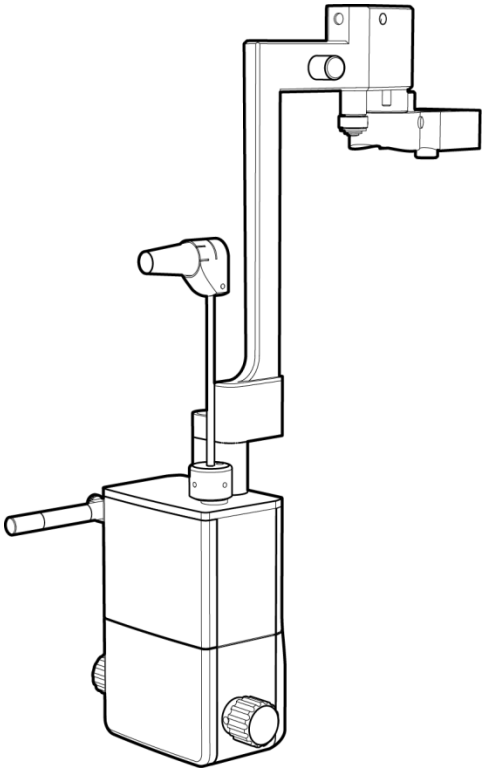
User's Manual

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.

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(2025.03.13)

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Revision History

Revision	Date	Approval	Description
A	2013.10.11		First Issued
B	2018.02.10		Manufacturer Address Updated
C	2018.09.11		Updated Safety Information - Added French in safety information -Updated safety symbols and mark
D	2018.11.05		Updated Canada Authorized Representative Updated EMC information
E	2020.03.06		Updated information regarding period of use for measuring prisms
F	2020.07.15		Updated Authorized Representative information (US, Brazil) Added UL requirement - Added French in safety information
G	2022.05.12		Updated Authroized Representiatve Information (Canada, Switerland, Australia, UK)
H	2022.07.21		Revised based on Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)

I	2025.03.13		Updated Authorized Representative information (UK, Brazil)

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1. Safety Information

Safety is everyone's responsibility. The safe use of this device is largely dependent upon the installers, users, operators, and managers. It is prerequisite to read and understand these specifications before installing, using, cleaning, fixing or revising. Fully understanding the whole instructions must be the first priority. For this reason, 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 all signs of Warnings and Cautions.

WARNING

"Warning" indicates the presence of a hazard that could result in severe personal injury, death or substantial property damage if ignored.

"Warning" indique la présence d'un danger qui pourrait entraîner des blessures graves, la mort ou des dommages matériels importants si ignoré.

CAUTION

"Caution" indicates the presence of a hazard that could result in minor injury, or property damaged if ignored.

"Caution" indique la présence d'un danger pouvant entraîner des blessures légères ou des dommages matériels en cas d'ignorance.

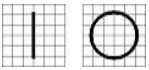
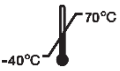
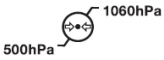
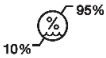
NOTE

This is used to emphasize essential information.
Be sure to read this information to avoid operating the device incorrectly.

Ceci est utilisé pour souligner les informations essentielles.
Assurez-vous de lire ces informations pour éviter de mal utiliser l'appareil.

1.1. Symbol Information

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.

Symbol	Indication
	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. (Ce symbole identifie une note de sécurité. Assurez-vous de comprendre la fonction de ce contrôle avant de l'utiliser. La fonction de contrôle est décrite dans le manuel d'utilisation ou d'entretien approprié.)
	I and O on power switch represent ON and OFF respectively. (O sur l'interrupteur d'alimentation représentent respectivement ON et OFF.)
	Temperature Limitation (Limitation de température)
	Atmospheric pressure limitation (Limitation de pression atmosphérique)
	Humidity limitation (Limite d'humidité)
	Stack direction (Direction de la pile)

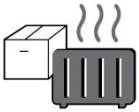
	Keep DRY (Garder au sec)
	Fragile, handle with care (Fragile, manipuler avec soin)
	Keep away from sunlight (Tenir à l'écart de la lumière du soleil)
	Stack layer limit (Limiter la couche de pile)
	CE Mark (Marque CE)
	Use no hook (N'utilisez aucun crochet)
	WEEE Symbol – EU only <u>Disposal of your old appliance</u> 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. 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. (Symbole WEEE- EU seulement <u>Mise au rebut de votre ancien appareil</u> Lorsque ce symbole de poubelle barrée est joint à un produit, cela signifie que le produit est couvert par la directive européenne 2002/96 / CE. Tous les produits électriques et électroniques doivent être éliminés séparément du flux des déchets municipaux via des

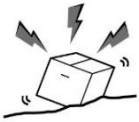
	installations de collecte désignées par le gouvernement oules autorités locales. L'élimination correcte de votre ancient appareil aidera à prévenir les conséquences negatives potentielles sur l'environnement et la santé humaine. Pour plus d'informations sur l'élimination de votre ancient appareil, veuillez contacter votre mairie, le service d'élimination des déchets ou le magasin où vous avez acheté le produit.)
EC REP	Authorized representative in the European Community – EU ONLY (Représentant autorisé dans la Communauté européenne-EU seulement)
	Manufacturer (Fabricant)
	Date of manufacture (Il indique l'année de fabrication et le fabricant.)
	Type B Isolated patient connection (Type B Connexion patient isolée.)
	QR code (QR code)
	Alternating Current (Courant alternative)

	Consult instructions for use (Consulter les instructions d'utilisation)
	The United States and Canada have mutual-recognition agreements. Therefore, if certified using a Canadian specification (CSA) for UL, the certification mark for the product will be a C-UL certification mark which means CSA specification compliance as follows. (Les États-Unis et le Canada ont conclu des accords de libre-échange. Par conséquent, si l'on obtient une certification au moyen d'une spécification canadienne (CSA) pour l'AMT, la marque de certification pour le produit sera une marque de certification C-UL, ce qui signifie la conformité de la spécification CSA comme suit.)
	CE for RoHS RoHS Directive Compliance 2011/65/EU (CE pour les RoHS Respect de la directive en matière de conformité 2011 / 65 / CE)
	Medical Device (dispositif medical)
	Authorized representative in Switzerland (Représentant autorisé dans la Suisse)
	Measuring Prism Expiry Date (Date d'expiration du prisme de mesure)

1.2 Environmental Considerations

Avoid the following environments for operation or storage**:**

	Where the device is exposed to water vapor. Don't operate the device with wet hands Indoor use only.
	Where the device is exposed to direct sunlight.
	A place where the equipment can be exposed to direct ultraviolet.
	Where there are big changes in temperature. Optimal temperature range for normal operation is from 10°C to 35°C (Humidity : 30 ~ 90%).
	Where there is hot equipment nearby.
	Where the humidity is extremely high or there is a ventilation problem.



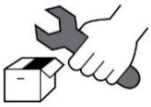
Where the device is exposed to excessive shocks or vibrations.



Where the device is exposed to chemical material or explosive gas.



Be cautious so that things like dust and metal do not fall inside the device.



Don’t disassemble or open the product. HUVITZ does not take responsibility for the possible problems



Be careful not to block the fan of the device.



Don’t plug the AC power cable into the outlet unless all parts of the device are completely connected. Otherwise, it will cause severe damage on the device.



Pull out the power cable with holding the plug, not the cord. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

This device can withstand the following conditions:

1. Operation

- An ambient temperature range of 10℃ ~ 35℃ (50°F ~ 95°F)
- A relative humidity range of 30% ~ 90% (with non-condensing)
- An atmospheric pressure range of 800 ~ 1060hpa
- An illuminance of the measuring room at 10~100 lux

2. Transportation

- An ambient temperature range of -40℃ ~ 70℃ (-40F ~ 158°F)
- A relative humidity range of 10% ~ 95%
- An atmosphere pressure range of 500 ~ 1060hpa

3. Storage

- An ambient temperature range of -10℃ ~ 55℃ (14°F ~ 131°F)
- A relative humidity range of 10% ~ 95% (with non-condensing)
- An atmosphere pressure range of 700 ~ 1060hpa

Avoid environments where the equipment is exposed to excessive shocks or vibrations.

Do not expose products or packing to environmental conditions outside of those specified above.

1.3 Safety Precautions

This equipment has been developed and tested in conformity with domestic & international safety standards and regulations, which guarantees the high stability of this product. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about the safety aspects in dealing with the device. The correct handling of this equipment is imperative for its safe operation. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.

1. This equipment must not be used (a) in an area that is in danger of explosions and (b) in the presence of flammable, explosive, or volatile solvent such as benzene or similar chemicals.

2. The device should neither be kept nor installed in the place with high humidity. For the optimal operation, the humidity should be at the range of 30%~90%. The machine should not be exposed to the place where water splashes, drips or sprays. Do not place containers containing fluids, liquids, or gases on top of any electrical equipment or devices

3. Modifications of this equipment may only be carried out by Huvitz's service technicians or other authorized persons.

4. Customer maintenance of this equipment may only be performed as stated in the User's Manual and Service Manual. Any additional maintenance may only be performed by Huvitz's service technicians or other authorized persons.

5. The manufacturer is only responsible for effects on safety, reliability, and performance of this equipment when the following requirements are fulfilled: (1) The electrical installation in the respective room corresponds to the specifications stated in this manual and (2) This equipment is used, operated and maintained according to this manual and Service Manual.

6. The manufacturer is not liable for damage caused by unauthorized tampering

with the device(s). Such tampering will forfeit any rights to claim under warranty.

7. The equipment may only be used together with accessories supplied by Huvitz's. If the customer makes use of other accessories, use them only if there are usability under technical safety aspects has been proved and confirmed by Huvitz or the manufacturer of the accessory.

8. Only persons who have undergone proper training and instructions are authorized to install, use, operate, and maintain this equipment.

9. User's manual or service manual should be kept in the place where the persons in chare of operation and maintenance can access easily any time.

10. Do not force cable connections. If a cable does not connect easily, be sure that the connector (plug) is appropriate for the receptacle (socket). If you cause any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.

11. This equipment may be used for the international application related to Tonometry according to this manual.

12. Before every operation, proceed with visual inspection on the equipment exterior to seek any mechanical damage(s) to ensure the proper functioning

13. Do not obstruct any ventilation outlet for proper heat dissipation.

14. External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC Standard (e.g., IEC60950 for IT equipment and IEC60601-1 series for medical electrical equipment). In addition, all such combination-system-shall comply with the standard IEC60601-1 harmonized national standard or the combination. If, in doubt, contact qualified technician or your local representative the operator should not touch the patient and accessible male parts of the SIP/SOP connectors simultaneously.

15. Do not place the substance or material on the top of the device including connected slitlamp microscope.

16. Installation, Dispatch
    - To avoid condensation, allow the device to adjust to room temperature 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.

17. 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 device is not to be sprayed.
    - Do not immerse tonometer body in solution
    - Do not use corrosive agents

18. Guareantee and third-party product liability
    - Device 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 device. For information regarding guarantee conditions, please refer to your local huvitz representative. The manufacturer guarantees cover 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 device then all guarantee liabilities are null and void. Should the device be used although damaged through incorrect use then this can lead to injury to persons In this case, the manufacturer rejects all liability.

19. In the event of a serious incident involving the device, the user shall report it to the manufacturer and the competent authority of the Member State in which the user and/or patient are established.

20. When packing box is unintentionally open before use or damaged, please call A/S center.

Intended User

This device must be operated only by a, or under direct supervision of properly trained and qualified person/s such as ophthalmologist.
(e.g., doctor, ophthalmologist)

1.4 Safety Warning

⚠ WARNING

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
- Check the prism under the slit lamp and make sure that there is no crack or chips. Do not use the prism if there is crack or any sign of crack /chips.

Make sure to clean and use the measuring prism

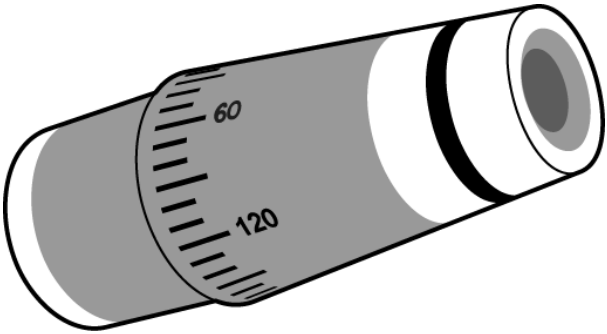
Clean and Disinfect the measuring prism properly.

⚠ WARNING

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. The measuring prisms are engraved with manufacturing date (YYYY-MM). Service life of HUVITZ measuring prism is five years from manufacturing date.

HUVITZ measuring prism recommends using of two years after first use in normal conditions. The given time periods are not valid for damaged measuring prisms, they must be immediately replaced.



2. Introduction

2.1 System Outline

The Applanation Tonometer HT-5000 is indicated for measurement of intraocular pressure (IOP). Intraocular pressure (IOP) is a very important physiological parameter and has always been an indispensable part of the diagnosis and treatment of ophthalmology, especially for glaucoma.

The operation principle is based on Goldmann applanation method, which is considered as the gold standard for measuring intraocular pressure. The applanation tonometer plays an important role in the diagnosis and treatment of ophthalmic diseases. The Applanation Tonometer HT-5000 can assemble slit lamp microscope.

2.2 Intended Use

The Applnation Tonometer HT-5000 is a manual device intended to measure an intraocular pressure by applanation to aid in the diagnosis of glaucoma.

2.3 Classification

- Classification of Product: Classification of product: Class IIa according to Annex VIII (Rule 10) of the Medical Device Regulation 2017/745
- Resistance against electric shock: Class I (earthed)
- Protection Class against electric: Type B

2.4 Contraindication

This device should not be used for:

- Patients who has active corneal infections.
- Patients who has corneal epithelium defects.
- Patients who underwent eye burn.
- Patients who underwent recurring epithelial erosion.

There is no any known residual risk other than risks arising from violating contraindication. But, when unexpected event occurs or you encounter different problems, please contact your local distributor or Authorized Representatives.

2.5 Patient Requirement

The patient who undergoes and examination by this device must maintain concentration for a few minutes and adhere to the following instructions;

- After his/her face to the chinrest, headrest.
- Keep the eye open
- Understand and follow instructions when undergoing an examination.

If the patient does not conform to these conditions, it is not possible to conduct examnination

2.6 Applied Standard

- IEC/EN 60601-1: MEDICAL ELECTRICAL EQUIPMENT
  - Part 1: General requirements for safety
- IEC/EN 60601-1-2: Medical electrical equipment Part1: General requirements for safety- Collateral Standard: Electromagnetic Compatibility-Requirements and tests
- ISO15004-1: Ophthalmic instruments
  - Fundamental requirements and test methods
  General Requirements applicable to all Ophthalmic instrument
- ISO8612: Ophthalmic Instruments - Tonometer

2.7 How IOP (Intraocular Pressure) is measured

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.

2.8 Benefits of Applnation Tonometer

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 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.

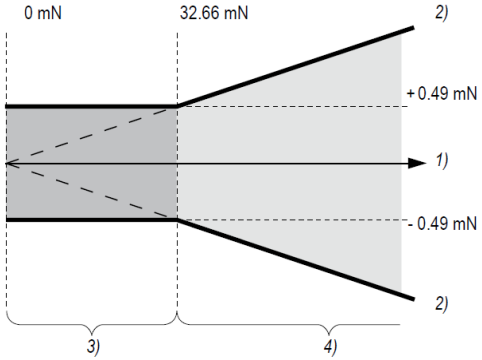
2.9 Measurement Deviation

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

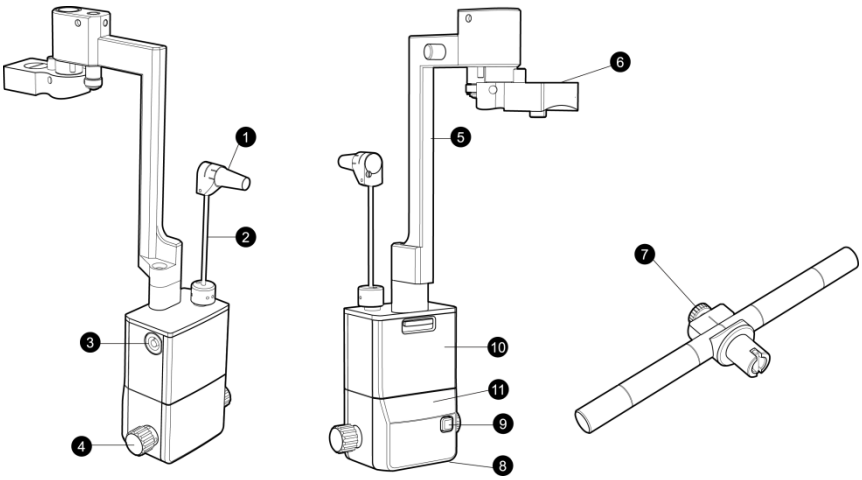
3. Installation

⚠ 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.

Ce produit doit être fourni dans un état d'emballage qui correspond à divers transports et conditions de stockage standard. Si le produit est défectueux, doit être appelé immédiatement au HUVITZ.

3.1 Configuration



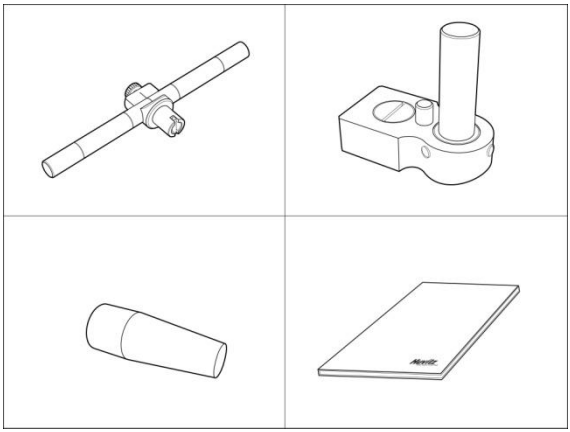
1. Measuring prism: Part for contacting to patient's cornea
2. Feeler arm: Part for locking up the measuring prism
3. Control weight insertion: Part for connecting the weight bar

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.

3.2 Accessories (Optional)

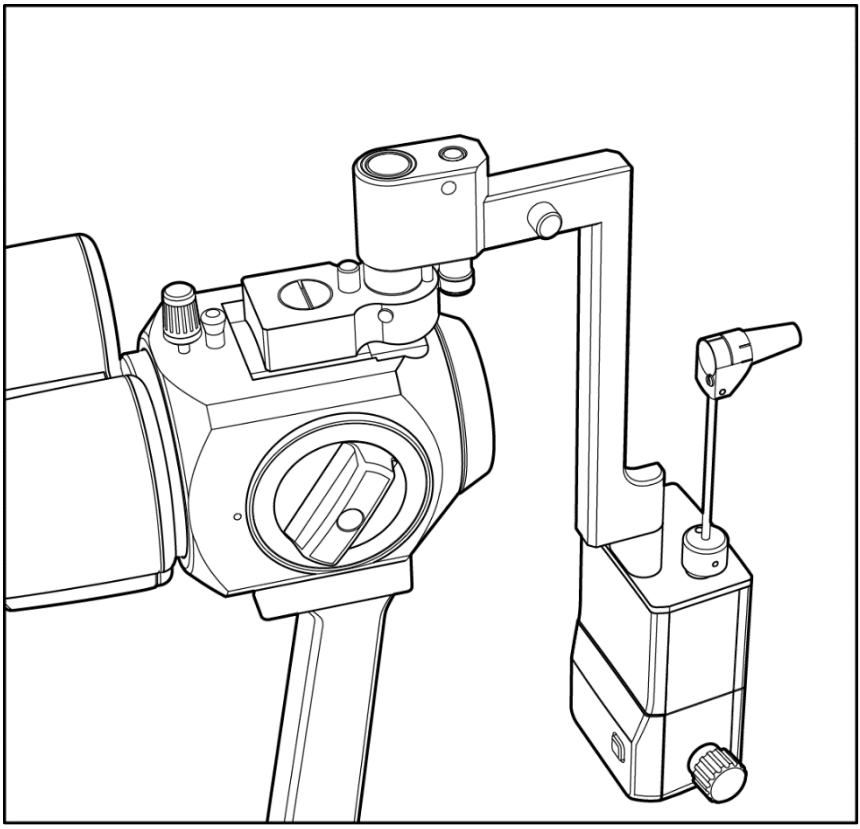
This product supplied in the condition which is packed packing. Take out a product from packing and must check the next parts.

- Weight Bar
- Connection Arm
- Measuring prism (2EA)
- User's manual



3.3 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.



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.

Seule l'utilisation de prismes de mesure 'HUVITZ' peut garantir un fonctionnement sans problème. Le papier de fluorescéine sténilisé doit toujours être utilisé car les excitateurs pathogènes se développent bien dans les solutions de Flrourescein.
Si le prisme de mesure entre en contact avec la cornée sans que la pression n'ait été préalablement correctement réglée, des vibrations sonores peuvent se produire dans le bras palpeur, ce qui produira des chutes désagréables pour le 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

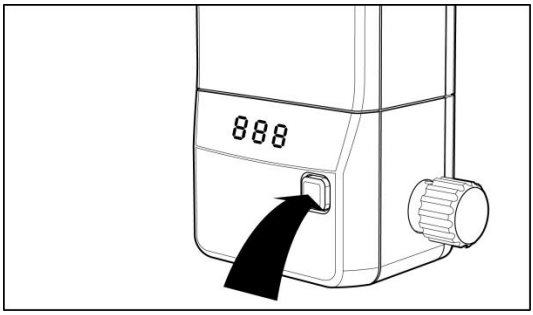
① Press the head firmly on the chin rest and forehead support. If necessary, use a holding band to fix the head's position.

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

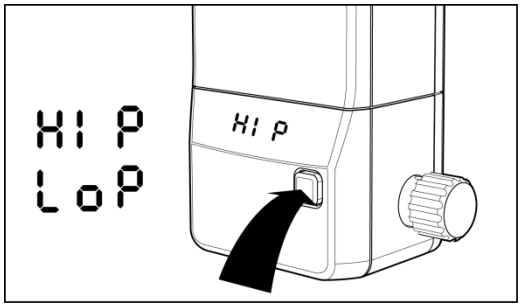
③ It is recommended that the patient should be repeatedly requested to open the eyes wide during the examination. The examiner must perhaps keep the eye open by splaying the eyelids with thumb and index finger. This must be done without pressure to the eye.

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.

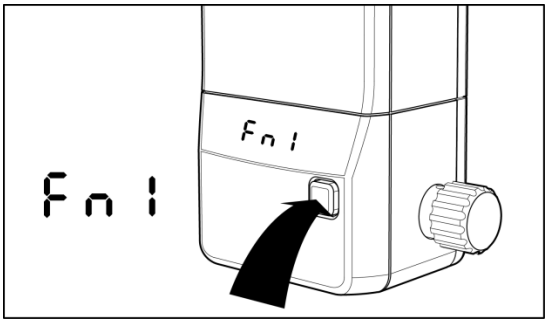


2. Display
   - The FND (Flexible Numeric Display) indicates whether the sensor is within the measurable range. If it is out of the measurable range of “3 – 75 mmHg”. It is displayed as below. [LoP] / [HiP]



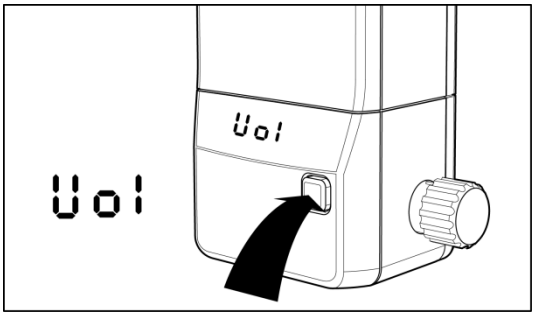
3. Adjust display brightness

   - 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]

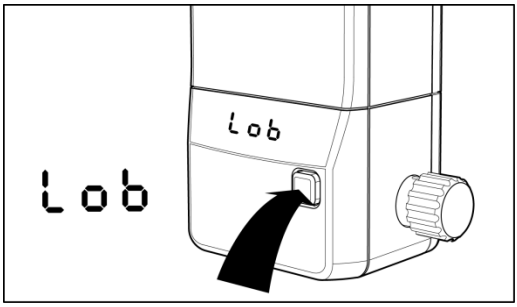


4. Adjust volume

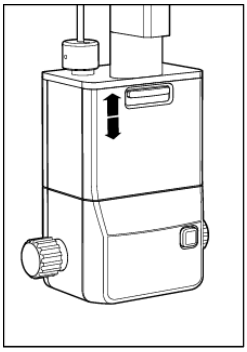
   - The volume can be changed with the function button. Hold down the function button 1 second. The display shows [---] (three dashes) and an audible signal sounds. Release the button again. The display shows [Vo] and a level from 1 to 3. By briefly pressing the button you can adjust the volume. By pressing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



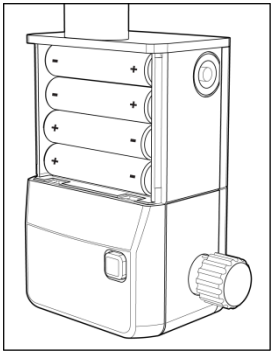
5. Status of batteries
   - If after the activation of the tonometer the screen displays [LoB], the batteries should be changed (4x1.5V batteries type AAA). [LoB]



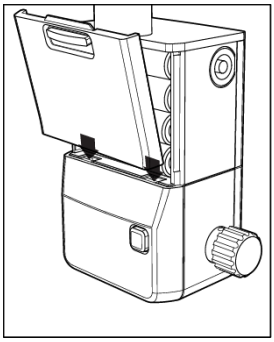
6. Replacement of batteries
   - Drag carefully “Battery SW" to the bottom and remove the battery compartment cover while tilting it back.



- 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.

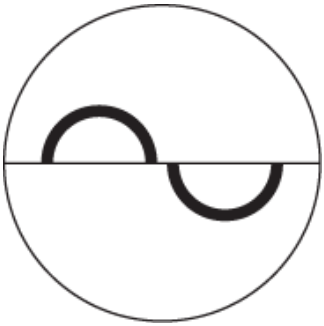


- Press gently on the cover and lock the battery compartment by pushing “Battery SW” back in its place.
- Remove these batteries if EQUIPMENT is not likely to be used for some time.

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

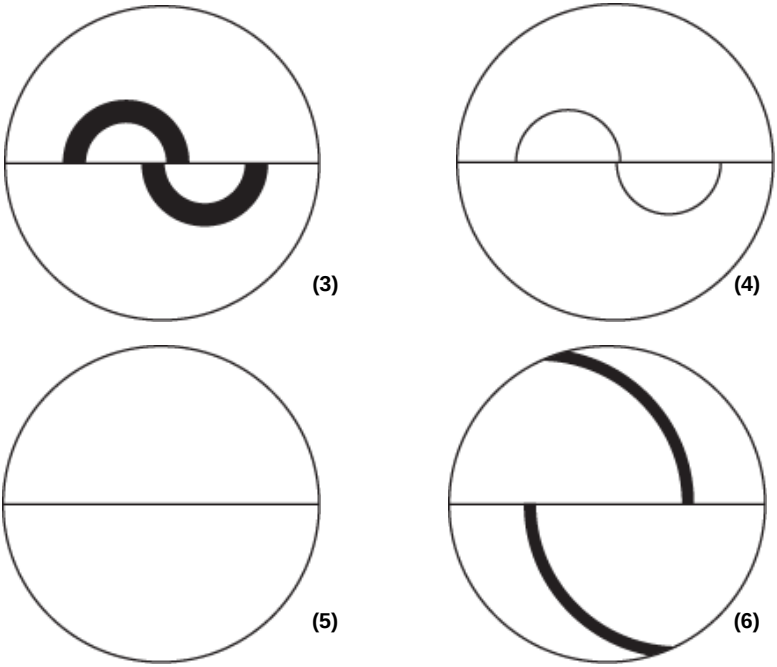
prism touches the eye only at times. If the patient retreats still further, then the Fluorescein rings disappear completely.

➢ *Use a headband as necessary.*

- Only parts of both oversize semicircles are visible (6)

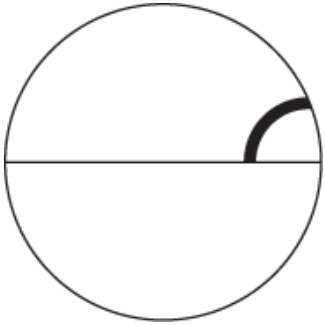
✓ If the slit lamp is pushed too far against the patient or the patient moves towards the slit lamp, the feeler arm pushes against a spring stop. The applanation surface is too large.

➢ *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.*

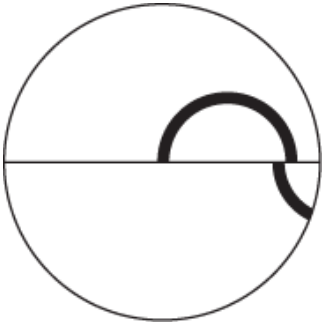


- **Position too far to the right / left : 7 ~ 10**

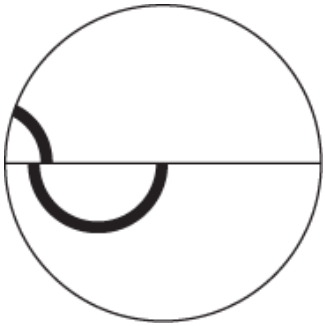
  - Only part of the upper semicircle. (7)
    - ✓ Measuring prism not centered on the eye, eye much too far to the right.
      - ➢ *Using the control lever move the slit lamp to the right.*
  - Only part of the upper semicircle. (8)
    - ✓ Measuring prism not centered on the eye, eye much too far to 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.



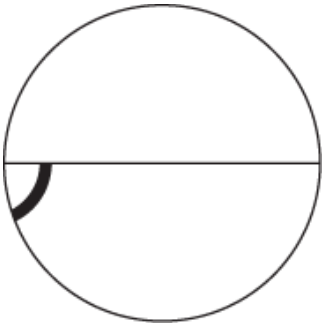
(7)



(8)



(9)



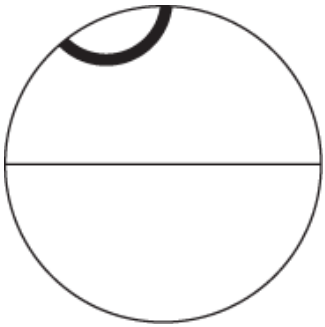
(10)



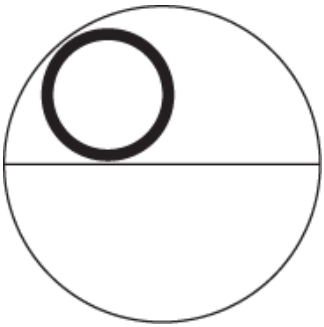
(11)

- **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)



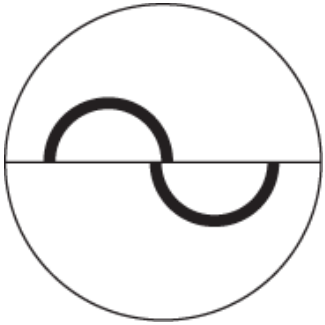
(15)



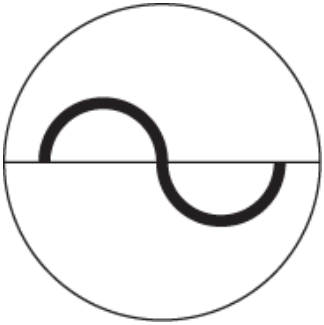
(16)

- **Incorrect pressure : 17 ~ 19**

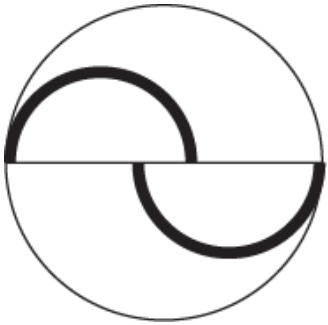
  - Contact with the outside borders of the fluorescein bands. (17)
    - ✓ Not enough pressure.
      - ➢ *Increase the pressure slightly by turning the knob on the tonometer.*
  - Fluorescein bands are superimposed to form a band. (18)
    - ✓ Pressure slightly too little.
      - ➢ *Increase the pressure 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.

Les mesures doivent être effectuées le plus rapidement possible. Si l'épithélium de la cornée présente des signes de sécheresse, vérifiez l'acuité visuelle et le champ visuel.

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. (Please follow as 5.1clause)

This check should be carried out once a month.

NOTE

If there is specific national regulation for maintenance of accuracy, you should meet the standard. If not, please contact to Huvitz person who has calibration qualification. We recommend to calibrate the device every 1month.

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

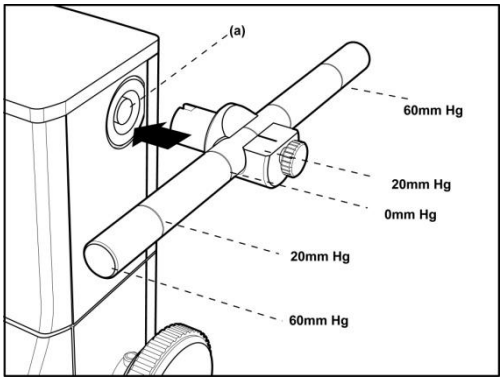
HUVITZ offers a repair and service packet. For further information, give direct liaison to HUVITZ.

HUVITZ propose un kit de réparation et de service. Pour plus d'informations, contactez directement HUVITZ.

5.1 Applanation Tonometer HT-5000 Check

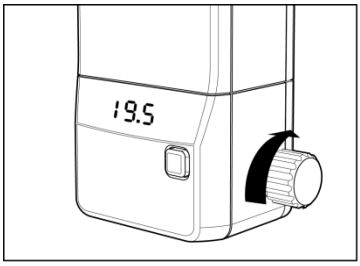
1. Starting position 20 mm Hg

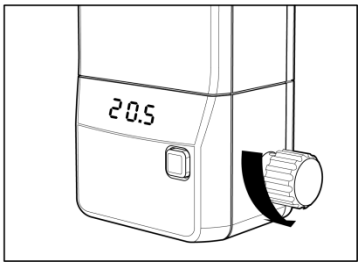
- The control weight is intended to do this. On the control weight there are 5 rings. The middle position is 0 mm Hg, both directly to the left and right correspond to 20 mm Hg, and the two extremes to 60 mm Hg. Adjust the control weight on one of the starting positions (40 or 60 mm Hg) exactly on the 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 Checking position 19.5 - The feeler arm must not leave the area of free movement prior to the indication of 19.5 mm Hg, and no later than 20.5 mm Hg to move forward in the direction of the examiner.

② Checking position 20.5 - The feeler arm must not leave the area of free movement prior to the indication of 20.5 mm Hg, and no later than at 19.5 mm Hg to push against the thrust in the direction of the patient. The feeler arm must move to make contact with the stop limiter on the patient side.



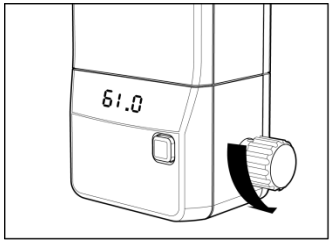


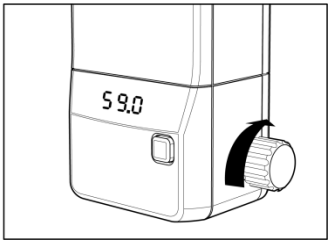
2. Check at 60 mmHg

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

① Checking position 59 - The feeler arm must not leave the area of free movement prior to the indication of 59.0 mm Hg, and no later than at 61.0 mm Hg to push against the thrust in the direction of the examiner.

② Checking position 61 - The feeler arm must not leave the area of free movement prior to the indication of 61.0 mm Hg, and no later than at 59.0 mm Hg to push against the thrust in the direction of the patient.



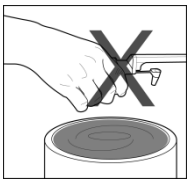


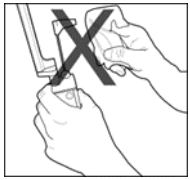
6. Cleaning and Disinfection Procedure

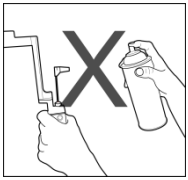
6.1 Cleaning Tonometer Body

This instrument should only be cleaned by manual non-immersion:

- Wipe the external surface with a clean and non-shedding cloth dampened with water, detergent solution (2% detergent by volume) or Isopropyl alcohol solution (70% of Isopropyl alcohol solution by volume)
- Do not let the cloth saturated with solution
- Carefully dry the surface manually with a clean, non-shedding cloth.
- Have safe disposal of used cleaning materials



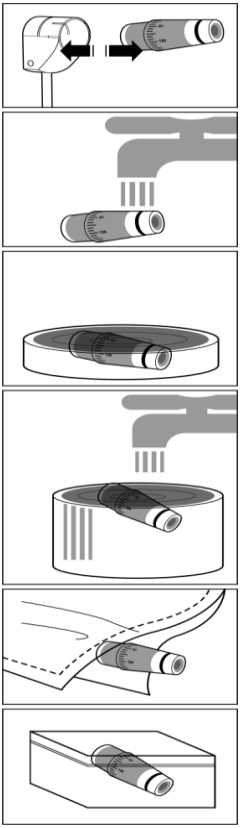




6.2 Disinfecting Prisms

WARNING

Always Disinfect measuring prisms before use.
Clean and disinfect the measuring prism properly.



1. Remove the prism from the prism holder

2. Wash the prism under cold running water for 1minutes. To ensure that the prism is clean before disinfection process.

3. Immese the prism in the disinfectant fluid for 10 minutes.

4. Rinse the disinfectant from the prism with cold running water for minimum 10 mintues to maximum 60 minutes.

5. The prism should be dried after cleaning. Dry the prism with a clean soft non-shedding cloth.

6. Store the prism in the closed container and discard the used disinfectant fluids safetly.

⚠ WARNING

The use of following products or procedures for disinfecion will be forbidden:

- Alcohol
- Acetone
- UV radiation
- Sterilisation with steam or ethylene oxide
- Immersing in fluid longer than one hour
- Temperatures over 60°C

Note

Follow disinfectant solution guidelines for concentration and time of immersion.

- Pantasept: 3% aqueous solution for 10 minutes
- Hyprogen Peroxide- 3% aqueous solution for 10 minutes
- Sodium Hypochlorite- 10% aquesos solution for 10 minutes

7. Specification

1) Measuring force: by leverage weight

2) Assembly: Fits on a pin on the microscope

3) Measurement range: 3 - 75 mmHg (1mmHg = 1.33kPa)

4) Accuracy: amounts to a maximum of ±1.5% and to a minimum of ±0.49 mN of the nominal value.

5) Net weight: 0.640 Kg (without accessories)

6) Power Consumption: 3V

Note

The safety precautions and operating procedures must be thoroughly understood prior to operation of the device.

The device complies with ISO 8612(Ophthalmic intruments - Tonometers), Medical Device Regulation (EU) 2017/745 , ISO 13485(Quality Management System), RoHS Directive Compliance 2011/65/EU

8. EMC Information

Manufacturer announcement – electromagnetic waves trouble

Electromagnetic waves trouble	
HT-5000 should be used in the below mentioned electromagnetic wave environment. HT-5000 purchaser or user needs to confirm whether HT-5000 is used in this type of environment.	
Trouble test	**Question of appropriateness**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/flicker IEC 61000-3-3	N/A

Manufacturer announcement – electromagnetic waves tolerance

HT-5000 is to be used in the below designated electromagnetic wave environment. HT-5000 customer and user need to guarantee that the HT-5000 will be used in this type of environment.

Tolerance test	IEC 60601 test level	Appropriateness level
Electrostatic discharge(ESD) IEC 61000 - 4 - 2	contact ±8 kV in the air ±15 kV	contact ±8 kV in the air ±15 kV
Power frequency magnetic field (50/60 Hz) IEC 61000 - 4 - 8	30 A/m	30 A/m
Radioactivity RF electromagnetic field tolerance IEC 61000 - 4 - 3	10 V/m 80 MHz~2.7 GHz scope	10V/m

9. Service Information

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

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

Supply of parts required for repair:

- The preservation period of parts required for repair of this machine is by seven (7) years

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.)

■ How to Contact Huvitz Co., Ltd.

Huvitz Co., Ltd.

38, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea

Tel: +82-31-428-9100 Fax: +82-31-477-9022(F/A)

E-mail : svc@huvitz.com website : www.huvitz.com

■ EU Representative

Medical Device Safety Service GmbH (MDSS)

Schiffgraben 41, 30175 Hannover, Germany

■ Canada Representative

AXIS Medical Canada Inc.,

9820 Boulevard Du Golf
Anjou, QC
H1J 2Y7

■ U.S. Representative

COBURN TECHNOLOGIES

83 Gerber Road West, South Windsor, CT 06074, United states
Tel: +1-860-648-4906

■ Brazil Representative

QR Consulting

Rua das Acácias, 297, loja 309. Vale do Sereno. Nova Lima-MG. CEP: 34.006-003.
Tel : +55-31-3021-8091

■ UK Representative

MDSS-UK RP Ltd.

6 Wilmslow Road, Rusholme, Manchester M14 5TP, United Kingdom

Tel.: +44 (0)7898 375115

■ Australia Representative

OPTICARE

118 Adderley St, Auburn NSW 2144

■ Authorised representative for Switzerland

MDSS CH GmbH

Laurenzenvorstadt 61

5000 Aarau

Switzerland