

HX-400

Pupilometer

User Manual



Version: 1.5

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Product Name: Pupilometer
Nome do produto: Pupilômetro
Nombre del producto: Pupilómetro
Ürün Adı: Pupilometre
Nome prodotto: Pupillometro
Produktname: Pupillometer
Nom du produit : Pupilomètre
Име на продукта: Пупилометър
Produkto pavadinimas: Pupilometras
Nazwa produktu: Pupilometr
Název produktu: Pupilometr
Toote nimi: Pupilomeeter
Produkta nosaukums: Skolēna mērītājs
Όνομα προϊόντος: Μαθητή

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Preface

Thanks for purchasing and using our pupilometer.



Please read this User Manual carefully before using this device. We sincerely hope that this User Manual will provide you with sufficient information to use the device.

Our pursuit is to provide people with high-quality, complete-function and more personalized devices. Information in promotional materials and packing boxes is subject to changes due to performance improvement without additional notice. Chongqing Yeasn Science - Technology Co., Ltd. reserves the rights to update the devices and materials.

If you have any questions during using, please contact at our service hotline: (86-023) 62797666, we will be very happy to help you.

Your satisfaction, our impetus!

Information of manufacturer

Name: CHONGQING YEASN SCIENCE-TECHNOLOGY CO., LTD.

Address: 5 DANLONG ROAD, NANAN DISTRICT, CHONGQING, CHINA

Tel: 86-23 62797666

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1. Introduction

1.1 Uses

Principle: The pupilometer takes the advantage of the image-forming principle of optical lens. Optical lens imprints the observed object at a specified distance, then the patient watches at the observed object, and the optometrist can find out the bright points of the observer's eyes via the measuring window, meanwhile the optometrist moves the left and right measuring keys to make the related mechanical hairsprings to coincide with the bright points of the observer's eyes, so as to measure the distance of the pupils.

Intended use: To measure the distance between the pupils of the human eye.

Medical purpose: To measure the distance between the pupils of the human eye.

Target groups of patients: adults, children.

Contact with human body parts: Nose and forehead.

Intended users: optometrists in hospital ophthalmology and optical shops.

Specific qualifications of device users and/or other persons: have a qualification certificate for optometry and glasses.

Contraindications: none.

1.2 Characteristics

This device is designed in a scientific and reasonable way, integrating technologies on mechanical hairspring orientation

measurement system, optical system, ESS and microcomputer into a whole.

* Using mechanical hairspring to level at the reflecting point of human cornea to realize the consecutive measurement. It features directness of point-sampling and high accuracy of orientation.

* Adopting line-shaped sensors of high definition, advanced intellectualized electronic systems and digital display which allow the testing results more visible, legible and accurate.

* LED lamp-house and a design of low-power consumption ensure the prolonged service life of batteries.

* PD and VD measurement is available.

* It offers the +2.00D compensation for the degree of eyesight.

* The brightness of LED lamp-house is adjustable.

1.3 Main technical indexes

1.3.1 Effective range of measurement

Binocular pupillary distance: 45mm ~ 82 mm

Left or right pupillary distance: 22.5mm ~ 41 mm

1.3.2 Indication error: $\leq 0.5\text{mm}$

1.3.3 Asymmetrical error: $\leq 0.5\text{mm}$

1.3.4 Distance of target: 30cm ~ ∞

1.3.5 Power source: Voltage: DC 3V

Specification: 5# AA battery

Quantity: 2 pieces (2×1.5V AA batteries)

1.3.6 Time for automatic shut-off:

About 1 minute after stopping operation

1.3.7 Size: 221mm(L)×165(W)×63mm(H)

1.3.8 Weight: 0.64 kg

1.3.9 The product is expected to run continuously.

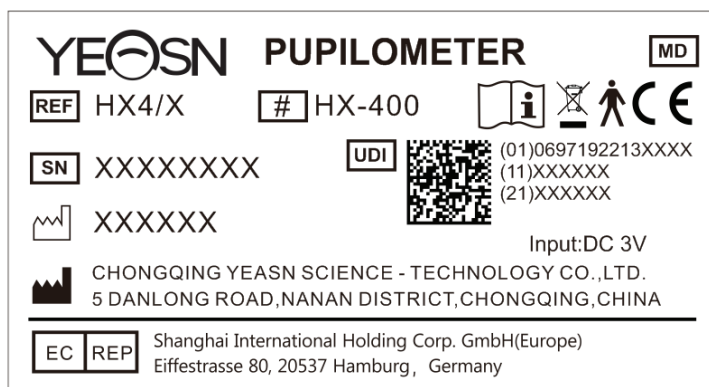
1.3.10 Software version number: V3.00

1.3.11 Protection class: IPX0

1.4 Symbol Description

Name plate and indications are pasted on the instrument to arise end-users' notice.

In case the name plate is not pasted well or the characters become unclear to recognize, please contact authorized distributors.



Manufacturer



Date of manufacture



Serial number



Country of manufacture



CE marking



Correct Disposal of This Product (Waste Electrical & Electronic Equipment)



Type B applied part (Nose Bearer and Forehead bearer)



Medical device



Consult instructions for use



Refer to instruction manual / booklet



Authorized European representative



Catalogue number



Unique Device Identifier



Model number

G.W.

Gross Weight

DIM.

Dimension



Fragile, handle with care



Keep dry



Temperature limit



Humidity range identification



Atmospheric pressure range identification

1.5 Part List


- | | |
|----------------|--------|
| 1) Pupilometer | 1 set |
| 2) User Manual | 1 unit |

2. Safety Notice



Please read the following precautions carefully to avoid personal injury, device damages or other possible hazards:

- Use the device indoors and keep it clean and dry; do not use it under inflammable, explosive, high temperature and dusty environment;
- Do not use the device near water; also be careful not to make any kinds of liquid drop onto the device. Do not place the device in damp or dusty places, nor place it where humidity and temperature change quickly;
- Do not dismantle or touch the interior parts of the device, otherwise it may cause electric shock or device failure;
- The device has passed electromagnetic compatibility test. Follow below instructions related to EMC (electromagnetic compatibility) when mounting and using the device:
 - Do not use the device with other electric devices to avoid electromagnetic disturbance to the device;
 - Do not use the device nearby other electric devices to avoid electromagnetic disturbance to the device;

- Not used in oxygen rich environment, Not intended for use with flammable anesthetics, Not intended for use with flammable agents.
 - Pay attention to the polarity when changing the battery to prevent battery short circuit.
 - Notification: Any serious event related to the device to the user and/or patient shall be reported to the manufacturer and competent authority of the Member State where the user and/or patient is located.
-  Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

3. Description of the structure

3.1 Description of the front panel

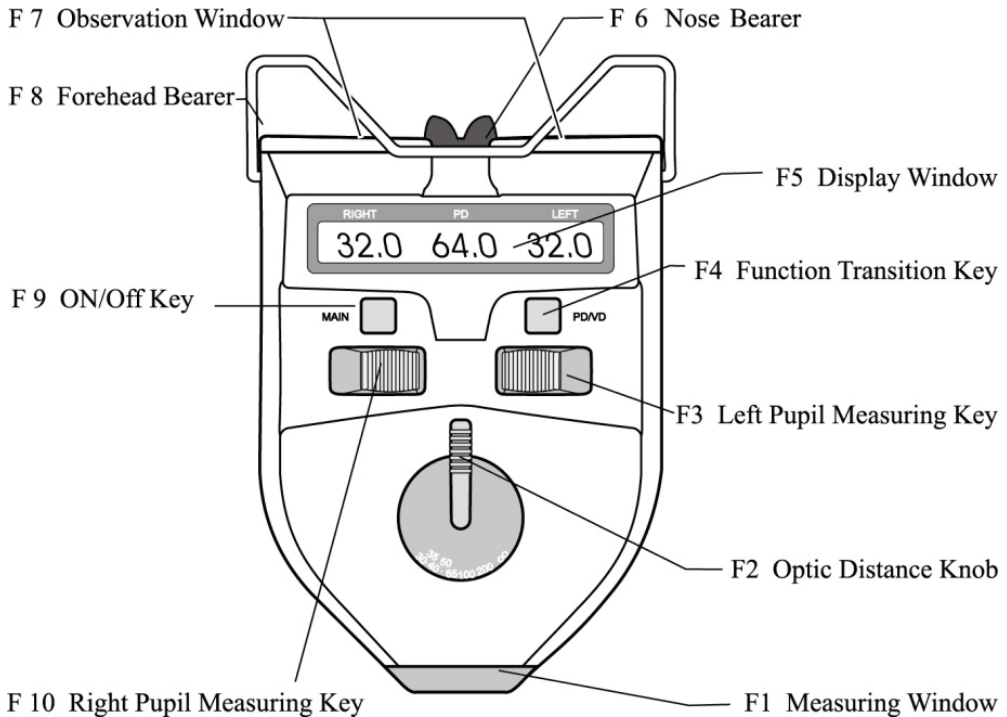


Fig.1

F1. Measuring Window

The working window of the testing personnel.

F2. Optic Distance Knob

It is used to conduct conversion of measured value of pupillary distance at different optic distances of 30cm ~ ∞ .

F3. Left Pupil Measuring Key

It is used to measure left pupillary distance. Sliding the key to the outer side will make pupillary distance pointer move in opposite direction of the nose bearer. At this time, the left eye pupillary distance and binocular pupillary distance rise in numerical value.

Sliding the key to the inner side will make the pupillary distance pointer move towards the direction of the nose bearer. Now numerical value of the pupillary distance decreases.

F4. Function Transition Key

PD and VD measurement mode can be switched by pressing Function Transition key. Besides, it can be used to set LED brightness, automatic power-off time and measurement precision.

F5. Display Window (as shown in Fig.2)

It displays the measured numerical value of PD or VD, and some other relevant information.

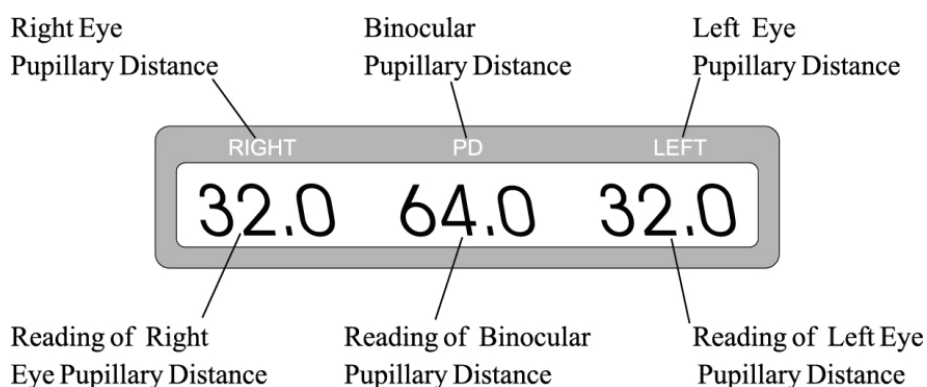


Fig.2

*When reading information on the display window, the Right value denotes the distance between center of nose bridge and right eye pupillary distance or VD of the right eye, and the Left value denotes the distance between center of nose bridge and left eye pupillary distance VD of the left eye. PD value stands for the distance between left eye pupil and right eye pupil. The unit is mm.

F6. Nose Bearer

The testee's bridge rests on the nose bearer so that the position of the testee's pupils is fixed.

F7. Observation Window

Two windows provided for a testee to stare at the target with his (her) eyes.

F8. Forehead bearer

The testee's forehead rests on the forehead bearer so that the position of his pupils is fixed.

F9 ON/Off KEY

Press this key once to turn on the device, and press it again to turn off.

F10. Right Pupil Measuring Key

It is used to measure right pupillary distance. Sliding the key to the outer side will make pupillary distance pointer move in opposite direction of the nose bearer. At this time, the right eye pupillary distance and binocular pupillary distance increase in numerical value. Sliding the key to the inner side will make the pupillary distance pointer move towards the direction of the nose bearer. Now numerical value of the pupillary distance decreases.

Nose Bearer, and Forehead bearer constitute a Type B applied part.

3.2 Description of rear panel

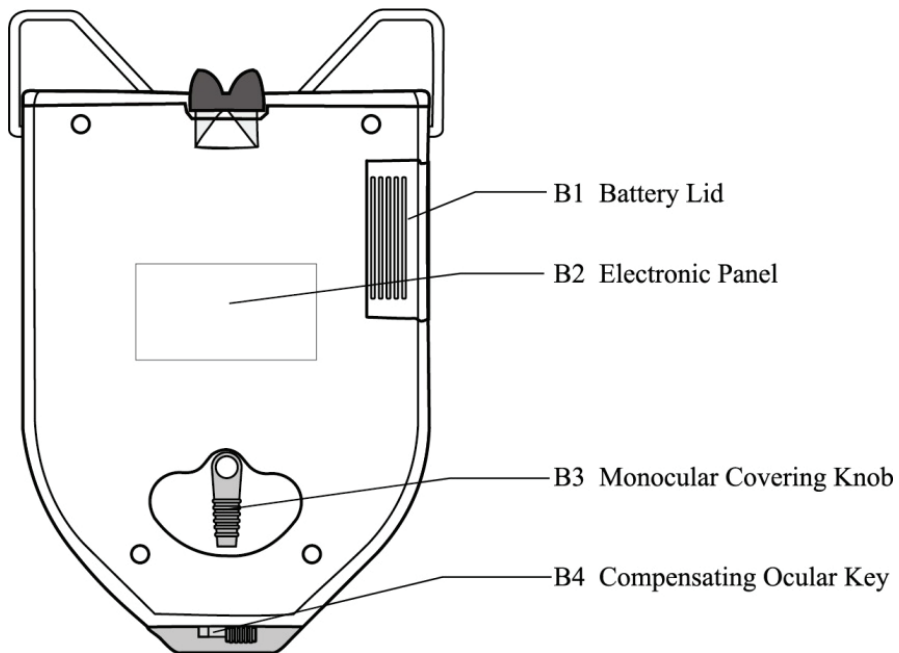


Fig.3

B1. Battery Lid

Move the lid parallel to change batteries.

B2. Electronic Panel

B3. Monocular Covering Knob

The covering of the testee's right or left eye will be realized by turning the knob.

B4. Compensating Ocular Key

Sliding the key can make a +2.00D compensation for the diopter of eyes.

3.3 Viewed from the Measuring Window

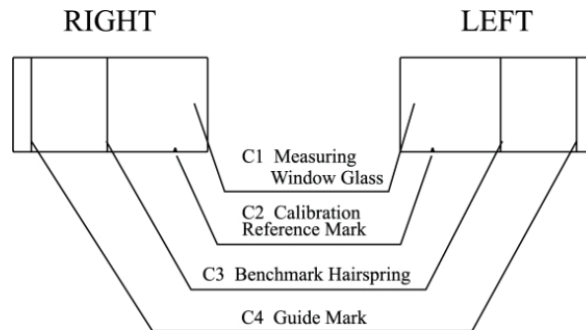


Fig.4

C1. Measuring Window Glass

Testee sees through it to the green target.

C2. Calibration Reference Mark

It is used to check measurement accuracy.

C3. Benchmark Hairspring

When the optometrists use the device, they can slide the key and make the benchmark hairspring level at the reflecting light spot of the testee's pupils.

C4. Guide Mark

Guide Mark is used to target at the top of cornea of the testee during the process of VD measurement.

3.4 Viewed from the Observation Window

Target to be stared at in the center of the device's inner visual field, an eyeball-shaped circle can be seen. It is a green target image surrounded with a bright ring. A testee should stare at the target with both eyes when measuring. To adapt to the favor of people's eyes, the device sets the adjustable function of LED brightness.

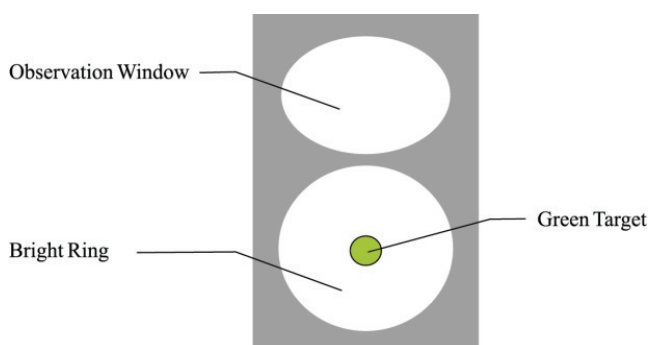


Fig. 5

4. Preventive inspection

The operator should conduct preventive inspections before use.

- 1) The observation window and measurement window should be clean.
- 2) The numbers displayed on the display window should be normal.
- 3) Inspection cycle: before use every day.

5. Operational Instructions

This is a high-tech intelligent instrument, which is very easy to operate. Please operate it according to the following procedures, thus you can get measured data easily and rapidly.

5.1 About Battery

Before using the device, please put 2 pieces of 5# AA alkali batteries into its battery box. When it is not used, please take them out to save electric energy.

*Only high energy alkali battery is applicable, and please do not use common acidic one so as to avoid leakage of battery liquid which may cause damage to the device.

*Be care about the polarity of the battery when replacing it.

*Properly dispose of the used battery to avoid environmental pollution.

5.2 Device Startup and Shutdown

5.2.1 Device startup

Press ON/OFF key to make the start-up of the device initialized. The microprocessor in the device gets the position of pupillary distance pointers and then the data display on the corresponding LCD window. Now you are able to conduct measurement.

5.2.2 Device shutdown

Press ON/OFF key to turn off the device.

5.3 Measurement of Binocular Pupillary Distance

- a. Start-up. The initialized setting of the device is just the binocular pupillary distance for measuring ∞ optic distance.
- b. Put the forehead bearer lightly on the testee's forehead, and nose bearer lightly on testee's nose bridge, then keep the device in a horizontal state(as shown in Fig.6).

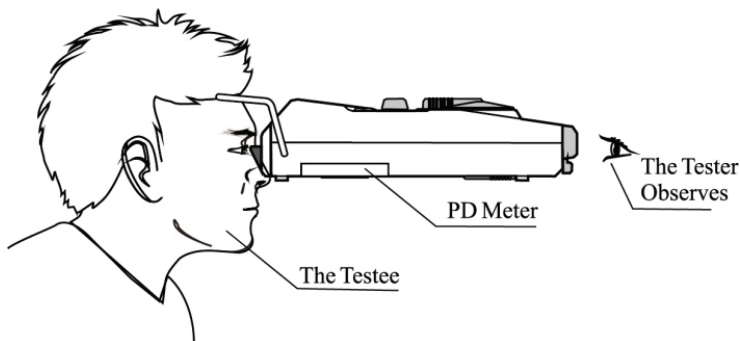


Fig.6

- c. Let the testee stare at the green target of the device.

d. The tester observes the reflecting light spot on the testee's pupil through measuring window. Slide the Left and Right Pupillary Measuring Keys, the left and right pupillary distance pointers will coincide with the reflecting light spots of the testee's left and right pupils, respectively(as shown in Fig.7a and Fig.7b). The data shown in the display window are the measured pupillary distance.

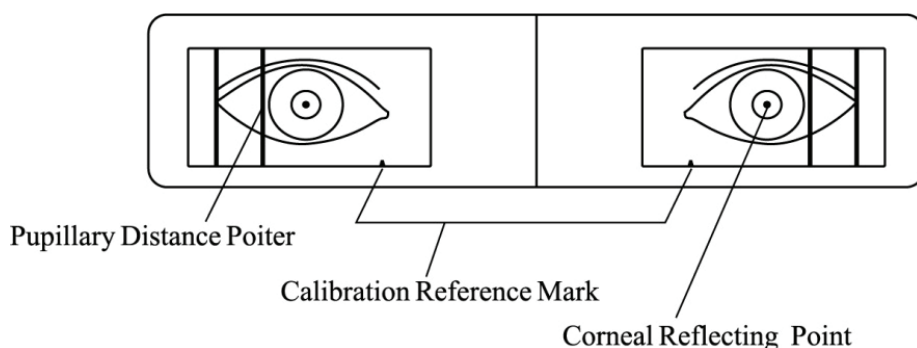


Fig. 7a (The sight the tester observes through measuring window)

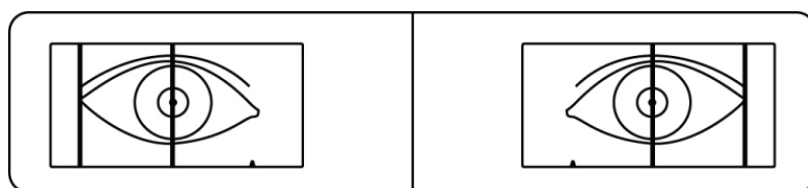


Fig.7b (The left and right pointers coincide with the reflecting bright dots)

e. In order to measure the pupillary distance at different optic distances, please turn the Optic Distance Knob (as shown in Fig.1 NO.2) to your optic distances first and then make your measurement. This device sets some different optic distance locations such as 30cm, 35cm, 40cm, 50cm, 65cm, 1m, 2m and ∞ .

*In the process of measurement (and the measurement of monocular pupillary distance described in the following section), to achieve precise data of measurement and make process of measurement

easily and quickly, the tester should remind the testee to always stare at the green target in a level state, without moving his (her) eyeballs.

5.4 Measurement of Monocular Pupillary Distance

a. When needing to measure the left or right pupillary distance, please turn the Monocular Covering Knob (as shown in Fig.3 B3) which can cover the other eye completely (as shown in Fig.8a and Fig.8b)

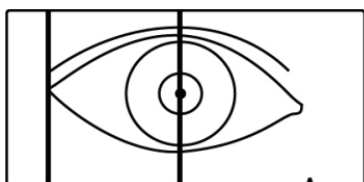


Fig.8a (Measuring right pupillary distance)

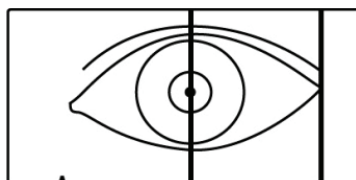


Fig.8b (Measuring left pupillary distance)

b. The tester observes the reflecting bright dot on the testee's pupil through measuring window. Slide the Left and Right Pupils Measuring Keys, the left or right pupillary distance pointers will coincide with the reflecting bright dots of the testee's left or right pupils, respectively. The datum shown in the display window is just the measured pupillary distance.

5.5 Measurement of the VD

a. Press F4 Function Transition key (PD/VD) to enter into VD measurement mode.

- b. The optician makes inspection standing by the side of the testee, and the latter is preferably situated against the light. Place the instrument in the horizontal level (see Fig.9a), and target the guide mark at the top of cornea of the testee.
- c. After targeting is finished. Optician slides left/right pupil Measuring key to coincide the Benchmark spring with the top of the lens (Fig.9b). The distance from the top of the cornea to the mounted lens can be obtained by deducting the thickness of the lens from the value digitally displayed at that time.

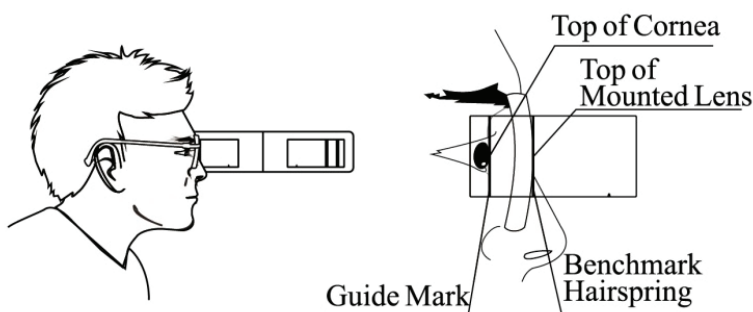


Fig. 9a

Fig. 9b

5.6 LED and automatic power-off settings

- a. Put F3 left pupil measuring keys to the left end and F10 right key to the left end and keep them there, then press F4 (Function Transition Key) continuously 5 times till the screen shows image of “-----”. After this, move F10 right measuring key to the right end and press Function Transition Key again, then we get in the LED brightness and automatic power-off setting mode.

- b. In such mode, moving F3 left measuring key is to adjust automatic power-off time, which will be shown on the screen (time range: 0.5-3 minutes with the 0.5-minute interval).
- c. Moving F10 right measuring key is to adjust LED brightness and the corresponding LED current value (the bigger the LED current value, the brighter the LED lamp shines) is shown on the screen. (Current value range: 0.5-5 mA with the interval of 0.5 mA).
- d. When the two above are well set, another pressing of the Function Transition Key can save the set values and the device is again into the measuring mode.

5.7 Setting of Measurement precision

- a. Under PD or VD measurement mode, Slide F3 left pupil measuring key to left end, and slide F10 right pupil measuring key to left end, then press F4 Function Transition key continuously 5 times till the screen shows image of “-----”Slide F3 left pupil measuring key to the right end, press F4 Function Transition key to set the precision.
- b. Under this mode, sliding Left Pupil Measuring Key can set display precision to be 0.1, 0.2 or 0.5 for PD being set from 45to 82mm and 0.5mm for others. When the precision is set, press Function Transition Key again to save, then the machine returns to the measurement mode.

5.8 Usage of Calibration Reference Mark

Before using PD meter, we recommend you check whether the display value is normal and to perform “the inside check of PD 46mm”.

Slide C3 Benchmark hairspring and make it coincide with C2 Calibration reference mark, if the PD is 46mm with left and right PD being 23mm respectively, it is normal.

6. Clean and disinfection of application parts

- 1) Do not use any corrosive chemicals when cleaning the product.
- 2) Nose bearer and forehead bearer are the parts that are in frequent contact with testee, which should be cleaned and disinfected promptly. Dirt should be cleaned with soft cloth dipped in soluble cleaner or water, then wipe the product with medical alcohol to disinfect. It is recommended to do this before each test.

7. Maintenance

- 1) It has been precisely adjusted before delivery. Please do not dismantle it so as to keep it precise.
- 2) It shall be stored and used in an indoor well-conditioned dry place.
- 3) As a high-tech product, the device shall be prevented from vibration or impact.
- 4) Keep it clean and do not touch surface of its window glass.
- 5) Any corrosive chemical is forbidden for cleaning it.

6) Fingerprint, dust or stain should be cleaned with absorbent cotton dipped with mixed solution of alcohol and ether.

7) In case of malfunction, do not dismantle it by yourself. Please contact the local sales agent or the manufacturer for help.

8) Provided there is no display on the display window after start-up, please check the polarity of the battery to see if it is well placed and electrified.

Caution: No servicing and maintenance can be performed while the product is in use.

Warning: No modification of this equipment is allowed.

Warning: Remove the battery if the product is not likely to be used for some time.

Statement: Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to Service Personnel in parts repair.

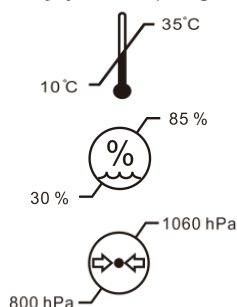
8. Troubleshooting

In the event of device trouble, please check the device as per below chart to obtain guidance. If the trouble is not shot, please contact with Chongqing Yeasn Science & Technology Co., Ltd. Maintenance Department or the authorized dealer.

Trouble	Reasons	Solutions
No data displayed in the display window	Wrong installation of battery	Install the battery correctly
	Insufficient battery capacity	Replace the battery

9. Environmental Conditions and Service Life

9.1 Environmental conditions for normal operation



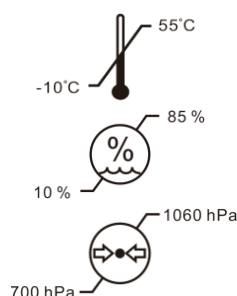
Environment temperature: 10 °C ~ 35 °C

Relative humidity: 30%~85% (no condensation)

Atmospheric pressure: 800hPa~1060hPa

Indoor conditions: clean and without direct high light.

9.2 Environmental conditions for transportation and storage



Environment temperature: -10 °C ~ 55 °C

Relative humidity: 10%~85% (no condensation)

Atmospheric pressure: 700hPa~1060hPa

Indoor conditions: good ventilation and without corrosive gas.

9.3 Service life

The service life of the device is 8 years from first-time use with proper maintenance and care.

10. Disposal and Environmental Protection



INFORMATION FOR USERS

This product bears the selective sorting symbol for waste electrical and electronic equipment (WEEE). This means that this product must

be handled to the local collecting points or given back to retailer when you buy a new product, in a ratio of one to one pursuant to European Directive 2012/19/EU in order to be recycled or dismantled to minimize its impact on the environment.

Very small WEEE (no external dimension more than 25 cm) can be delivered to retailers free of charge to end-users and with no obligation to buy EEE of an equivalent type. For further information, please contact your local or regional authorities. Electronic products not included in the selective sorting process are potentially dangerous for the environment and human health due to the presence of hazardous substances. The unlawful disposal of the product carries a fine according to the legislation currently in force.

11. Manufacturer's Responsibility

The company is responsible for the safety, reliability and performance impact under below circumstances:

- Assembly, addition, modifications, alterations and repairs are carried out by authorized personnel by the company;
- Electrical facilities in the room are in conformity with relevant requirements, and
- The device is used according to the User Manual.

12. Guidance of EMC and other interference



1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the


other equipment should be observed to verify that they are operating normally.

2* **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

3* **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacture's declaration – electromagnetic emission		
The HX-400 is intended for use in the electromagnetic environment specified below. The customer or the user of the HX-400 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The HX-400 uses 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.
RF emissions CISPR 11	Class B	The HX-400 Pupilometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The HX-400 is intended for use in the electromagnetic environment specified below. The customer or the user of the HX-400 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to lines ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 %  UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 %  UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HX-400 requires continued operation during power mains interruptions, it is recommended that the HX-400 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The HX-400 is intended for use in the electromagnetic environment specified below. The customer or the user of the HX-400 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3V 0.15 MHz to 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz</p> <p>10 V/m 80 MHz to 2,7 GHz</p>	<p>Not applicable</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the HX-400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ <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 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.^b Interference may occur in the vicinity of equipment marked with the following symbol: </p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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 HX-400 is used exceeds the applicable RF compliance level above, the HX-400 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HX-400.</p> <p>b Over the frequency range 0.15Hz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Guidance and manufacture's declaration - IMMUNITY to proximity fields from RF wireless communications equipment

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC61000-4 -3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.