INSTRUCTION MANUAL

US

KOWA APPLANATION TONOMETER

Kowa HA-2

HAND-HELD Type

Instruments included in the case

KOWA APPLANATION TONOMETER HA-2	1
Finder eyepieces (6 ×)	1
Rest ring for calibration	1
Weight for calibration (20 mmHg)	1
Weight for calibration (50 mmHg)	1
Spare bulb	1
AA size batteries	2
Instruction manual	1

■ INTRODUCTION ■

Thank you for your purchase of KOWA APPLANATION TONOMETER HA-2. This manual provides a description of the operating procedure of the KOWA APPLANATION TONOMETER HA-2 along with important precautions to be observed during its use.
Please read this entire manual carefully to ensure that the system is able to demonstrate its full capabilities and be used effectively.
After you have finished reading it, please keep it in an easily accessible location near the system for future reference.

■ OPERATIONAL CONSIDERATIONS FOR SAFETY ■

This manual describes important precautions to be observed during its use to assure that the equipment can be used safely without causing any damage to the human body and property of its purchaser and other persons. The designations and their pictorial symbols have the following meanings. These should be fully comprehended before reading the text of this manual.

Meanings of markings

⚠ Warning

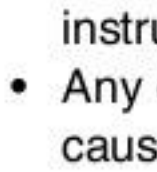
If the equipment should be operated wrongly, there may occur a danger of causing death or serious injury.

⚠ Caution

If the equipment should be operated wrongly, there may result an injury to the human body (not so serious as to cause death though)*1 or damage to property*2.

*1: An injury to the human body means any injury, burn, electrical shock and so forth that will not necessitate hospitalization or long-term outpatient treatment.
*2: Damage to property means an extensive damage to the house and household goods as well as the domestic animal and pet.

Meanings of symbols



Graphical indication of any danger (including warning and caution). What is warned is explicitly and pictorially indicated by a picture or its associated message on or near a pictorial symbol.

Graphical indication of prohibited operation (prohibitive item). What is prohibited is explicitly and pictorially indicated by a picture or it's associated message on or near a pictorial symbol.

Graphical indication of mandatory action (obligatory item). What must always done is explicitly and pictorially indicated by a picture or it's associated message on or near a pictorial symbol.

Kowa is not responsible for:

- Any damage caused by fire, earthquake, third party's action, any other accident or user's intentional or unintentional error, abuse or use under abnormal conditions;
- Any damage resulting from use of the product or its malfunction (e.g. Operating loss, shutdown, change/loss of stored data and so forth).
- Any damage resulting from disobedience of what is described in the instruction manual.
- Any damage resulting from, for instance, malfunctioning of the equipment caused by a combination of connected devices.

⚠ Warning

 Warning	Be sure that the tips of equipment are not in contact with the eye when in operation. (Otherwise, the patient may likely be injured.)
 Prohibitory	Install at a location away from, for instance, a cup containing liquid. If liquid should be spilled into the equipment, there may occur electrical shock. If so, turn OFF the equipment. Contact your Kowa's dealer where you purchased it or your nearest repair shop for inspection.
 Disassembly prohibited	Do not disassemble, modify or repair the equipment yourself. Otherwise, there may occur a fire, electrical shock, equipment malfunctioning or the human body may be injured. Contact your Kowa's dealer where you purchased the equipment for repair. The product assembled by yourself will not get warranty or any other service.

⚠ Caution

 Caution	Avoid subjecting the device to excessive shocks or vibrations.
 Caution	When storing, return the pressure dial to the initial position (not lit), and store in a clean location free of humidity.
 Caution	When not using for a long period of time, remove the batteries from the battery compartment.

■ PRECAUTIONS CONCERNING USE ■

- Handle the system with care to prevent it from being subjected to strong shocks.
- Avoid installing or storing the system in locations subjected to high temperatures and humidity, direct sunlight or high levels of dust.

	In operation	Transportation,storage
Environmental Temperature	10°C~40°C	-15~60°C
Relative humidity	30%~75%	10~95%

- When not in use store the system in its carrying case to protect its components.
- The manufacturer is not liable for malfunctions or injuries resulting from maintenance or repairs performed by persons other than the specified repair service.
- The manufacturer is not liable for malfunctions or injuries resulting from modification, maintenance or repairs using parts other than the specified repair parts.
- The manufacturer is not liable for malfunctions or injuries based on results obtained by not observing the cautions or operating procedure described in this instruction manual.
- The manufacturer is not liable for malfunctions or injuries caused by use of this system under ambient conditions that deviate from the conditions of use of this system, including the power supply and environmental conditions, as described in this instruction manual.
- The manufacturer is not liable for malfunctions or injuries caused by fire, earthquake, flood, lightning or other natural disasters.
- The pressurization dial should be returned to the initial position (lamp is off) before storing the device. Remove the battery from the battery case when storing the device for a long period of time.
- When disposing of this equipment , comply with the regulations of countries or areas in which the equipment is used.

■ PRECAUTIONS CONCERNING USE OF MEDICAL ELECTRICAL EQUIPMENT ■

1. Equipment should only be operated by qualified personnel.

2. The following items must be observed when installing equipment.
   (1) Install in a location free of moisture.
   (2) Install in a location where there is no risk of detrimental effects caused by air pressure, temperature, humidity, ventilation, sunlight, dust, salt or air containing sulfur and so forth.
   (3) Install the equipment in a stable manner while paying attention to inclines, vibrations and shock (including that during transport).
   (4) Do not install in locations where chemicals or pharmaceuticals or stored or where there is generation of gas.
   (5) Confirm the status of battery-powered power supplies (degree of discharge, polarity, etc.).

3. The following items must be observed before using the equipment.
   (1) The equipment must be inspected for switch contact, polarity, dial settings and meter readings to confirm that is operating properly.
   (2) Avoid combined used of equipment since this can lead to errors in accurate diagnoses and danger.
   (3) Re-inspect any external circuits that come in direct contact with patients.
   (4) Check any battery-operated power supplies.

4. The following items must be checked during use of the equipment.
   (1) Do not exceed the time or quantity required for diagnosis or treatment.
   (2) Continuously monitor the equipment for any abnormalities as well as the status of the patient.
   (3) When an abnormality is noticed in the equipment or patient, appropriate measures must be taken such as terminating operation of the equipment while ensuring the safety of the patient.
   (4) Do not allow the patient to touch the equipment.

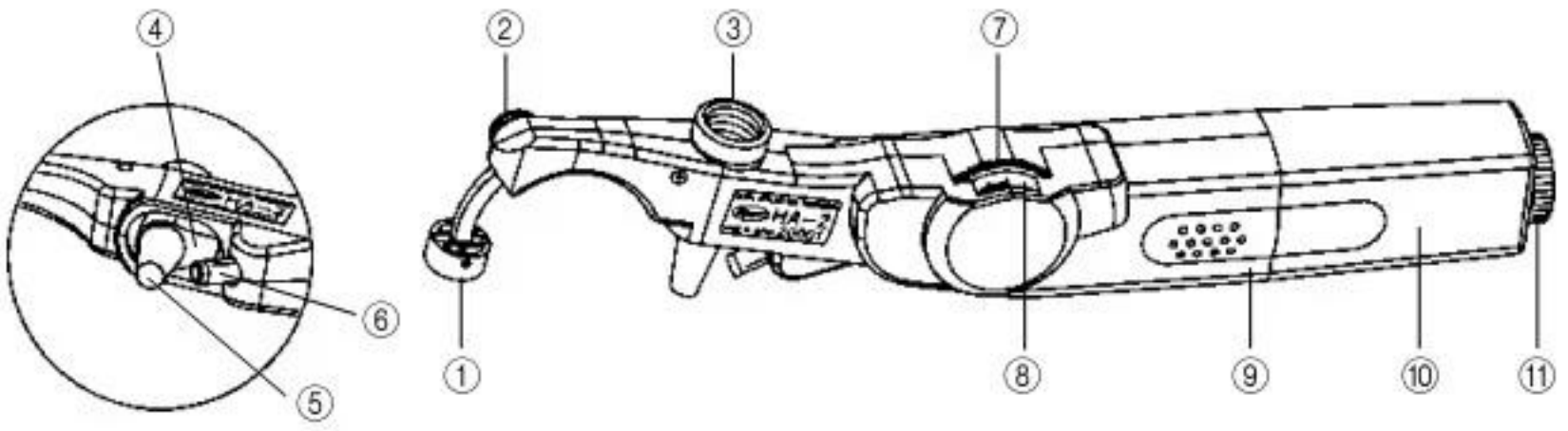
5. The following items must be observed following use of the equipment.
   (1) Turn off the power after first returning all operating switches, dials and other components to their status prior to use in accordance with the specified procedure.
   (2) The following items must be observed with respect to the location where the equipment is stored.
      (a) Store in a location free of moisture.
      (b) Store in a location where there is no risk of detrimental effects caused by air pressure, temperature, humidity, ventilation, sunlight, dust, salt or air containing sulfur and so forth.
      (c) Store the equipment in a stable manner while paying attention to inclines, vibrations and shock (including that during transport).
      (d) Do not store in locations where chemicals or pharmaceuticals or stored or where there is generation of gas.
   (3) Store all accessories, cords, leads and other components in an organized manner after cleaning.
   (4) Always make sure to clean the equipment so that it functions properly the next time it is used.

6. In the event equipment should malfunction, the operator should not attempt to correct the problem, but rather appropriately indicate that the equipment is not operating properly and await repairs by qualified personnel.

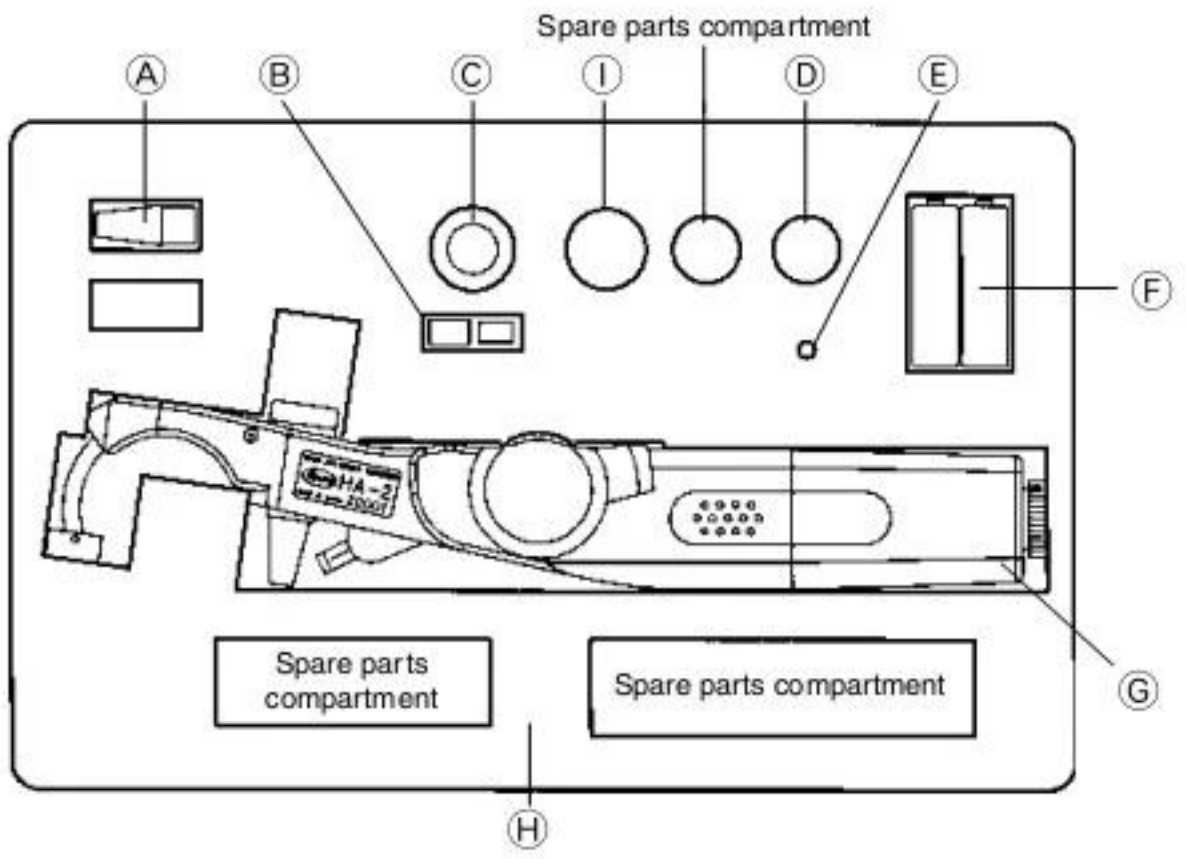
7. Never attempt to disassemble or modify the equipment.

8. Maintenance and Inspection
   (1) All equipment and components should be inspected regularly.
   (2) When resuming use of equipment that has not been used for a long time, always confirm that the equipment operates properly and safety before use.

■ NAMES OF WORKING PARTS ■



① Forehead rest
② Locking knob for forehead rest
③ Finder eyepieces (6×)
④ Prism holder
⑤ Doubling prism
⑥ Illumination and filter rod
⑦ Thumb wheel for applanation pressure
⑧ Scale
⑨ Main casing
⑩ Battery casing
⑪ Fixing knob



Ⓐ Doubling prism (optional part)
Ⓑ Weight for calibration (20 mmHg, 50 mmHg)
Ⓒ Rest ring for calibration
Ⓓ Finder eyepieces (6×)
Ⓔ Spare bulb
Ⓕ Batteries (2 pcs. AA size)
Ⓖ KOWA APPLANATION TONOMETER HA-2
Ⓗ Carrying case
Ⓘ Long eye relief 3× (optional part)

■ EQUIPMENTAL PREPARATION ■

KOWA APPLANATION TONOMETER HA-2 is supplied with its accessories in a compact carrying case, as shown in the illustration above. Set up the KOWA APPLANATION TONOMETER HA-2 as follows.
Refer to the manual of Charge Type system for installation of the battery case and the battery.

1. Attach eyepiece
   Attach the desired eyepiece to the finder screw by turning it clockwise.

2. Attach doubling prism
   1) Sterilize the doubling prism ⑤ and wipe solution drops off before use.(see page6)
   2) Insert the doubling prism into the prism holder ④ so that the index is aligned to 180° or 0°.

3. Insert the batteries
   1) Remove the battery housing by turning fixing knob ⑪ counterclockwise.
   2) Insert two batteries with their + and – signs aligned accordingly.
   3) Replace the housing and fix it by pressing and turning the knob in the direction of the arrow.

4. Adjust extension of forehead rest
   Loosen locking knob for forehead rest ② by turning it counterclockwise, extend forehead rest ① as far as it may maintain an adequate distance when the prism touches the cornea. To stabilize turn the knob clockwise.

5. Adjust direction of illumination
   The rod can be directed to any side within a small range. Adjust the direction so that the illumination lights up the view finder field evenly when the prism nearly touches the cornea.

■ HOW TO USE ■

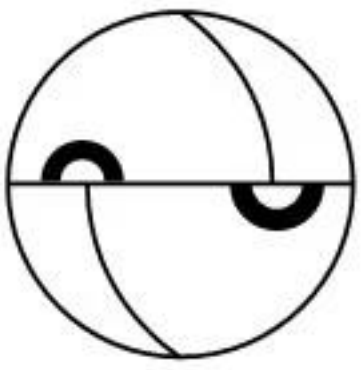
Preparation

(Patient) Apply anaesthetic to the cornea to be examined, then apply a small amount of fluorescent stuff to color the eye.

(Equipment) The contacting portion of the prism should be sterilize and cleaned perfectly. A prism surface smudged with tears or mucus lowers the accuracy of measurement.

Examination

1. Have the patient gaze straight forward with eye fully opened.
2. Hold the KOWA APPLANATION TONOMETER HA-2 straight with your thumb on the thumb wheel ⑦.
3. Turn the thumb wheel until the scale reads "1" (10 mmHg).
4. Hold the KOWA APPLANATION TONOMETER HA-2 close enough as so that the prism is almost on the cornea and ensure that the forehead rest ① comes in contact with the patient's forehead.
5. Look through the finder. The finder field will be bright from the reflection of cornea.
6. Get a light applanation on the cornea by the doubling prism gently. Two green semi-circles split on both sides will be visible as shown in Fig.1.



Correct **Fig. 1**

If an undesired applanation such as those shown in Figs 2, 3 and 4 is obtained, repeat step 4 and below and obtain correct semi-circles.

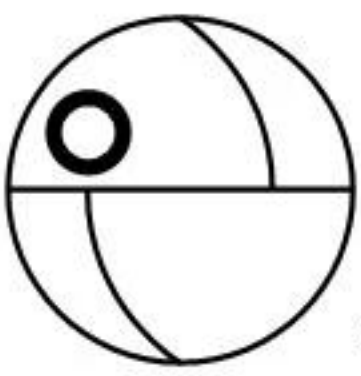


Fig. 2

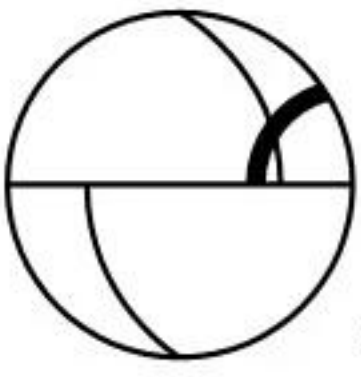


Fig. 3

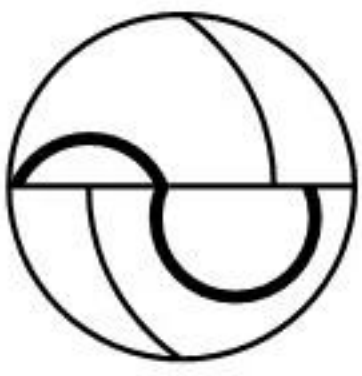


Fig. 4

Fig. 2 ~ Fig. 4 Incorrect applanation

7. Turn the thumb wheel ⑦ gently to increase applanation pressure. The said semi-circles will increase in size and become clear and definite.
8. When the semi-circles contact each other at their inside edges, cease turning. (Fig. 5)

Fig. 5

9. Remove the KOWA APPLANATION TONOMETER HA-2 from the cornea while keeping your thumb still on the thumb wheel. Read the scale and multiply the reading by ten.

■ LIMITS OF ACCURACY ■

Degree of accuracy claimed for devices with a measuring function.

±1mmHg	more than 0 and less than 30mmHg
±2mmHg	more than 30, 60mmHg or less

■ DISINFECTION METHOD OF THE DOUBLING PRISM ■

1) The doubling prism is not sterilized or disinfected before shipment. Follow the procedure below to disinfect the product before using it.

2) Leave the doubling prism in either the solution of 1~2 % glutaraldehyde or the solution of 0.2~0.5% chlorhexidine gluconate for 5~10 minutes. Avoid leaving the doubling prism in the solution for longer period of time since it may cause damage to the doubling prism.

⚠ Caution

Cautions for disinfection and sterilization

Do not use the following methods when disinfecting or sterilizing the doubling prism since it may cause damage to the doubling prism.

- Disinfection by autoclave, boiling, or concentrated alcohol
- Sterilization by electron ray, EO gas, or radio-frequency

Long immersion in an antiseptic solution may produce swelling of plastics, splitting of glued portions and moisture inside the doubling prism.

■ MAINTENANCE ■

Taking care of the KOWA APPLANATION TONOMETER HA-2

a. Avoid shock and vibration as these will damage your KOWA APPLANATION TONOMETER HA-2.
b. When you put away the equipment, be sure to turn the thumb wheel to "0" (illumination off) on the scale and remove the batteries. Replace the main body and accessories in the case and store it in a cool, dry place.

Replacement of illumination bulb

Pull out the illumination rod ⑥ and the bulb will be accessible. Simply pull out the bulb and replace it. A spare bulb is provided in the carrying case for replacement. When the last one is used, order a new set from your dealer.

Periodical Inspection

It is recommendable to periodically inspect your equipment once every two years. For information about what is to be inspected and costs, contact Kowa's distributor where your purchased the KOWA APPLANATION TONOMETER HA-2.

Repairing the Equipment

If there is a need to return your KOWA APPLANATION TONOMETER HA-2 to the manufacturer for repair or maintenance, please contact one of Kowa's distributors indicated on the back cover of INSTRUCTION MANUAL.

■ ZERO POINT ADJUSTMENT ■

After some period of time, you may find your calibration readings do not stay within acceptable tolerances. In such a case, adjust the zero point, following the procedures outlined below.

1. Remove the battery casing and lay the KOWA APPLANATION TONOMETER HA-2 on a desk, as for calibration.
   Hold the remaining body to level it. (Fig. 6)

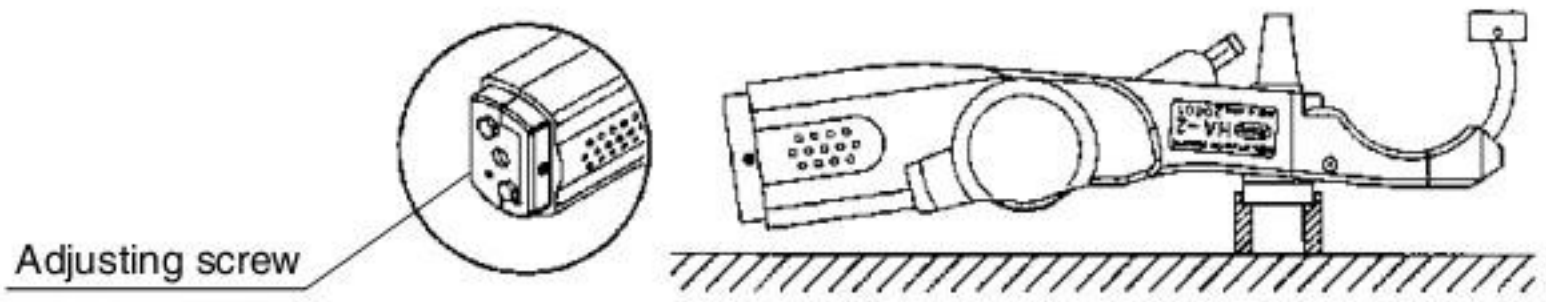


Fig. 6

2. After removing the battery case, turn the adjusting screw that was covered by the case until the doubling prism reaches the STANDARD level. With this adjustment a small amount of shift will be produced in every reading.
3. Calibrate and check that "0", "20 mmHg" and "50 mmHg" readings fall within acceptable tolerances. If the result is unsatisfactory, repeat the above mentioned adjustment and check until the desired result is obtained.
4. If adjustment fails, consult your dealer or contact us for more information.

■ CALIBRATION ■

1. Lay the KOWA APPLANATION TONOMETER HA-2 on a desk as shown in Fig. 7, fitting the eyepiece to the calibration rest ring Ⓒ.

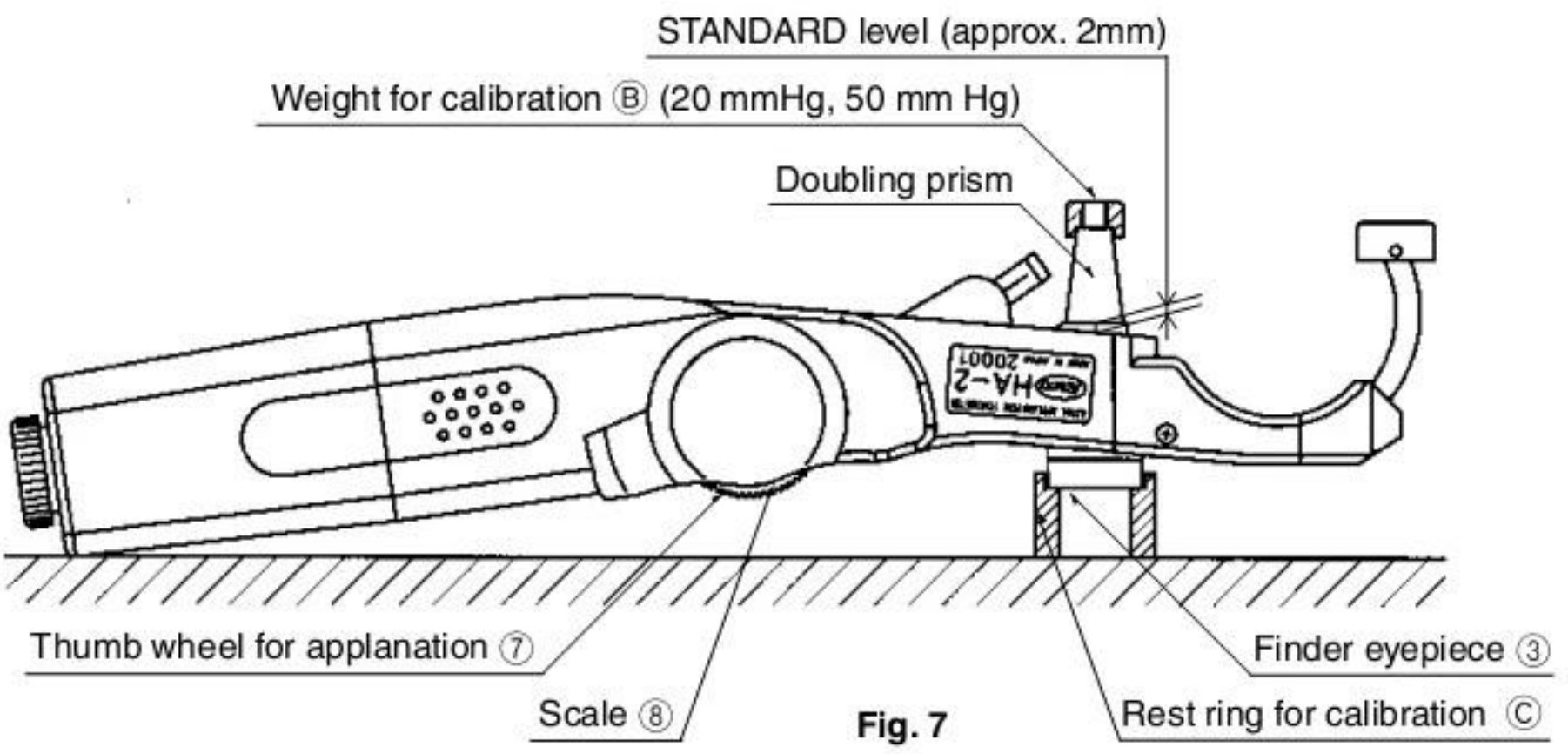


Fig. 7

2. Set the scale ⑧ to "0" (illumination is off at this point), then turn the thumb wheel ⑦ to raise the doubling prism holder ④ to the STANDARD level, where the rim of the doubling prism holder ④ is 2 mm above the body surface.
3. Put a 20 mmHg weight gently on the doubling prism and turn the thumb wheel ⑦ to raise the doubling prism to the STANDARD level. Read the scale.
4. Put a 50 mmHg weight gently on the doubling prism and turn the thumb wheel to raise the rim to the STANDARD level. Read the scale.
5. Compare the readings to the tolerance tabulated below. Ensure that the readings fall within acceptable limits.
6. If your results are unsatisfactory, repeat calibration. If the second calibration is also unsatisfactory, consult your dealer or inform us directly.

■ TOLERANCE TABLE ■

Weight	Tolerance
0 (No weight)	0 ± 1 grad.
20 mmHg	2 ± 1 grad.
50 mmHg	5 ± 1.5 grad.

■ SPECIFICATIONS ■

Type	Hand-held applanation tonometer
Applanation prism	HAAG-STREIT doubling prism interchangeable (option)
Scale range	0~60mmHg (1mmHg division)
Illumination a) ON/OFF b) Bulb c) Battery used	 Interlocked with thumb wheel Lens bulb 2.5V, 0.25A interchangeable 1.5V, 2pcs Interchangeable
Eyepiece Magnification Forehead rest Length Weight	 6x Movable 290mm 240g with batteries

Safty standard and classification

- IEC60601-1:1988
- IEC60601-1 Amendment 1:1991
- IEC60601-1 Amendment 2:1995

According to the type of protection against electric shock
INTERNALLY POWERED EQUIPMENT
According to the degree of protection against electric shock
TYPE B APPLIED PART
According to the degree of protection against ingress of water
as detailed in the current edition of IEC60529
IPX0
According to the degree of safety of application in the presence
of a flammable anaesthetic mixture with air of with oxygen or nitrous oxide.
Equipment not suitable for use in the presence of a flammable
anaesthetic mixture with air or with oxygen or nitrous oxide.
According to the mode of operation
CONTINOUS OPERATION

- IEC60601-1-2:2001

■ OPTIONAL PART ■

Long eye relief 3×.

1. Remove the finder eyepiece 6× that comes with the system from the finder screw, and attach the long eye relief 3×.
2. Examinations can be made with an examiner's eye approximately 30cm distant from the finder.

■ ELECTROMAGNETIC COMPATIBILITY (IEC60601-1-2 : 2001) ■

KOWA APPLANATION TONOMETER HA-2 is a medical electrical equipment. The medical electrical equipment requires special care concerning electromagnetic compatibility(EMC). This section describes its suitability in terms of electromagnetic compatibility of this equipment. When installing or using this equipment, please read carefully and observe what is descried here.
(This equipment was tested on electromagnetic compatibility(EMC) based on IEC60601-1-2:2001.)

1. Carefully handle portable- or mobile-type radio frequency communication unit (radio frequency apparatus) since it may have an adverse effect on this equipment resulting in malfunctioning.
2. This equipment was tested on electromagnetic compatibility(EMC) with optional or accessory parts being assembled into it.
   Do not assemble into this equipment any optional or accessory parts other than those designated by Kowa.Otherwise, this equipment may be adversely affected by other equipment resulting in malfunctioning, or the latter itself may malfunction.

Doubling prism, Finder eyepieces (6x), Illumination and filter rod, Batteries (2pcs. AA size)

3. This equipment is not designed such that it can be used adjacent to other equipment or placing one on top of another. Therefore, do not apply such use. Nevertheless, if such use is inevitable, it is necessary to constantly monitor if the equipment is functioning normally after such user has been adopted.

[Compliance declaration and Guidance]

Guidance and manufacturer's declaration - electromagnetic emissions		
The KOWA APPLANATION TONOMETER HA-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the KOWA APPLANATION TONOMETER HA-2 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Harmonic emissions IEC61000-3-2	Not applicable	The KOWA APPLANATION TONOMETER HA-2 is not applied to this test because of the following. - no supply lines
Voltage fluctuations / flicker emissions IEC61000-3-3	Not applicable	
RF emissions CISPR 14-1	Complies	The KOWA APPLANATION TONOMETER HA-2 is not suitable for interconnection with other equipment.

Guidance and manufacturer's declaration - electromagnetic immunity			
The KOWA APPLANATION TONOMETER HA-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the KOWA APPLANATION TONOMETER HA-2 should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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 IEC61000-4-4	±2kV for power supply lines ±1kV for input / output line	Not applicable	The KOWA APPLANATION TONOMETER HA-2 is not applied to this test because of the following. - no supply lines - no input / output line
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode <5% U_T (>95% dip in U_T)	Not applicable	The KOWA APPLANATION TONOMETER HA-2 is not applied to this test because of the following. - no supply lines.
Voltage dips, short interrup-tions and voltage variations on power supply input lines. IEC61000-4-11	for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% UT (95% dip in U_T) for 5 sec	Not applicable	The KOWA APPLANATION TONOMETER HA-2 is not applied to this test because of the following. - no supply lines
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The KOWA APPLANATION TONOMETER HA-2 is intended for use in the electromagneteic environment specified below. The customer or the user of the KOWA APPLANATION TONOMETER HA-2 should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the KOWA APPLANATION TONOMETER HA-2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where *P* is maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation destance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1	At 80MHz and 800MHz, the higher frequency range applies.		
NOTE2	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 KOWA APPLANATION TONOMETER HA-2 is used exceeds the applicable RF compliance level above, the KOWA APPLANATION TONOMETER HA-2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the KOWA APPLANATION TONOMETER HA-2.		

Recommended separation distances between portable and mobile RF communications equipment and the KOWA APPLANATION TONOMETER HA-2

The KOWA APPLANATION TONOMETER HA-2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KOWA APPLANATION TONOMETER HA-2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KOWA APPLANATION TONOMETER HA-2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80mHz	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01		0.12	0.23
0.1		0.37	0.74
1		1.2	2.3
10		3.7	7.4
100		12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply inall situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Kowa

Manufacturer

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Printed on recycled paper.

Printed in JAPAN AT06 V3.0K 041030MS