requested to open the eyes wide during the examination. The examiner must perhaps keep the eye open by splaying the eyelids with thumb and index finger. This must be done without pressure to the eye.

4.2 Equipment Control and Battery Replacement

1. Turn On / Off

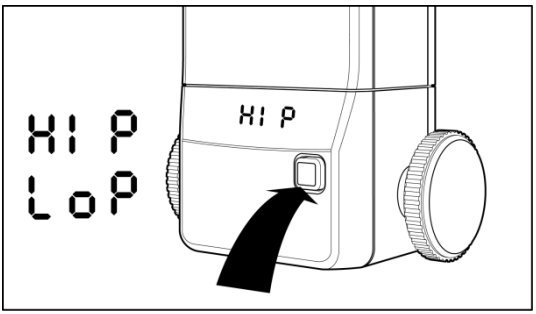
   - Turn the tonometer on, by briefly pressing the function button. The tonometer is ready for use when the digital display lights up and displays the last set tonometer value. The tonometer turns off automatically after 90 seconds, if no other adjustment has been made.



2. LED Display

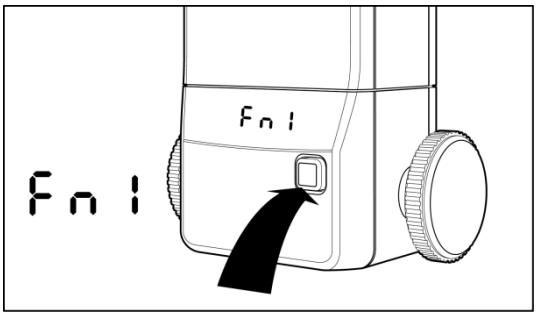
   - The LED below the display is to check whether the measuring prism works in the allowable range during the measurement. It glows red, if the tonometer is not in contact with the cornea, and changes to “LED off” when measure body is in a good distance to the cornea. If the tonometer is too close to the eye, the led color changes to red again. A warning indicates the user that he has left the measuring range and that the sensor is operating in the allowable range. The measuring range is 3 to 75 mmHg. Above this range, the display will

show. [LoP] / [HiP]



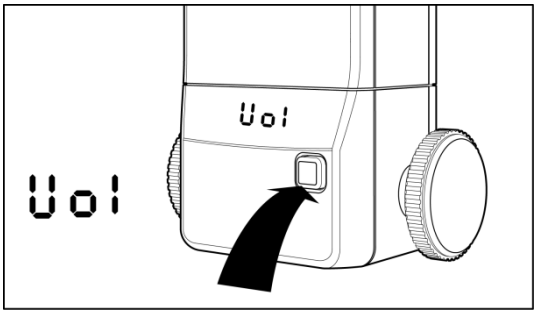
3. Adjust display brightness

- The brightness of the display can be changed with the function button. Hold down the function button about 1 second. The display shows [---](three dashes) and an audible signal sounds. Release the button again. The display shows [Fn] and a level from 1 to 3. By briefly pressing the button you can adjust the brightness. It is recommended that you use the device on the basic attitude [Fn2] to ensure a long operation time of the batteries. If you set [Fn1], you save more batteries power. By pressing the button again for more than one second the tonometer enters to the mode to adjust the volume. [Fn1]



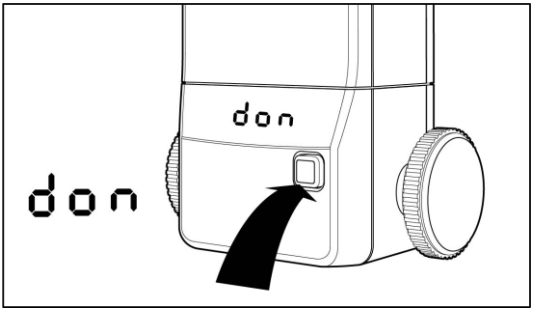
4. Adjust volume

- The volume can be changed with the function button. Hold down the function button 1 second. The display shows [---](three dashes) and an audible signal sounds. Release the button again. The display shows [Vo] and a level from 1 to 3. By briefly pressing the button you can adjust the volume. By pressing the button again for more than one second the tonometer returns to the normal measuring mode. [Vo1]



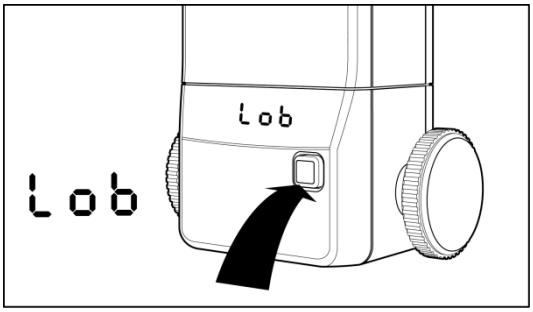
5. Set rounded off function

- The rounded off function can be set with the function button. Hold down the function button about 1 second. The display shows [---](three dashes) and an audible signal sounds. Release the button again. The display shows [don]. By briefly pressing the button you can set the rounded off function in order of [don] -> [doF]. If you set [don], the IOP is displayed up to decimal point in measuring mode. Otherwise, if you set [doF], it is runded off the nearest tenth. By pressing the button again for more than one second the tonometer returns to the normal measuring mode. [don]



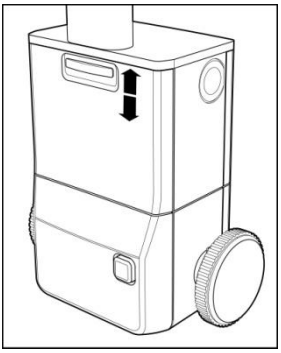
6. Status of batteries

- If after the activation of the tonometer the screen displays [LoB], the batteries should be changed (4x1.5V batteries type AAA). [LoB]



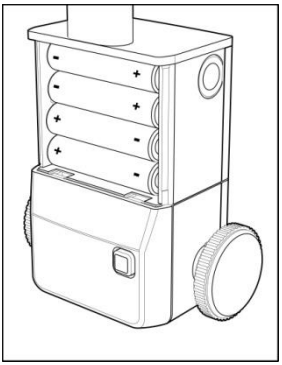
7. Replacement of batteries

- Drag carefully “Battery SW" to the bottom and remove the battery compartment cover while tilting it back.

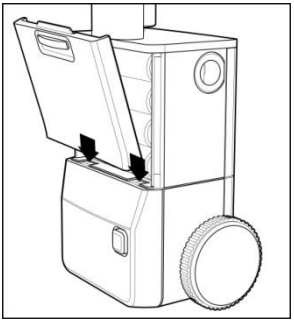


- Remove the cells. Always replace all batteries with new ones, do not combine old batteries with new batteries. Always use sealed 1.5V, AAA batteries.
- Pay attention to the polarity of the batteries. Please take the old batteries to a professional disposal. Pay attention to respect the

correct order according the inscription in the battery compartment.



- Once the batteries are exchanged, put the tabs on the underside of the lid into the grooves of the housing and close it by tilting upwards.



- Press gently on the cover and lock the battery compartment by pushing “Battery SW” back in its place.
- Remove these batteries if EQUIPMENT is not likely to be used for some time.

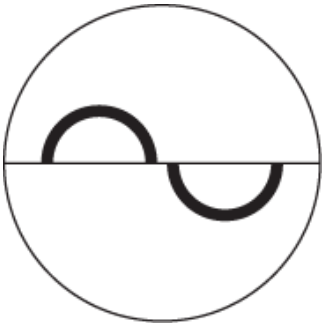
4.3 Correct Measurement

1. Immediately before taking the measurements, the patient should be made to close the eyes briefly so that the cornea becomes sufficiently

moistened with the lacrimal fluid and fluorescein.

2. By moving the slit lamp forward, the measuring prism is brought into contact with the center of the cornea over the pupils. The limbus of the cornea will be illuminated with a bluish hue. This illumination is best observed by direct sight from the opppsite side of the illumination unit by the examiner.As soon as the limbus of the cornea illuminates, cease any further forward movement of the slit lamp immediately.
3. After obtaining contact, commence observing the cornea through the microscope. A regular pulsation of the two semi circular fluorescein rings, which can be of varying size dependent on the ocular pressure, will show that the tonometer is on the correct measuring posion. The required correction is made with the guide lever until the applanated surface is observed as two semi circular surfaces of the same size in the center of the field of sight (picture.1).
4. Increase the pressure by turning the measuring drum on the tonometer, untile the edges of both fluorescein rings just meet(picture.2). The width of the fluorescein ring should be 1/10 approximately of the diameter of the applanation surface.
5. Reading the display in mmHg.

- If the number of display is 10.0, It means 10mmHg.



(1)

(2)

6. Sources of error

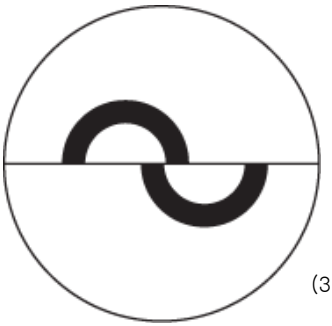
- **Fluorescein band incorrect : 3 ~ 4**

  - Fluorescein band too wide. (3)
    - ✓ The measuring prism was not dried after cleaning or the eyelids came into contact with the measuring prism.
      - ➢ *The slit lamp must be pulled back and the measuring body dried with a cotton-wool ball.*
  - Fluorescein band too narrow. (4)
    - ✓ The tear fluid has dried during a longer lasting measuring.
      - ➢ *One lets the patient close the eyes a few times and then repeat the measurement.*

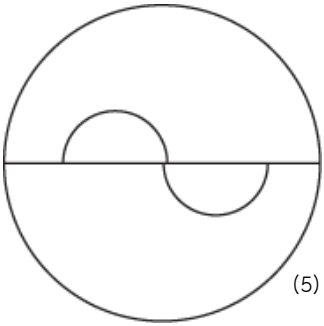
- **Wrong distance to patient : 5 ~ 6**

  - No semi circular image visible, only markings (5)
    - ✓ The measuring prism does not contact the cornea! If the patient retreats the head a little, irregular pulsations are caused because the measuring prism touches the eye only at times. If the patient retreats still further, then the Fluorescein rings disappear completely.
      - ➢ *Use a headband as necessary.*
  - Only parts of both oversize semicircles are visible (6)
    - ✓ If the slit lamp is pushed too far against the patient or the patient moves towards the slit lamp, the feeler arm pushes against a spring stop. The applanation surface is too large.
      - ➢ *The image does not change when the control knob is moved. Pull the slit lamp back until uniform pulsations show an appropriately smaller surface as the correct measuring position.*

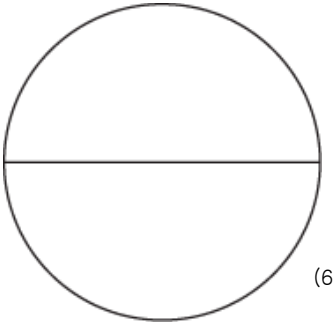
Pressure changes lead immediately to changes in area.



(3)



(5)



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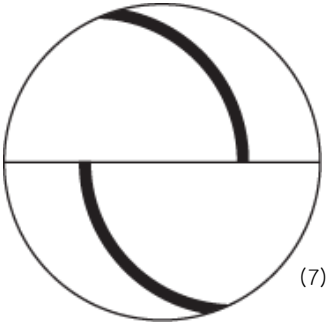
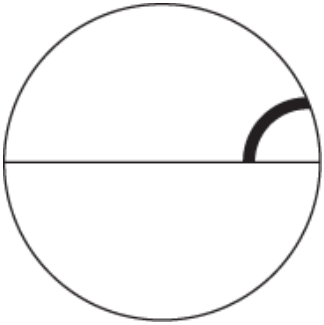


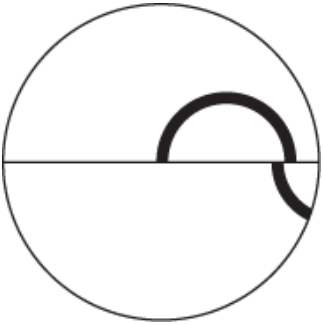
(7)

- Position too far to the right / left : 7 ~ 10

- Only part of the upper semicircle. (7)
  - ✓ Measuring prism not centered on the eye, eye much too far to the right.
    - ➢ *Using the control lever move the slit lamp to the right.*
- Only part of the upper semicircle. (8)
  - ✓ Measuring prism not centered on the eye, eye much too far to the right.
    - ➢ *Using the control lever move the slit lamp to the right.*
- Only part of the lower semicircle. (9)
  - ✓ Measuring prism not centered on the eye, eye too far to the left.
    - ➢ *Using the control lever move the slit lamp to the left.*
- All of the lower semicircle – part of the upper semicircle. (10)
  - ✓ Measuring prism not centered on the eye, eye is too far to the left.
    - ➢ *Using the control lever move the slit lamp to the left.*
- Correct setting! (11)
  - ✓ Two semicircles appear exactly in the middle of the ocular.



(7)



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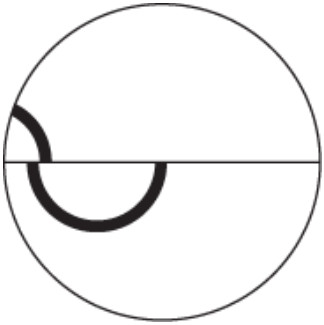
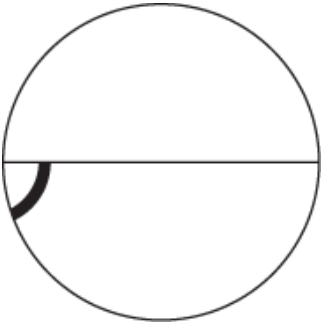


(9)

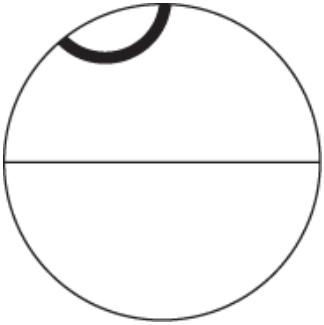


(10)

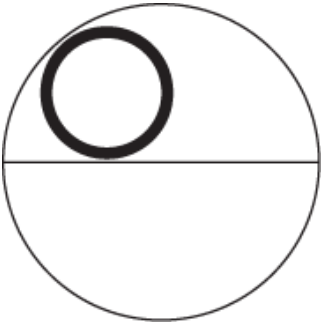
(11)

- Position too high / low : 12 ~ 15

- Only part of a semicircle in the upper half. (12)
  - ✓ Measuring prism not centered on the eye, eye too high.
    - ➢ *Using the control lever move the slit lamp upwards.*
- Complete circle in the upper half. (13)
  - ✓ Measuring prism not centered on the eye, eye is still too high.
    - ➢ *Using the control lever move the slit lamp upwards.*
- Nearly complete circles above, incomplete circles below. (14)
  - ✓ Measuring prism not centered on the eye, eye is still too high.
    - ➢ *Using the control lever move the slit lamp upwards.*
- Two incomplete circles, the larger above. (15)
  - ✓ Measuring prism is nearly centered on the eye, eye is still too high.
    - ➢ *Using the control lever move the slit lamp upwards.*
- Correct setting! (16)
  - ✓ Two semicircles appear exactly in the middle of the ocular.



(12)



(13)

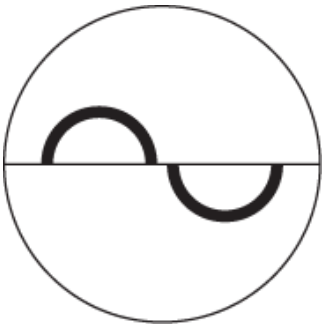
(14)

(15)

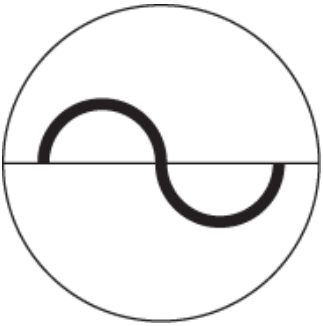
(16)

- Incorrect pressure : 17 ~ 19

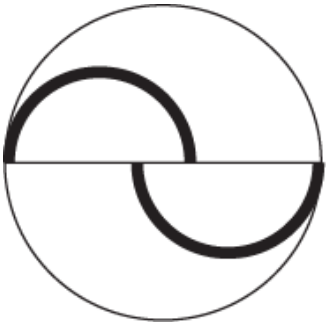
- Contact with the outside borders of the fluorescein bands. (17)
  - ✓ Not enough pressure.
    - ➢ *Increase the pressure slightly by turning the knob on the tonometer.*
- Fluorescein bands are superimposed to form a band. (18)
  - ✓ Pressure slightly too little.
    - ➢ *Increase the pressure slightly by turning the tonometer adjustment knob.*
- Bands are not in contact. (19)
  - ✓ Pressure is clearly too high.
    - ➢ *Lower the pressure by turning the tonometer adjustment knob in the opposite direction.*
- Correct setting! (20)
  - ✓ The inner edges of the fluorescein rings touch each other.



(17)



(18)



(19)

(20)

4.4 Tips for the Measurement

⚠ CAUTION

The measurements should be carried out as quickly as possible. Should the cornea epithelium show signs of dryness then check visual acuity and visual field.

The measurement can be repeated. Excited and anxious patients frequently have a higher intraocular pressure on the first measurement. In the first minute a falling tension occurs as the patient notices that a tonometry does not cause any unpleasant feelings.

With an appropriate anaesthesia and fully opened eyes the patient does not notice anything. This is why a test measurement is carried out on both eyes. The results are discarded and then three further measurements are carried out on both eyes. The values are correct when the pressure has stabilized. The scattering results correspond to ± 0.5 mmHg with the correct procedure.

It can come to drying of the cornea epithelia in both eyes when the measurement takes a long time. A ring containing fluorescein is formed on the eye to be measured where the measuring prism contacts the cornea. On the other eye dry irregular fluorescein patches are formed that are unsuitable for taking measurements. Extensive dryness disappears quickly without any particular treatment. The visual acuity is influenced by this light epithelium defect.

4.5 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 calculated that, in cases of larger corneal astigmatisms, a surface of 7.354 mm2 (ø 3.06 mm) is to be applanated, when the measuring prism is at an angle of 43° to the meridian of the greatest radius.

Example)

If the corneal astigmatism amounts to

6.5 mm / 30° = 52.0 D / 30° and

8.5 mm / 120° = 40.0 D / 120°

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

8.5 mm / 30° = 40.0 D / 30° and

6.5 mm / 120° = 52.0 D / 120°

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

5 Maintenance

1. Storage after using is according to “safety information”.
2. Checking the HT-5000 regularly.

This check should be carried out once a month.

When getting wrong results the following points must be checked.

① Is the measuring prism set correctly?

② Is the control weight correctly set?

③ Repeat the check.

Defective equipment must be sent immediately to the HUVITZ

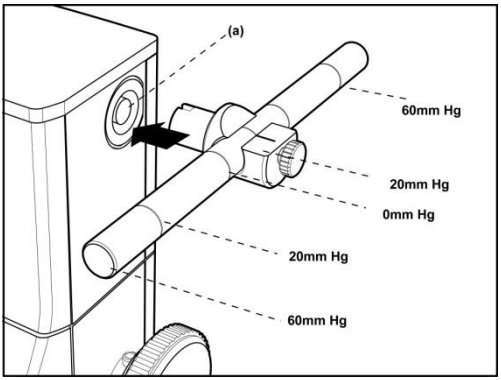
⚠ CAUTION

HUVITZ offers a repair and service packet. For further information give direct liaison to HUVITZ.

5.1 Applanation Tonometer HT-5000 Check

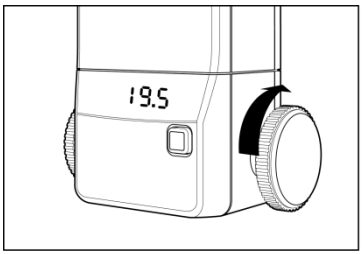
1. Starting position 20 mm Hg

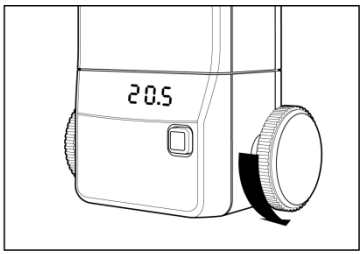
   - The control weight is intended to do this. On the control weight there are 5 rings. The middle position is 0 mm Hg, both directly to the left and right correspond to 20 mm Hg, and the two extremes to 60 mm Hg. Adjust the control weight on one of the starting positions (40 or 60 mm Hg) exactly on the control support (a). Then insert the control weight in the opening of the tonometer so that the longest part of the bar points in the direction of the examiner.



① In the position less than 19.5, the color of LED must be red. If you turn Control drum, LED's color will change to green. And If you turn more, the color will change to red (RED -> GREEN -> RED , Please turn gradually) At that time, IOP value must be between 19.5 and 20.5

② In the position more than 20.5, the color of LED must be red. If you turn Control drum, LED's color will change to green. And If you turn more, the color will change to red (RED -> GREEN -> RED , Please turn gradually) At that time, IOP value must be between 19.5 and 20.5





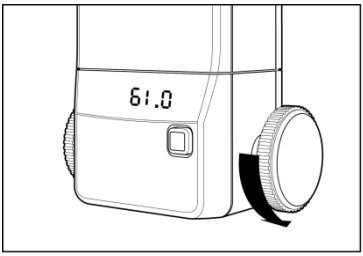
2. Check at 60 mmHg

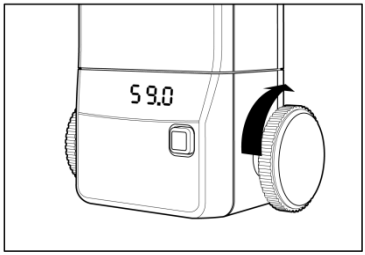
- Adjust the control weight at starting position 60 so that the longest part of the bar points in the direction of the examiner.

① In the position less than 59, the color of LED must be red. If you turn Control drum, LED's color will change to green. And If you turn more, the color will change to red (RED -> GREEN -> RED , Please turn gradually) At that time, IOP value must be between 59 and 61

② In the position more than 61, the color of LED must be red. If you turn Control drum, LED's color will change to green. And If you turn more, the color will change to red (RED -> GREEN -> RED , Please turn gradually) At that time, IOP value must be

between 59 and 61.

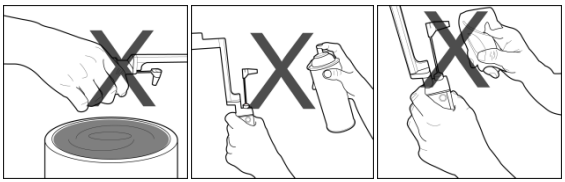




6 Cleaning / Disinfection of Prism

6.1 Disinfection of Prism

1. Must use after clean because measuring prisms are dispatched in a non-disinfected condition.
2. Measuring prisms are cleaned and disinfected correctly. For an optimal cleaning and disinfection the measuring prisms must be submerged and must move freely in the fluid.
3. Prior to disinfection the measuring prisms must be rinsed under cold running water for 30 to 60 seconds. Extremely dirty measuring prisms can additionally be cleaned using a soap and a cotton-wool ball.
4. Measuring prisms to end disinfection are rinsed cold running water.
   - Caution : Time to rinse in water is 10 to a maximum 60 minutes.
5. The measuring prisms should be dried after cleaning, and stored in closed container.
6. To the measuring prisms must not be a residue. Residues can injure to irritation of the patient's eye or chemical burns.



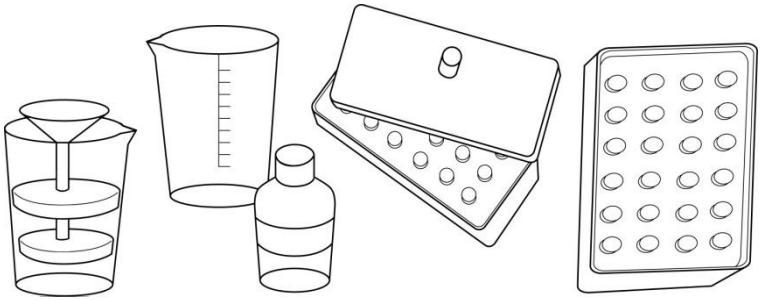
#To the measurement prism there not must be a residue.

Forbidden!

- Disinfection with alcohol
- Cleaning with acetine
- Disinfection with UV irradiation
- Sterilisation with steam or ethylene oxide
- Immersion in fluid longer than one hour
- Temperatures over 60°C

6.2 Accessories Disinfection / Storage

1. Cleaning instrument
2. Storage
3. Disinfectant 'Pantasept®'



7 Technical Standard

1. Measuring force : by leverage weight
2. Assembly : Fits on a pin on the microscope
3. Measurement range : 3 – 75 mmHg
4. Measurement deviation : The measurement deviation is the measuring prism is in the measurement range from 0 – 58.84mN and amounts to a maximum of ±1.5%. This is a minimum of ±0.49mN of the nominal value.

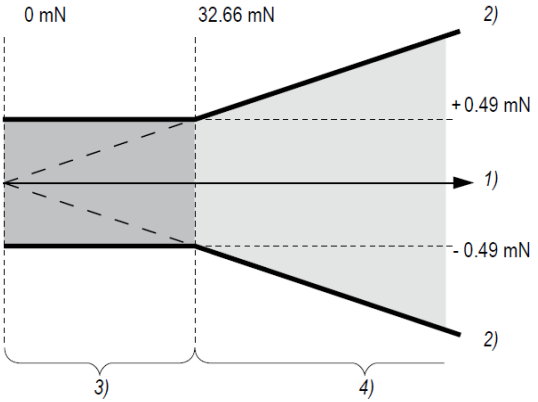
Illustration

① Normal value

② Maximum limiting derivation

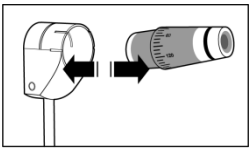
③ Limiting deviation of 0 to 32.66 mN : Maximum = 0.49 mN

④ Limiting deviation from 32.66 mN : Maximum = 1.5% of nominal value

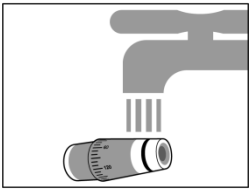


- Reverse span : ≤ 0.49 mN
- Net weight : HT 5000 0.640 Kg(without accessories)

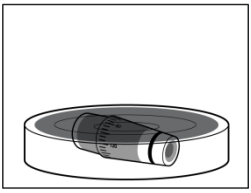
Only in the USA



1. Remove measuring prism carefully from holder.

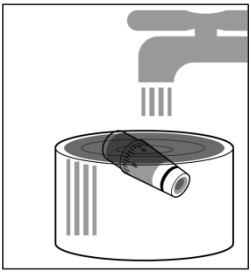


2. Clean : Wipe prisms clean before finsing for 30-60 seconds in running cold water.



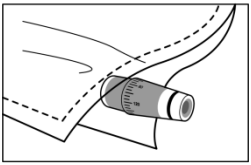
3. Disinfect :

Hydrogen Peroxide(10 minutes) or Sodium Hypochlorite(10 minutes)



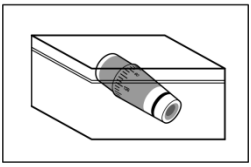
4. Rinse

Rinse thoroughly in running, cold drinking water.(rinsing time in water may not exceed 60 minutes)



5. Dry

With a one-way tissue, clean and soft



6. Store

Place into container clean nad dry.

8 EMC Information

Manufacturer's declaration - electromagnetic emission

The Model Applanation Tonometer HT-5000(Huivtz,Tonometer) is intended for use in the electromagnetic environment specified below. The customer or the user of Applanation Tonometer HT-5000should assure that it is used in such an environment

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model Applanation Tonometer HT-5000uses RF energy only for its internal function. Therefore. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
	Class A	The Model Applanation Tonometer HT-5000is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonics emission IEC 61000-3-2	N/A	
Voltage fluctuation IEC 61000-3-3	N/A	

Manufacturer's declaration - electromagnetic immunity

The Model Applanation Tonometer HT-5000(Huivtz, Tonometer) is intended for use in the electromagnetic environment specified below.
The customer or the user of the Model Applanation Tonometer HT-5000 should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV Contact 8 kV Air	6 kV Contact 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast Transient / burst IEC 61000-4-4	N/A	N/A	N/A
Surge IEC 61000-4-5	N/A	N/A	N/A
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A

Note: U_T is the a.c. mains voltage prior to application of the test level.

The Model Applanation Tonometer HT-5000is intended for use in the electromagnetic environment specified below. The customer or the user of the Model Applanation Tonometer HT-5000should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	N/A	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	**Recommended separation distance** 80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, (a) Should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) *U*r is the A.C. mains voltage prior to application of the test level.
NOTE 2) At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 3) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Applanation Tonometer HT-5000(Huivtz Tonometer).

The Model Applanation Tonometer HT-5000is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Applanation Tonometer HT-5000can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Applanation Tonometer HT-5000as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output Power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.37	0.74
1	N/A	1.17	2.33
10	N/A	3.70	7.37
100	N/A	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Immunity and Compliance Level			
Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	3 V/m

Guidance and manufacturer's declaration - electromagnetic immunity

The Model Applanation Tonometer HT-5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Applanation Tonometer HT-5000 should assure that it is used in such an environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	N/A	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.a Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

9 Service Information

If any problem persists or the instrument is damaged or malfunctioning, contact Huvtiz or local distributor for service with the following information:

- Name of the instrument: Applanation Tonometer HT-5000
- Serial number of the instrument: refer to the 9-digit number on its product label or name plate
- Descriptions of Problem: In detail

Date of Purchase: _____

Dealer's Name: _____

Dealer Address: _____

Dealer Phone No.: _____

Model No.: _____

Serial No.: _____

(※ Huvitz recommends customers to fill up the following form after purchase and retain this manual as a permanent record of purchase.)

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