

Tian Song®

EJ Otoscope
Operating Manual

ZHEJIANG TIANSONG MEDICAL INSTRUMENT CO., LTD

- **Production License No., Product Registration No. and Implementation of standards of the enterprise**

——Zhejiang Food and Drug Administration Production No 20100200

——Zhejiang Food and Drug Administration No 2014 No 2220774

— This product has passed the Certification of Medical Devices Quality Management System which meets the demand of GB/T 19001-2016idt ISO 9001:2015 and YY/T 0287-2017idt ISO 13485:2016

Certification No: **04719Q10763R6M、04719Q10000879**

— This product has passed the Certification of EC Medical Devices Quality System which meets the demand of EN ISO 13485:2016

Certification No.: **CE—0197 SX 60123619 0001**

CE—0197 HD 60123618 0001

- **After-sales service**

— Repair guide: **After-sales service department of Zhejiang Tiansong Medical Instrument Co., Ltd requires the product which needs repairing should meet the demand of Warranty Statement.** We will repair the product and do an overall check as well. We provide free service if the product is before the limited period and paid service if it is out of the guarantee scope or exceeds the limited period.

— If you want to buy our products or have consultation, please contact with our Sales Department.

— Tel: +86(0)571-64241878、64241388; Fax: +86 (0)571-64241818

We have set up offices all over the provinces and cities in China to do service, try best to make sure the customers believe us, their contacts would be known if you phone our Sales Department.

— After-sales Tel: +86(0)571-64241168

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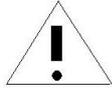
Website: www.zj-tiansong.com; www.chinaendoscope.cn

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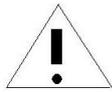
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Symbol description

In this manual we use the symbols as below:



Warning: mean the potential harm, if not avoid, may lead to die or the strong result.



Attention: mean the potential harm, if not avoid may lead middle or light result, also use as unsafe operation or potential harm.

Operator qualify

The products operator should be the specialist or the medical affairs under the specialist' s supervision; they should be passed the fully special clinical otoscope training. All the using method and the contraindication are only for reference.

1. Product usage

Otoscope is mainly used for ear inspection and operation.

2. Main structure

Otoscope is mainly composed of lens body, light pencil joint, eyepiece casing and light guide cable. The construction features are as follows:

2.1 EJ-4 Type Otoscope

Out diameter $\Phi 2.7\text{mm}$, working length 107.5mm, Direction of view 0° 、 30° 、 70° . The outer tube which is touched is made by 1Cr18Ni9Ti material. Objective lens' s protection glass is made by smooth and abrasion resistant sapphire.

2.2 EJ-5 Type Otoscope

Out diameter $\Phi 4\text{mm}$, working length 45mm, Direction of view 0° 、 30° 、 70° . The outer tube which is touched is made by 1Cr18Ni9Ti material. Objective lens' s protection glass is made by smooth and abrasion resistant sapphire

3. Main feature, specification and configuration

3.1 Main feature

Name Item	EJ-4 Type Otoscope	EJ-5 Type Otoscope
Out diameter	$\Phi 2.7\text{mm}$	$\Phi 4\text{mm}$
Working length	107.5mm	45mm
Field Of View	$\geq 50^\circ$ (utmost deviation -2.5°)	
Direction of view	0° (utmost deviation $\pm 5^\circ$)	
	30° (utmost deviation $\pm 7^\circ$)	
	70° (utmost deviation $\pm 7^\circ$)	

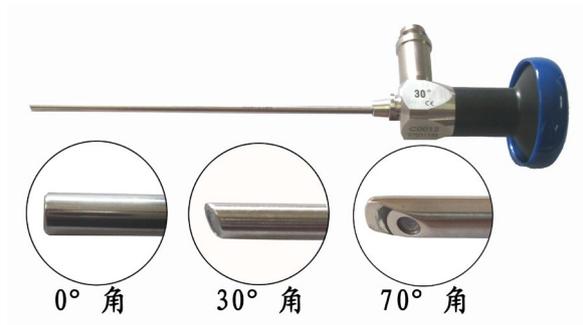
Magnification	$>1^{\times}(L=10\text{mm})$
Resolution	7.34Lp/mm (L=10mm)
Illumination	$\geq 3000\text{Lx}(L=10\text{ mm})$

The product meets the demand of GB 9706.1、GB 9706.19.

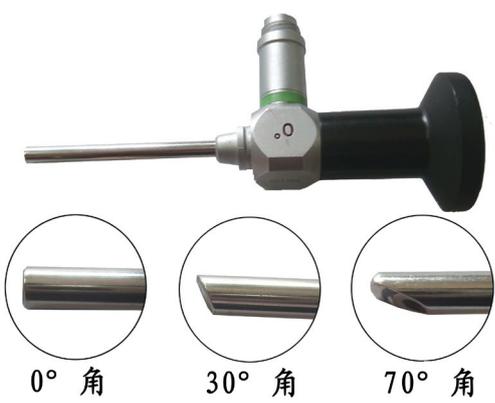
Sketch map of product:

1) Endoscope

- EJ-4 Type Otoscope, Code NO. : C0010 (0°)、C0012 (30°)、C0013 (70°)，
Out diameter $\Phi 2.7\text{mm} \times 107.5\text{mm}$;



- EJ-5 Type Otoscope, Code NO. : C0030 (0°)、C0032 (30°)、C0033 (70°)，
Out diameter $\Phi 4\text{mm} \times 45\text{mm}$;



3.2 Configuration

Item	Name	Serial No.	Specification	QTY
EJ-4 Type Otoscope	Endoscope	C0010	0° $\Phi 2.7 \times 107.5\text{mm}$	1PC
	Endoscope	C0012	30° $\Phi 2.7 \times 107.5\text{mm}$	1PC

	Endoscope	C0013	70° ϕ 2.7× 107.5mm	1PC
	Optional parts			
	Middle ear polyp forceps	C2001	Occlusal head	1PC
	Middle ear polyp forceps	C2002	Ring head	1PC
	Middle ear polyp forceps	C2003.1	Large triticeous head	1PC
	Middle ear polyp forceps	C2003.2	Small triticeous head	1PC
	Middle ear polyp forceps	C2004	45° angled cup head	1PC
	Middle ear polyp forceps	C2005.1	Large cup head	1PC
	Middle ear polyp forceps	C2005.2	Small cup head	1PC
	Middle ear polyp scissors	C2006	Straight	1PC
	Minitype Cerumen hook	C2080	9 PCs Combination	1Set
	Light guide cable	T5012	1800mm	1PC
EJ-5 Type Otoscope	Endoscope	C0030	0° ϕ 4×45mm	1PC
	Endoscope	C0032	30° ϕ 4×45mm	1PC
	Endoscope	C0033	70° ϕ 4×45mm	1PC
	Optional parts			
	Middle ear polyp forceps	C2001	Occlusal head	1PC
	Middle ear polyp forceps	C2002	Ring head	1PC
	Middle ear polyp forceps	C2003.1	Large triticeous head	1PC
	Middle ear polyp forceps	C2003.2	Small triticeous head	1PC
	Middle ear polyp forceps	C2004	45° angled cup head	1PC
	Middle ear polyp forceps	C2005.1	Large cup head	1PC
	Middle ear polyp forceps	C2005.2	Small cup head	1PC
	Stapes fix forceps	C2013		1PC
Middle ear	C2006	Straight	1PC	

	polyp scissors			
	Minitype Cerumen hook	C2080	9 PCs Combination	1Set
	Light guide cable	T5012	1800mm	1PC

Optional parts

No.	Name	Serial No.	Specification	Remark
1	Endoscope	C0020	0° Φ 3×55mm	1PC
2	Endoscope	C0022	30° Φ 3×55mm	1PC
3	Endoscope	C0023	70° Φ 3×55mm	1PC
4	Endoscope	C0030	0° Φ 4×45mm	1PC
5	Endoscope	C0033	30° Φ 4×45mm	1PC
6	Endoscope	C0032	70° Φ 4×45mm	1PC
7	Endoscope	C0010.1B	0° Φ 3×90mm	1PC
8	Endoscope	C0010.1C	0° Φ 3.3×90mm	1PC

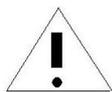
Note: EJ-4 type otoscope and EJ-5 type otoscope, because of their higher frequency of use, our Company rank them as the main configuration, but in order to meet the different market demand, we specially add several other specifications otoscopes in order to meet the requirements of different customers.

4. Applying field

Otoscope is used for ear examination and operation.

5. Using Method

5.1 Preoperative preparation



Attention: During the use of otoscope, it may occur otoscope's failure (such as unclear imaging of lens body) or a subsidiary of equipment failure (such as the cold light bulb lighting failure), resulting in the loss of equipment's function. Therefore, we suggest preparing spare equipment and parts before the operation to prevent any eventuality.

- 1) Realize the patient' s state of illness, clear the purpose of inspection;
- 2) Explained to the patients about the state of illness, inform relating matters to inspection, and get the patient' s consent;
- 3) Prepare the necessary preoperative examination, such as heart, liver and renal function measurement;
- 4) Earnestly do a good preparatory work of otoscope, cold light source and other accessories in order to check whether its function is good.

Required inspection items:

- ,1 Definition of endoscopic imaging, on outer surface whether there are sharp edges, corner.
- ,2 Whether the connection of endoscope and light guide cable is good, as well as the light guide cable and cold light source.
- ,3 Whether the cold light source works well. When connecting you should confirm if the temperature of insert part is over 41 °C and electrical security is good;

5.2 Steps

1) Anesthesia: Generally, without anesthesia, but to infants and those who can not cooperate, you can use proper sedative hypnotics drug in order to facilitate the operation.

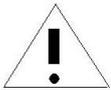
2) Body posture: Adults and juveniles can have seat check; mental tension ones and children can have lateral position check;

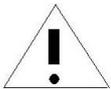
3) Connect the endoscope with cable and light source, open the light source and adjust to proper lightness.

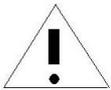
4) The patient's head position should be fixed during examination, doctor can sit or stand on the right side, hold otoscope gently to send into the ear canal, the direction should be consistent with the longitudinal axis of the external auditory canal. Then examination can be started.

6. Attention

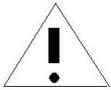
6.1 Warning and Attention

1)  **Attention:** Before using the otoscope, please read the manual carefully and accessories manual.

2)  **Warning:** The operator should be the certain qualification, and after the training and with the good operating skill. Before the operation, they should read the relative document include the technique, relative disease and the harm.

3)  **Warning:** If the sterilizing not totally and the sterilizing liquid over the term or not sterilizing not follow the general requirement, all that case will possibly lead to intercross

infection. Especially for the contagion and the cancer patient, must disinfect in time!

- 4)  **Attention:** Please check the inserted part of otoscope if there is some roughened surface, acuity edge or the prominence on the instrument.

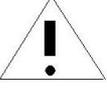
- 5)  **Attention :** Otoscope is the important guarantee of observation and diagnosis. Be careful when using. Always be mild, step by step, can' t push by force, bump and bend.

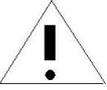
- 6)  **Warning:** Whenever discovering the anomaly of otoscope, he should immediately stop using it and extract slowly. It would be harmful to patients if operating with faulted otoscope.

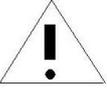
- 7)  **Warning:** The temperature of otoscope will increase to 41 °C to 50 °C because of the light irradiation. The surface temperature over 41 °C would lead to mucosa burning. Therefore, the operator need to use the smallest illumination, the shortest time and the most appropriate distance for observation. Fixed-point observation should be avoided as far as possible, do not let the otoscope close mucosal for too long time.

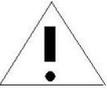
- 8)  **Warning:** Before and after using of otoscope, please try to

refrain from the use of lighting. Persistent lighting will rise the temperature of objective lens, resulting in burn of patients or operators.

- 9)  **Warning:** If the otoscope uses endoscopic annex with energy, then the patients will increase leakage current.

- 10)  **Warning:** Do not ever directly look at the cold light source, fiber optic cable or endoscope light, which would damage the eyes.

- 11)  **Attention:** Otoscopy set is a kind of reusable medical devices. The long-term usage or improper maintenance will cause the aging of the reused otoscope and the instruments. Please make sure every part of the otoscope is safe and reliable before using.

- 12)  **Attention:** Before using please put the front part of disinfected endoscope in the distilled water about 40 °C in order to avoid the fog which will affect the observation.

6.2 Cleaning, disinfection and sterilization

6.2.1 Cleaning

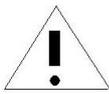
- Cleaning



Attention: The products are not disinfected and sterilized before the transportation. So that, before you first time use, you should

do the cleaning, disinfecting and sterilizing as below.

- 1) Before disinfection, please discharge the cable from the otoscope, and give the endoscope a thorough clean-up. Please separate the endoscope and other components when cleaning.
- 2) After using the otoscope, it should be thoroughly washed with flowing water immediately to remove blood, mucus and other residue material. Then drying it.
- 3) About the otoscope after drying, it should be soaked in a dedicated multi-enzyme cleaning lotion to prevent organic matter and protein coagulating, the soaking time of multi-enzyme lotion refers to the manual, and rinse under running water.
- 4) Otoscope after washing, please dry it, to be disinfected.



Attention: Bending of the endoscope should be avoided, do not spin to lose or remove eyepiece cover (except special products), do not put heavy on the endoscope or drop or rough dispose. Avoid cleaning endoscopes with ultrasonic.

6.2.2 Disinfection and sterilization

● Ethylene oxide sterilization

—This is the preferred method for the endoscope which can not bear pressure steam sterilization methods.

—Mini ethylene oxide sterilizer relative condition

Ethylene oxide sterilizer gas concentration...600mg/L~800mg/L

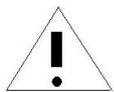
Temperature..... 37°C ~ 63°C

Relative humidity..... 40%-80%

Sterilizing time..... 1h-6h

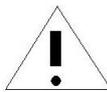
● Glutaraldehyde sterilization

—Put the cleaned and dry endoscope to the 2% Glutaraldehyde vessel, cover and after 10 hours, take out by aseptic technique, clean it by aseptic water, then aseptic dry.



Note: The Glutaraldehyde must with the valid concentration the valid term, if not please change in time

● The other sterilizing method under the ministry of health



Attention:

1) Openness concretion, hepatitis, AIDS patient or the pathogen carrier should use the special otoscope, patient and the otoscope should do the strictly sterilization, and the sterilizing vessel also should be separately strictly from the other patient. If using the special otoscope is difficult, also should do the sterilizing or high-level disinfecting.

2) The otoscope sterilized by the chemosterilant, firstly should be cleaned by aseptic water to clean the rest disinfectant.

● Sterilization and disinfection of other parts

1) The surgical instruments used with otoscope should be sterilized after cleaning.

2) Ethylene oxide sterilization can also be used, the methods and notes refer to the sterilization of otoscope.

3) Sterilization by soaking in 2% glutaraldehyde for 10h, all parts should be soaked in disinfectant, all channels should be filled with disinfectant.

4) Fiber optic cable and other accessories can be disinfected by 75% alcohol cloth to wipe both sides, or adopt disposable sterile plastic cover to achieve the purpose of isolation disinfection, but the contact part should still be disinfected by alcohol.



Note: All the clean, disinfecting and chemical method, steps and the technical parameters are only for reference. The detail should be accord with the operating manual.

7. Contraindication (Only for reference)

Otoscopy doesn't have absolute contraindication. But to infants and those who can not cooperate, you can use proper sedative hypnotics drug in order to facilitate the operation.

8. Maintenance and Repair



Note: The products are can not repaired by customer. Please do not disassemble, modify or try to maintain, otherwise that will do harm to the patient or the operator, even damage the otoscope.

The otoscope should be use carefully and lightly, avoid damaging the

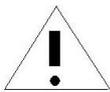
surface. Should be kept well.

1) When finish the operation, please clean in time and keep them well, even when you do the disinfecting, also should rulely, can not disinfected by random. Disinfecting strictly follow the regulation avoid damagement.

2) If the otoscope will be no use for long time, they should be put in the pneumatic drying place, checked every one to teo weeks, be careful not to mould and rust.

3) Fiber optic cable can not be over-bending, the radius of curvature shall be not less than 5cm, in order to avoid damage to optical fiber.

4) Otoscopic removal, storage should be handled with care, no bump, collision, extrusion, etc.



Note: Otoscopy set is a kind of reusable medical devices

Using condition: Environment temperature: 10°C ~ 40°C

Relative humidity: 30%~75%

Air pressure: 700KPa~1060KPa

Storing condition: Environment temperature: -20°C ~ +60°C

Relative humidity: 10%~80%

Air pressure: 500KPa~1060KPa

Please store them to the no corrosiveness and the well-ventilated room, the sterilized otoscopy set should be kept according to the requirement for the asepsis.

From the date of the factory, product does not work within 12 months because

of quality issues, we will repair for free, replace parts or products, life-long maintenance.

The following situations is not in the scope of warranty, we will provide paid service:

- 1) Human factors, e. g. using improperly, bump, choosing wrong disinfection method and maintenance;
- 2) Broken lens;
- 3) Demolition by self;

All kinds of the products can be updated or improved. If the configuration change, forgive us inform further.

9. Marking and signal

- 1) Tian Song®----- Company registered brand
- 2)“A0013” and so on-----Product series number
- 3) Series code: The first two number is the year, next two is the month, then the work number, the last two is the quantity of this lot number. For example:05071120, it means the production date is July,2005, work number is 11, and the quantity of this lot number is 20.

 72004 / C0030 - 72007 / C0010 - 72008 / C0012

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M-72004-GB-Rev.3.02.20