REV	ECN	Revision History	Date	Editor
A03	D00056420	Added endoscope parts names Added disinfectant and sterilization methods	2018-12-17	Xu Lin
A02	D00041301	Change the design sketch Delete the total length 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

EG-500 Series Video Gastroscope

Technical Specifications

SonoScape

SonoScape Medical Corp

1 General Description

The EG-500 series video gastroscope is customized for examination and diagnosis of the upper digestive tract. It integrates the high-definition CMOS imaging technology, digital image processing technology, micro optical lens technology, and advanced software technology to implement high-quality image, improving the safety of the diagnosis and treatment process, accuracy of the judgment, and stability of the operation.

The device is configured with functions including real-time video collection, water feeding, air feeding, suction, and allows an operator to remotely operate such functions as image freezing and amplification.

The device complies with international standards and national standards.

2 Advanced Technology

- High-definition CMOS image technology (2 million pixels)
- Micro optical lens technology
- Large-view-field imaging lens technology
- Auxiliary water-feeding
- High-conductivity and small-diameter insertion section with different rigidity at different segments
- Quick switch between air feeding and water feeding
- Small bending radius and large bending angle
- Adoption of polymer engineering material, high durability against disinfectant
- Light handle

3 Ports

- Electrical connector
- Air-feeding port
- Light guide port
- Air/water feeding port
- Suction port
- Auxiliary water-feeding port
- Electrosurgical equipment connector

4 Connector Section

- Electrical connector
- Suction port
- Auxiliary water-feeding port
- Cap for the auxiliary water-feeding port
- Waterproof cap
- Electrosurgical equipment connector
- Air/water feeding port

5 Control and Insertion Sections

- 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, IRIS, image enhancement, color enhancement, CHb, light transparent, contrast enhancement, AGC, image size, screenshot, video print, video, timer, PBP, content display, one-key export and upload.

- Instrument channel
  - Feeding liquid to the endoscope distal end
  - For the biopsy accessories of the endoscope
  - Used as the suction tube after covering the biopsy valve cap firmly
- Insertion limitation 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.

6 Distal End

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

7 Auxiliary Examination

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

8 Disinfectant and Flush Liquid

- Recommended high-level disinfectant:
  - Phthalic dicarboxaldehyde (OPA)

    Level: 0.55% (0.5%-0.6%)
  - Glutaraldehyde (GA)

    Level: ≥ 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 flushing liquid: ethyl alcohol (75%) or isopropanol

9 Physical Specifications

Net weight: 1.3 kg

Others: see the Appendix A

10 Package List

- Endoscope
- Biopsy valve

- Cleaning brush
- Leakage detector
- Syringe (30mL)
- Injection tube
- Auxiliary water-feeding tube
- Channel plug
- Waterproof cap
- Cap for endoscope distal end cap
- User manual

11 Applicable Range

The video gastroscope is used with the image processor 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.

12 Compatible Equipment

- Light source: HDL-500X/HDL-500E
- Image processor: HD-500 series
- Trolley: HDT-330

13 Safety Standard

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

14 Environmental Requirements

- Operating environment
  - Temperature: +5°C - +40°C
  - Relative humidity: 30% - 80% (non-condensing)
  - Atmosphere pressure: 700hPa - 1060 hPa
- Storage environment
  - Temperature: -5°C - +40°C
  - Relative humidity: 30% - 80% (non-condensing)
  - Atmosphere pressure: 700hPa - 1060 hPa
- Transportation environment
  - Temperature: -20°C - +55°C
  - Relative humidity: 20% - 90% (non-condensing)
  - Atmosphere pressure: 700hPa - 1060 hPa
- Safety types
  - Degree of protection against electric shock: Type BF applied part
  - Degree of protection against harmful liquid: IPX7

Appendix

Appendix A Endoscope Specifications Table

No.	Parameter	EG-500	EG-500L
1	View direction	Front	
2	Field of view	140°, allowance: -10% to 10%	
3	Resolution	Resolution ≥12.50lp/mm (when working distance is 10 mm)	
4	View depth	3 to 100 mm	
5	Outer diameter of the distal end	Φ 9.3 mm Allowance: 10%, not considering lower limit	Φ 9.8 mm Allowance: 10%, not considering lower limit
6	Outer diameter of the bending section	Φ 9.3 mm Allowance: 5%, not considering lower limit	Φ 9.8 mm Allowance: 5%, not considering lower limit
7	Maximum outer diameter of the insertion section	≤ Φ 10.5 mm	≤ Φ 11.5 mm
8	Angle	Up 210°, down 90° Allowance: -10%, not considering lower limit	Up 210°, down 90° Allowance: -10%, not considering lower limit
		Left 100°, right 100° Allowance: -10%, not considering lower limit	Left 100°, right 100° Allowance: -10%, not considering lower limit
9	Minimum inner diameter of the instrument channel	≥ Φ 2.8 mm	≥ Φ 3.2 mm
10	Insertion section length	1050 mm (±10%)	
11	Minimum viewing distance of instrument channel	3 mm	
12	Illumination	≥ 18000 Lx	

No.	Parameter	EG-500	EG-500L
13	Aspirated amount	≥ 400 mL/min	
14	Water/air feeding	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 Methods for High-level Disinfectant

Disinfectant	High-Level Disinfection	Contact Period	Contact Type	Precautions
Phthalic dicarboxaldehyde (OPA)	Level: 0.55% (0.5%-0.6%)	≥ 5 minutes	Immersion	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	Immersion	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.

		or other mycobacterium bacteria.		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	1. This disinfectant has irritation on the skin, eye, and respiratory tract.
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	3 - 5 minutes	Immersion	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.

Appendix C Recommended Sterilization Method

Sterilant	Sterilization Parameter	Contact Period	Contact Type	Precautions
Glutaraldehyde (GA)	Level:≥2% (alkaline)	≥ 10 hours	Immersion	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.

NOTE:

- The specifications of this system may change without any prior notification.
- Some products or features may not be available in some countries.
- Please contact your local SonoScape sales representative for more information.

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D00056420

完成

文件发行/变更/报废流程 • VLS-50英文技术规格书
HD-500英文技术规格书
HDL-500E英文技术规格书
HDL-500X英文技术规格书
EG-500英文技术规格书
EC-500英文技术规格书 升级

封面

号码: D00056420
变更类型: 文件发行/变更/报废流程
变更描述: VLS-50英文技术规格书
HD-500英文技术规格书
HDL-500E英文技术规格书
HDL-500X英文技术规格书
EG-500英文技术规格书
EC-500英文技术规格书 升级
原因代码: 12-其它
变更分析师: 李 赞 (lizan)
创建日期: 12/17/2018 09:59:24 上午 CST
最终完成日期:

状态: 完成
变更分类: 09-其它
变更原因: VLS-50英文技术规格书 初次发行
HD-500英文技术规格书
HDL-500E英文技术规格书
HDL-500X英文技术规格书
EG-500英文技术规格书
EC-500英文技术规格书 升级
工作流程: [Sono]文件发行/变更/报废流程
创建者: 徐 琳 (xul1)
发行日期: 01/03/2019 11:39:15 上午 CST
项目编号/产品型号: PJ150202-EUS HD-500高清内窥镜系统; PJ150203-EUM 500系列高清电子胃/结肠镜; PJ160305-EUM VLS-50多波长光源

第二页

备注:

第三页

是否需要培训: 否
不需要培训原因说明:

受影响的物件

物件号码	旧物件的描述	物件描述	旧版本	新版本	旧的生命周期阶段	生命周期阶段	旧版物料号	生效日期	发放范围	采购数量	确认价格	实际采购数量	单位	其他费用(开机/治具/刀模等)	币种	总价	财务备注	供应商	采购工程师	预计到货日期	实际到料时间	备注
901-02630	HD-500图像处理器英文技术规格书	HD-500图像处理器英文技术规格书 更改点：补充软件功能描述	A01	A02	发行	发行					无权限	无权限		无权限	无权限	无权限		无权限				
901-03570	HDL-500E冷光源英文技术规格书	HDL-500E冷光源英文技术规格书 更改点：补充功能及参数说明	A01	A02	发行	发行					无权限	无权限		无权限	无权限	无权限		无权限				
901-03571	HDL-500X冷光源英文技术规格书	HDL-500X冷光源英文技术规格书 更改点：补充功能及参数说明	A01	A02	发行	发行					无权限	无权限		无权限	无权限	无权限		无权限				
901-03572	EC-500系列肠镜英文技术规格书升级，更改点如下：1. 更换外观效果图 2. 删除总长度 3. 更改安全标准 4. 更改送水量	EC-500系列肠镜英文技术规格书升级，更改清洗消毒部分内容及镜体规格信息。	A02	A03	发行	发行					无权限	无权限		无权限	无权限	无权限		无权限				
901-03607	EG-500系列胃镜英文技术规格书升级，更改点如下：1. 更换外观效果图 2. 删除总长度 3. 更改安全标准	EG-500系列胃镜英文技术规格书升级，更改清洗消毒部分内容及镜体规格信息。	A02	A03	发行	发行					无权限	无权限		无权限	无权限	无权限		无权限				
901-06082	VLS-50系列医用内窥镜冷光源英文技术规格书	VLS-50系列医用内窥镜冷光源英文技术规格书 初次发行		A01		发行					无权限	无权限		无权限	无权限	无权限		无权限				

工作流程

状态代码	工作流程状态	审阅者	操作	工作流程	必需	签署用户	状态变更者	本地客户端时间	签署注解	Signoff Duration
当前流程	完成			[Sono]文件发行/变更/报废流程						
流程已前移	批准			[Sono]文件发行/变更/报废流程			李 赞 (lizan)	01/03/2019 11:39:15 上午 CST		
流程已前移	批准	田 辉省 (tianhs)	已批准	[Sono]文件发行/变更/报废流程	是	田 辉省 (tianhs)		01/03/2019 09:14:53 上午 CST		0
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流程已前移	审核			[Sono]文件发行/变更/报废流程			高 慧梅 (gaohm)	01/03/2019 09:12:29 上午 CST		
流程已前移	审核	刘 淋 (liul1)	已批准	[Sono]文件发行/变更/报废流程	是	刘 淋 (liul1)		12/18/2018 09:08:01 上午 CST		0
流程已前移	审核	张 维维 (zhangww)	已批准	[Sono]文件发行/变更/报废流程	是	张 维维 (zhangww)		12/26/2018 10:15:09 上午 CST		6
流程已前移	审核	徐 英华 (xuyh)	已批准	[Sono]文件发行/变更/报废流程	是	徐 英华 (xuyh)		12/18/2018 10:40:35 上午 CST		0
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流程已前移	提交			[Sono]文件发行/变更/报废流程			李 赞 (lizan)	12/17/2018 04:12:05 下午 CST		
流程已前移	拟制			[Sono]文件发行/变更/报废流程			徐 琳 (xul1)	12/17/2018 04:03:03 下午 CST		