


REV	ECN	Revision History	Date	Editor
A07	ECN05106	1. Modify the "Depth of field" and "Minimum visible distance of instrument channel".	2023-12-20	Xu Lin
A06	ECN04208	1. Delete the maximum outer diameter of the insertion section. 2. Modify the "outer diameter of the bending section" to the "outer diameter of the insertion tube".	2022-08-18	Xu Lin
A05	ECN03839	1. Delete syringe in the Packing List 2. Change the font 3. Add total length	2022-05-06	Xu Lin
A04	D00059410	Update the manufacturer address	2019-06-24	Xu Lin
A03	D00056420	1. Add endoscope part names 2. Add disinfectant and sterilization methods	2018-12-17	Xu Lin
A02	D00041301	1. Change the design sketch 2. Delete the total length 3. Modify the safety standard	2017-09-18	Kang Jiajun
A01	D00029319	First Release	2016-07-14	Shu Rong

Title EG-500 Series Video Gastroscope Technical Specifications

This document contains intellectual property information that is proprietary to SonoScape Medical Corp. and is protected by law. Neither the document nor the information contained therein should be used or reproduced in whole or partially, without prior written agreement consent of SonoScape Medical Corp.

 SONOSCAPE MEDICAL CORP.	Document Number 901-03607		Distribution Number
	Version A07	Effective Date	Page Page 1 of 10

EG-500 Series Video Gastroscope Technical Specifications



SonoScape

SONOSCAPE MEDICAL CORP.

Contents

1. General Description	4
2. Advanced Technologies.....	4
3. Connector Section.....	4
4. Control Section and Insertion Section.....	4
5. Distal End.....	5
6. Auxiliary Examination.....	5
7. Disinfectant, Sterilant and Flush Liquid	5
8. Specifications.....	5
9. Packing List.....	5
10. Application Range.....	5
11. Compatible Devices.....	6
12. Safety Standards	6
13. Environment Requirements	6
14. Appendix	7

1. General Description

The EG-500 series video gastroscope is specially designed for the examination, diagnosis and treatment for the upper digestive tract of human body. The CMOS imaging technology, digital image processing technology, micro-optical lens technology, and advanced software technology are applied on the device to provide high-quality images, making the diagnosis and treatment safer, the judgment more accurate and the operation more stable.

The product supports real-time video acquisition, air/water-feeding, suction and remote control of image freezing, magnification, etc.

The product complies with the relevant international and national standards.

2. Advanced Technologies

- High-definition CMOS imaging technology (2 million pixels)
- Micro optical lens technology
- Large-view-field imaging lens technology
- Auxiliary water-feeding
- High conductive section hardness insertion tube with finer diameter
- Quick switch between air-feeding and water-feeding
- Small bending radius and larger bending angle
- Adoption of polymer engineering material with higher disinfectant tolerance
- Light handle

3. Connector Section

- Electrical connector
- Air-feeding port
- Light guide
- Air/water feeding port (including water-feeding port and air-feeding port)
- Suction port
- Auxiliary water-feeding port
- Electrosurgical equipment connector

4. Control Section and Insertion Section

- Left/right angulation lock
- Left/right angulation control knob
- Up/down angulation control knob
- Up/down angulation lock
- Remote buttons (0-3)
 - Customize the functions of the four remote buttons by using the image processor.
 - The customizable functions include freeze, zoom, VIST, photometry mode, image enhancement, color enhancement, CHb pseudo-color image, transillumination mode, contrast enhancement, AGC, image size, screenshot, video print, video recording, timer, PBP, content display, one-key export and upload.
- Instrument channel
 - Used for feeding liquid to the distal end

- Used for the endotherapy accessory
- Used as a part of the suction tube after covering the biopsy valve cap firmly
- Insertion limit mark
- Suction valve
- Air/water valve
 - Block the valve hole with fingers to feed air.
 - Press the valve to feed water and clean the lens.
 - Press the valve to feed air or water to clean the blood, debris and mucosal adhered to the objective lens.

5. Distal End

- Objective lens
- Air/water nozzle
- Light guide lens
- Auxiliary water-feeding port
- Instrument channel outlet

6. Auxiliary Examination

- Biopsy forceps sampling
- Cytology brush sampling
- Feeding liquid by syringe

7. Disinfectant, Sterilant and Flush Liquid

- Recommended high-level disinfectant:
 - Phthalic dicarboxaldehyde (OPA)
Level: 0.55% (0.5%-0.6%)
 - Glutaraldehyde (GA)
Level: $\geq 2\%$ (alkaline)

- Peroxyacetic acid (PAA)
Level: 0.2%- 0.35% (W/V)
- Acidic electrolyzed oxidizing water (AEOW)
- Active chlorine level: (60 ± 10) mg/ L, pH value: 2.0 - 3.0, chlorination reduction potential: ≥ 1100 mV, residual chloride ion level: < 1000 mg/L
- Recommended flush liquid: 75% ethyl alcohol or isopropanol

8. Specifications

Refer to the Appendix A
(Net weight: 1.3 kg)

9. Packing List

- Endoscope
- Biopsy valve
- Cleaning brush
- Leakage detector
- Injection tube
- Auxiliary water-feeding tube
- Channel plug
- Waterproof cap
- Distal end cap
- User manual

10. Application Range

The product is used with the image processor, light source, and other peripherals provided or recommended by the manufacturer. It is intended for use in examination and diagnosis of the upper digestive tract (including the esophagus,

gastric cavity and duodenum). It also can be used with surgical instruments, such as biopsy forceps, snare and high-frequency endoscopic surgical instruments but not the laser equipment.

11. Compatible Devices

- Light source: HDL-500X,
HDL-500E, VLS-50
series
- Image processor: HD-500, HD-500S
- Trolley: HDT-330

12. Safety Standards

- IEC 60601-1:2005 + A1:2012
- IEC 60601-2-18:2009
- IEC 60601-1-2:2014

13. Environment Requirements

- Operating environment
 - Temperature: +5°C - +40°C
 - Relative humidity: 30% - 80%
 - Atmospheric pressure: 700 hPa - 1060 hPa
- Storage environment
 - Temperature: -5°C - +40°C
 - Relative humidity: 30% - 80%
 - Atmospheric pressure: 700 hPa - 1060 hPa
- Transportation environment
 - Temperature: -20°C - +55°C
 - Relative humidity: 20% - 90%
 - Atmospheric pressure: 700 hPa - 1060 hPa

- Safety types

- Degree of protection against electric shock: Type BF applied part
- Degree of protection against harmful liquid: IPX7

14. Appendix**Appendix A Specifications**

No.	Parameter	Model	
		EG-500	EG-500L
1	Direction of view	Front viewing	
2	Field of view	140°, allowance: ±10%	
3	Resolution	≥12.50 lp/mm (working distance is 10 mm)	
4	Depth of field	2-100 mm	
5	Outer diameter of the distal end	Φ 9.3 mm Allowance: 10%, not considering the lower limit	Φ 9.8 mm Allowance: 10%, not considering the lower limit
6	Outer diameter of the insertion tube	Φ 9.3 mm Allowance: 5%, not considering the lower limit	Φ 9.8 mm Allowance: 5%, not considering the lower limit
7	Bending angle	Up 210°, down 90°, Left 100°, right 100° Allowance: -10%, not considering the upper limit	
8	Min. inner diameter of the instrument channel	≥ Φ 2.8 mm	≥ Φ 3.2 mm
9	Working length	1050 mm±10%	
10	Total length	1350 mm±10%	
11	Minimum visible distance of instrument channel	2 mm	
12	Illuminance	≥ 18000 Lx	
13	Aspirated amount	≥ 400 mL/min	
14	Water/air-feeding	<ul style="list-style-type: none"> • Amount of fed water ≥ 40 mL/min, • Amount of fed air ≥ 800 mL/min 	
15	Auxiliary water feeding	Support	
16	Endoscope information storage	Support	

Appendix B Recommended High-level Disinfectant and Methods

Disinfectant	Concentration	Contact Period	Contact Type	Precautions
Phthalic dicarboxaldehyde (OPA)	Level: 0.55% (0.5% - 0.6%)	≥ 5 minutes	Immersion	<ol style="list-style-type: none"> 1. The cloth, skin, and instrument are prone to dyeing. 2. Steam of this disinfectant may stimulate the respiratory tract and eyes.
Glutaraldehyde (GA)	Level: ≥ 2% (alkaline)	≥ 10 minutes Extend the contact period not lesser than 45 minutes if the endoscope is used by patients carrying mycobacterium tuberculosis or other mycobacteriu bacteria.	Immersion	<ol style="list-style-type: none"> 1. This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. It is suitable for use in the automatic disinfection machine. 2. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.
Peroxyacetic acid (PAA)	Level: 0.2%-0.35% (W/V)	≥ 5 minutes	Immersion	<ol style="list-style-type: none"> 1. This disinfectant has irritation on the skin, eye, and respiratory tract.

<p>Acidic electrolyzed oxidizing water (AEOW)</p>	<p>Active chlorine level: (60±10) mg/L, pH value: 2.0-3.0, chlorination reduction potential: ≥ 1100 mV, residual chloride ion level: < 1000 mg/L</p>	<p>3 - 5 minutes</p>	<p>Immersion</p>	<p>1. When organic matters exist, the disinfection effect decreases sharply. The endoscope should be cleaned completely before the disinfection. For endoscopes that are heavily contaminated or difficult to be cleaned, the cleaning frequency should be increased and the rinsing period should be extended. 2. Flowing immersion method should be adopted for disinfection. 3. The endoscope should be rinsed with sterile or filtered water for 30 seconds after disinfection.</p>
---	---	----------------------	------------------	---

Appendix C Recommended Sterilization Methods

Sterilant	Concentration	Contact Period	Contact Type	Precautions
<p>Glutaraldehyde (GA)</p>	<p>Level: ≥2% (alkaline)</p>	<p>≥ 10 hours</p>	<p>Immersion</p>	<p>1. This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. It is suitable for use in the automatic disinfection machine. 2. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.</p>

NOTE:

- The specifications of the product may change without any prior notification.
- Some products or features may not be available in some countries.
- Please contact your local distributor for more information.

SonoScape Medical Corp.

Address: Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle
2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen, 518057, Guangdong, China

Tel: +86-755-26722890

Fax: +86-755-26722850

E-mail: sonoscape@sonoscape.net

www.sonoscape.com