

66 VISION TECH



YZ25C

Binocular Indirect Ophthalmoscope

Instruction Manual

Thank you for purchasing
our YZ25C Binocular Indirect
Ophthalmoscope. Please
read this manual carefully
for the sake of your best use.

66 VISION TECH CO., LTD.

General Requirements for Safety




















Please read carefully about following precautions to avoid unexpected personal injury as well as the product being damaged and other possible dangers.

Precautions

1. Do not use this instrument in the environment prone to fire and blast or where there is much dust or with high temperature. Use it indoors and simultaneously be careful to keep it clean and dry.
2. Attention the ratings of electrical juncture and assure the correctness and fastness of installation before use.
3. Turn off the main power first before changing the bulb.
4. Illuminating power is as low as possible and after use, cut off the power.
5. Never scratch surface of lenses and reflecting mirrors by fingers or any hard materials.
6. In case there is any trouble, please first refer to the trouble shooting guide. If it still can't work, please contact the authorized distributor or our Repair Department.

⚠ WARNING: Do not modify this equipment without authorization of the manufacturer.

Symbol Descriptions

	Alternating Current		Caution
	"ON"(power)		Warning
	"OFF"(power)		Refer to instruction manual
	Serial Number		Warning : Hot Surface
	Date of Manufacture		Atmospheric pressure limitation
	Authorized Representative in the European Community		Humidity limitation
	The CE Conformity Marking		This way up
	Symbol for the Marking of Electrical and Electronic Equipment in accordance with WEEE		Keep dry
	Manufacturer		Fragile
	Medical Device		

Content

1. Usage.....	1
2. Construct feature of ophthalmoscope.....	1
3. Installation.....	2
3.1 Lists of parts.....	2
3.2 Battery installation.....	2
3.3 Inspection after installation.....	3
4. The adjustment and usage of the ophthalmoscope.....	3
4.1 Adjust the headband and optical main part.....	3
4.2 The usage of the ophthalmoscope.....	4
4.3 Assembling the teaching mirror	5
4.4 Recharging the battery.....	5
5. Maintenance.....	6
5.1 Safety use and maintenance	6
5.2 Cleaning.....	6
5.3 Protection.....	6
6. Responsibility.....	7
7. Transportation and storage.....	7
8. Trouble shooting guide.....	7
9. Specifications.....	8
10. Normal working conditions.....	8
11. Term of validity.....	8
12. The processing of the wastes.....	9
13. Output the spectrum.....	9
14. EMC result.....	9

1. Usage

This ophthalmoscope is an indispensable medical optical instrument for examine the fundus and operations of retina resetting.

2. Construct feature of the ophthalmoscope (Fig.1)

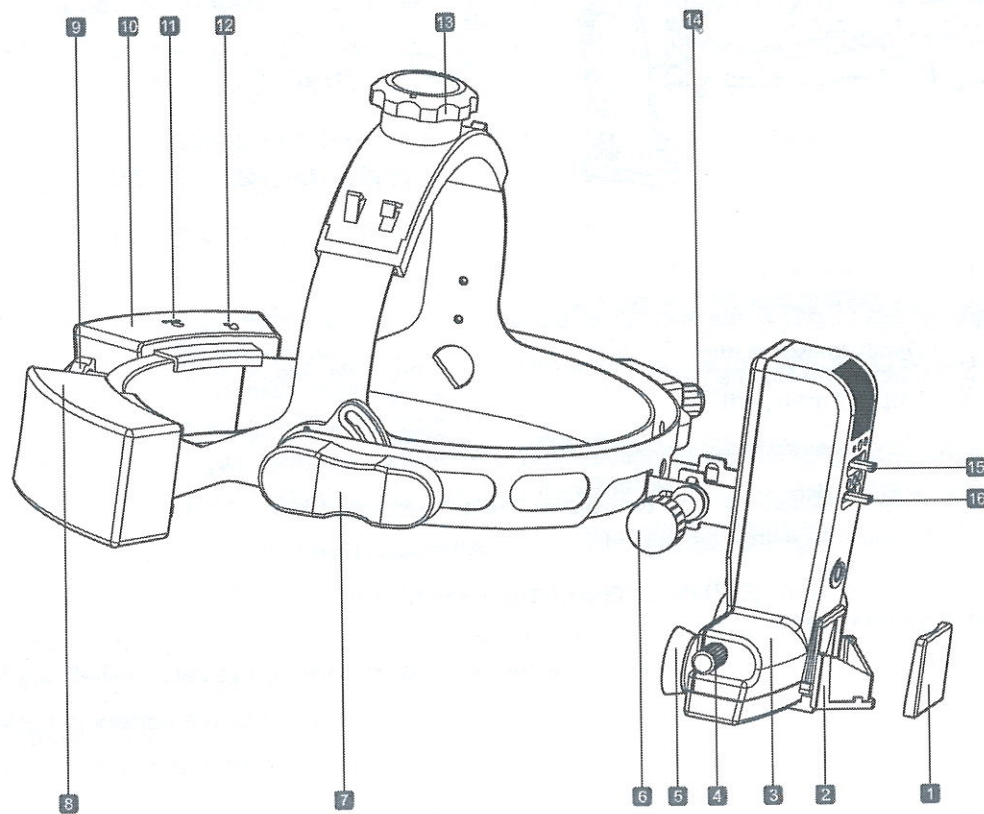


Fig.1

- | | | | |
|-------------------|----------------------|-------------------------|--------------------------|
| 1—Dustproof cover | 5—Ocular | 9—Cir-cum knob | 13—Vertical knob |
| 2—Teaching mirror | 6—Hand shank | 10—Power control module | 14—Light adjustment knob |
| 3—Optical unit | 7—Batch level cover | 11—Charge socket | 15—Aperture control |
| 4—Mirror control | 8—Battery box module | 12—Power indicator | 16—Filter control |

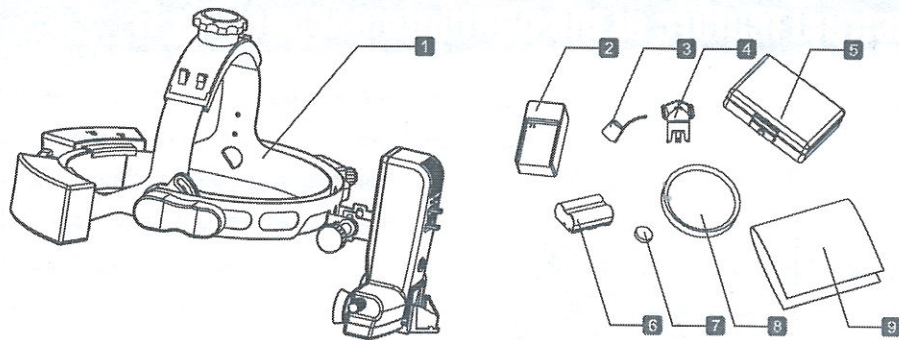
There is no potential electromagnetic or other interference between this instrument and other instruments.

3. Installation

All parts should be taken out from the packing case carefully before assembling.

3.1 Lists of parts(Chart.1)

Notes: No.3,4,7,9 are in the accessories box



Number	Name	Quantity
1	Ophthalmoscope (the headband and the optical main part)	1
2	Charger	1
3	Sclera depressor	Big and small each one
4	Teaching mirror	1

Number	Name	Quantity
5	Accessories box	1
6	Battery	2
7	Plane mirror (0D)	2
8	Aspheric lens (+20D)	1
9	Lens cleaning cloth	1

Chart.1 Lists of parts

3.2 Battery installation

As shown in Fig.2, put the thumb on the semi-circular groove on the battery shell, unplug the back cover of the battery shell according to the arrow direction, put the battery in battery shell as shown in Fig.3, make sure the metal piece of the battery has a good contact with the reed.

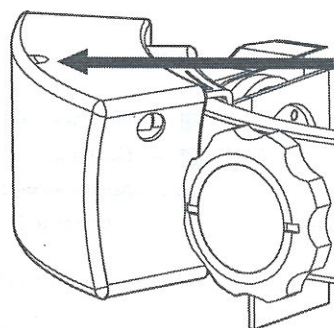


Fig.2

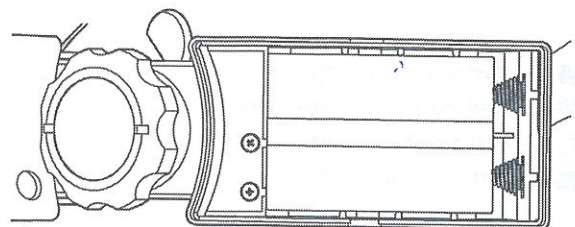


Fig.3

3.3 Inspection after installation

Dismantle the dustproof cover on the illumination window. To revolve the light adjustment knob with clockwise, you can see the light projecting and the bright ceaselessly increase, project the light spot on a flat surface about 40~50cm distance.

4. The usage of the ophthalmoscope

4.1 Adjust the headband and optical main part

◇For best performance, be sure the headband fits properly and is comfortable. Adjust the headband vertical adjustment knob so the instrument is supported comfortably. Position the main body of the headband on the forehead so it is comfortable and tighten the headband circumference adjustment knob. Position the headband so back of band fits comfortably under the natural ridge on the backside of head.

◇Place the overband approximately 1~2 fingers widths above the eyes. Position the BIO so the oculars are set on your visual axis by adjusting the optical portion adjustment knob. The BIO should also be as close to your eyes (or spectacles) as possible. If you prefer to adjust the optical portion with your left hand, the adjustment knob can be removed and reversed to the left side.

NOTE: The torque required to turn the vertical and circumference adjustment knob can be modified by adjusting the exposed screw. For more resistance, turn the screw clockwise; for less, turn it counterclockwise.

◇Set the interpupillary distance. The interpupillary distance (IPD) move the oculars and are located on the bottom of the optical portion. These oculars will move independently of one another. To set the IPD properly, observe your thumb or some other small object at arms length. Alternately view this object with your left and right eye. Position the oculars precisely centered.

NOTE: The oculars are shipped with +2.00D diopter lense in place. Plano lense are included and can be installed by removing the rubber eyepiece cups, tilting the instrument to remove lense. Replace with plano lenses, and stretch eyecups back in place.

◇Take down the instrument, check whether the IPD knobs have been adjusted to symmetry. If dissymmetry, adjust it according to the value of the left and right pupillary distance on the optical main part's top cover. Regulating optical main part accurately is very important, especially while checking small pupil.

4.2 The usage of the ophthalmoscope

◇ Turn the aperture size control, the light spot should have three kinds of size variety (Fig.4).

To use the large aperture, for fully dilated pupils, place the lever in the center.

To use the small aperture, suitable for patients with small undilated pupils, place the lever in the left position.

To use the medium-sized aperture, helpful for patients with cataracts, place the lever in the right position.

◇ Turn the filter selection control, the light spot should have three kinds of colour variety (Fig.5).

White light is obtained when the switch is in the middle position.

Cobalt blue light is obtained when the lever is in the left position.

Red-free light is obtained when the lever is in the right position.

small aperture large aperture medium-sized aperture

Fig.4

cobalt blue light white light red-free light

Fig.5

◇ The mirror control will allow the vertical location of the light beam to be positioned at a desired height within the viewing area. This is usually a point slightly above fixation. Turn the mirror control knob, the light spot should move up or down. Each operation should be operated flexible and located accurately.

◇ Put the aspheric magnifier in front of a patient eye to observe the fundus image.

◇ Examiner should face to the convex surface of the magnifier or patient face to the white and bright wreath surface on the bottom of the magnifier.

◇ Slightly incline the magnifier to minimize the reflection for a clear fundus image.

◇ Revolve to adjust the light knob to regulate the light brightness to adequate value.

◇ Mean agreeable the hour hand revolves to adjust the light knob, illuminating a gradual aggrandizement, whereas then from diminish greatly.

◇ After use, turn the light control knob anticlockwise to the position "0", the green light is off, means the power is turned off.

4.3 Assembling the teaching mirror(Fig.6)

◇The teaching mirror is installed in front of the viewing window on optical main part. To attach the teaching mirror, mount the "dovetail"piece onto the bottom of the optical portion using a screwdriver. Once the "dovetail"piece is mounted,it can remain attached.

◇ The teaching mirror then slides onto the front of the "dovetail"and snaps into position.

◇ To quickly remove the teaching mirror from the user's visual path,grasp the front edge and flip it down. To resume use of the teaching mirror,snap it back up into position.

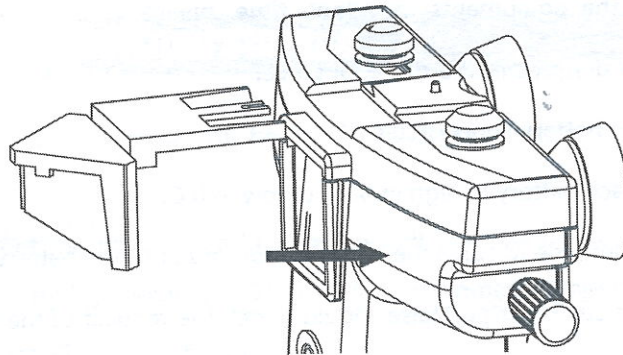


Fig.6

4.4 Recharging the battery

When the power instruction lamp is green, means that battery electricity quantity is ample; when yellow, mean that battery electricity quantity is shortage, but can still work; when the battery electricity measure the exhaustion, the equipments can't work.

Charging method 1:

Turn off the power, the plug of the charger charging socket on the device is inserted into the network socket, charger. Indicates that the battery is charging charger indicator light is yellow, the charger light turns green indicates that the battery has been full of.

Charging method 2:

Remove the battery, from the device into the charger, the charger plugged in the power socket on the net. Charging indicator light is orange indicates that the battery is charging; charging indicator lights show that the battery has been full.

The charging process takes about 3 hours. The equipments can't be used due to have a self-preservation to protect device while refreshing.

The normal charging time is about three hours.

5. Maintenance

5.1 Safety use and maintenance

- ◇ Refresh to complete or don't use the charger, please separate charger and the net power supplies, and take out the battery.
- ◇ Refresh forbid to overlay the charger, in order to prevent causes fire.
- ◇ If do not use the equipments in a long time, please keep battery in 50% - 80% electricity quantity, and stores in the dry cool place.
- ◇ Do not make the battery short circuit.
- ◇ Please not to place battery in high in 60°C or low in 0°C.
- ◇ Please not to dismantle to solve the battery or pound at to the battery machine.
- ◇ The charger that customer purchase should match the request of the IEC 60601-1 or IEC 62368-1

5.2 Cleaning

- ◇ The Lens and viewfinder can be wiped using the lens cleaning cloth dipped with alcohol.
- ◇ The surface of the instrument can be wiped using alcohol and soft cloth.
- ◇ The soft mat of headband can be wiped with soap water and soft cloth.

caution:

1. Never scratch the reflecting mirror with fingers or any other hard materials.
2. Don't wipe with any corrosive detergent lest that the surface should be damaged.

5.3 Protection

- ◇ This ophthalmoscope is rectified before delivery. Please do not disassemble it freely.
- ◇ The ophthalmoscope should be in clean circumstance. If it is not used for long time, it is recommended that it be put into the box in case of dust invasion.
- ◇ This ophthalmoscope should not be vibrated, impacted and dropped down.

6. Responsibility

◇According to the customer's maintain demands, our company can provide the circuit diagram, electric components list, correct regulations etc of this instrument.

◇If you need related data, relevant service and have any question, please contact with the authorized sales or directly with our company.

7. Transportation and storage

◇When transport this instrument, be careful to prevent tide and turning upside down, avoid shake violently.

◇This instrument should be stored under the well ventilated room without corrosive gas where the relative humidity should be 10% to 80%, environment temperature -40°C - 50°C and atmospheric pressure 500hpa - 1060hpa.

8. Trouble shooting guide

In case there is any trouble, please check according to the following table for reference. If it still cannot work, please contact an authorized distributor.

Trouble	Possible reason	Remedy
The bulb can't light	The battery contact is bad	Push out the battery and re-pushing it again
		Pull the contacting reed down
	Adjust the light knob is placed in the negative hour hand exactly	Turn the knob clockwise
	The power switch is damaged	Change new switch
	The back cover of bulb isn't in the position	Close the back cover, fasten the screw.
The brightness is not enough	The bulb is damaged	Replace the bulb
	The light control knob isn't in the position	Turn the knob clockwise continuous
	The bulb is old	Replace the bulb
	The selection of the filter isn't suitable	Change the selection of the filter
The light spot isn't complete	The lens or viewfinder has been stained	Clean the lens
	The diaphragm or filter isn't in position	Turn to the position

9. Specifications

Type:	Head-worn binocular non-contact ophthalmoscope
Working distance:	50.5mm (the distance of check cornea to +20D surface)
Interpupillary distance:	52mm-74mm
Intensity of illumination:	Step-less adjustable with the maximum intensity no less than 500Lx
Headband:	520-640mm in circumference, 85-125mm in depth
Light spots:	big, middle and small
Filters:	red-free, white and cobalt blue
Teaching mirror:	Coated mirror with both sides viewing
Light source:	3.2W LED
Battery model:	BP511A
Charger model number:	Pedestal charger; BP511
Electric safety standard:	IEC 60601-1:2005+AMD1:2012+AMD2:2020
Safe classification of equipments:	Internal power supply, IPX0, not AP and APG equipment
Main part's dimension:	142×48×128mm (long×breadth×high)
Main part's weight:	230g

⚠ WARNING : The lithium battery and its charger must be matched, otherwise it may cause electric shock injury.

10. Normal working condition

Temperature:	5°C - 40°C
Relative humidity :	30% - 75%
Atmospheric pressure:	700hPa - 1060hPa
Source of power:	Charger: 100-240V, 50/60Hz;

11. Term of validity

That product uses the term of validity is 5 years.

12.The processing of the wastes

Exceed to use the time limit or discard equipments and change bulb is no processing risk, can processing according to the general industry garbage.

13.Output the spectrum

Fig.7 is check the glasses to be placed in the output's spectrum diagram of hour of the biggest light strong and biggest bore column appearance for the YZ25C indirectly.

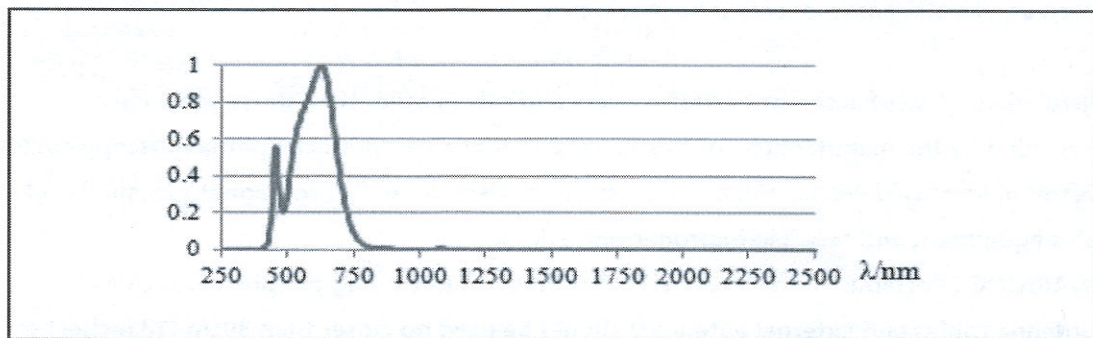


Fig.7

CAUTION - The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operator at maximum intensity will exceed the safety guideline after **6 min.**

⚠ **caution:** Battery and the charger damage or led the service life period after, please press local environmental protection regulation to carry on abandon.

★ We will not notice you if the design and specification are changed.

14.EMC result

YZ25C is a Group 1 Class A medical electrical equipment that requires special precautions against electromagnetic compatibility (EMC) and must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.

The YZ25C Binocular Indirect Ophthalmoscope is suitable for hospitals and professional healthcare facility environment, all hospital areas are suitable for using this Slit Lamp Microscope equipment.

The YZ25C Binocular Indirect Ophthalmoscope has no ESSENTIAL PERFORMANCE.

NOTE :

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠ WARNING : Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the YZ25C Binocular Indirect Ophthalmoscope could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING : Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the YZ25C Binocular Indirect Ophthalmoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions

The YZ25C Binocular Indirect Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of YZ25C Binocular Indirect Ophthalmoscope should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions (CISPR 11)	Group 1	The YZ25C Binocular Indirect Ophthalmoscope 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	Class A	The YZ25C Binocular Indirect Ophthalmoscope is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emission IEC61000-3-3	Complies	

⚠ 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.

Guidance and Manufacturer's declaration-electromagnetic immunity


The YZ25C Binocular Indirect Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment guidance
Electrostatic discharge(ESD) IEC 61000-4-2	$\pm 8\text{ kV}$ contact $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, $\pm 15\text{ kV}$ air	$\pm 8\text{ kV}$ contact $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, $\pm 15\text{ kV}$ 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	$\pm 2\text{ kV}$ for power supply lines	$\pm 2\text{ kV}$ for power supply lines;	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	$\pm 1\text{ kV}$ line(s) to line(s);	$\pm 1\text{ kV}$ line(s) to line(s);	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; 0,5cycle 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 cycle	0% UT; 0,5cycle 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 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the YZ25C Binocular Indirect Ophthalmoscope requires continued operation during power mains interruptions, it is recommended that the YZ25C Binocular Indirect Ophthalmoscope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	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 Manufacturer's declaration-electromagnetic immunity

The YZ25C Binocular Indirect Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	6Vrms	6V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the YZ25C Binocular Indirect Ophthalmoscope, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80MHz to 800MHz</p> <p>$d = 2.3\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as 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>
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,7 GHz;	10V/m 80 MHz to 2,7 GHz;	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,76 5MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

^bField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile 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 YZ25C Binocular Indirect Ophthalmoscope is used exceeds the applicable RF compliance level above, the YZ25C Binocular Indirect Ophthalmoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the YZ25C Binocular Indirect Ophthalmoscope. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the YZ25C Binocular Indirect Ophthalmoscope

The YZ25C Binocular Indirect Ophthalmoscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the YZ25C Binocular Indirect Ophthalmoscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the YZ25C Binocular Indirect Ophthalmoscope 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 Outside ISM and amateur radio bands $d = 1.2\sqrt{P}$	80MHz-800MHz $d = 1.2\sqrt{P}$	800MHz-2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.