


REV	ECN	Revision History	Date	Editor
A05	ECN05107	Modify the ”Depth of field” and ”Minimum visible distance of instrument channel”	2023-12-20	Xu Lin
A04	ECN04209	Delete the maximum outer diameter of the insertion section. Modify the ”outer diameter of the bending section” to the ”outer diameter of the insertion tube”	2022-08-18	Xu Lin
A03	D00056420	Added endoscope parts names Added disinfectant and sterilization methods	2018-12-17	Xu Lin
A02	D00041301	Change the design sketch Modify the safety standard Modify the amount of fed water	2017-09-18	Kang Jiajun
A01	D00029319	First Release	2016-07-14	Shu Rong
Title	EC-500 Series Video Colonoscope Technical Specifications			
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EC-500 Series Video Colonoscope

Technical Specifications



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1 General Description

The EC-500 series video colonoscope is customized for examination and diagnosis of the lower 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 imaging technology (2 MP) 1920x1080
- 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 ports
- Suction port
- Auxiliary water-feeding port
- Electrosurgical equipment connector

4 Connector Section

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

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 opening

7 Auxiliary Examination

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

8 Disinfectant and Flush Liquid

- Recommended disinfectant:
Glutaraldehyde (alkaline, concentration: $\geq 2\%$)
- Recommended flushing liquid: ethyl alcohol (75%) or isopropanol

9 Physical Specifications

Net weight: 1.5 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
- Distal end cap
- User manual

11 Applicable Range

The video endoscope is used with the image processor, light source, and other peripherals provided or recommended by the manufacturer. The video colonoscope is intended for use in examination and diagnosis of the lower digestive tract (including the rectum, colon and ileocecal valve). It also can be used with 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 - 1060hPa
- Storage environment
 - Temperature: -5°C - +40°C
 - Relative humidity: 30% - 80% (non-condensing)
 - Atmosphere pressure: 700hPa - 1060hPa
- Transportation environment
 - Temperature: -20°C - +55°C
 - Relative humidity: 20% - 90% (non-condensing)
 - Atmosphere pressure: 700hPa - 1060hPa

- 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	EC-500	EC-500T	EC-500L	EC-500L/T
1	View direction	Front			
2	Field of view	140°, allowance: -10% to 10%			
3	Resolution	Resolution $\geq 12.50\text{lp/mm}$ (when working distance is 10 mm)			
4	View depth	2mm to 100mm			
5	Outer diameter of the distal end	$\Phi 12.5\text{ mm}$ Allowance: 5%, not considering lower limit	$\Phi 12.5\text{ mm}$ Allowance: 5%, not considering lower limit	$\Phi 12.9\text{mm}$ Allowance: 10%, not considering lower limit	$\Phi 12.9\text{mm}$ Allowance: 10%, not considering lower limit
6	Outer diameter of the bending section	$\Phi 12.5\text{mm}$ Allowance: 10%, not considering lower limit	$\Phi 12.5\text{mm}$ Allowance: 10%, not considering lower limit	$\Phi 12.9\text{mm}$ Allowance: 10%, not considering lower limit	$\Phi 12.9\text{mm}$ Allowance: 10%, not considering lower limit
7	Minimum inner diameter of the instrument channel	$\geq \Phi 3.8\text{mm}$	$\geq \Phi 3.8\text{mm}$	$\geq \Phi 4.2\text{mm}$	$\geq \Phi 4.2\text{mm}$
8	Angle	Up/down 180°, allowance: -10%, not considering upper limit			
		Left/right 160°, allowance: -10%, not considering upper limit			
9	Working Insertion section length	1350mm \pm 10%	1700mm \pm 10%	1350mm \pm 10%	1700mm \pm 10%
10	Total Insertion section length	1500mm \pm 10%	1850mm \pm 10%	1500mm \pm 10%	1850mm \pm 10%

11	Minimum viewing distance of instrument channel	2mm
12	Illumination	$\geq 18000\text{Lx}$
13	Asperated amount	$\geq 400\text{ml/min}$
14	Auxiliary water feeding	Amount of fed water $\geq 40\text{ ml/min}$, amount of fed air $\geq 800\text{ mL/min}$
15	Endoscope information storage	Support
16	View direction	Support

Appendix B Recommended Methods for High-level Disinfectant

Disinfectant	Concentration	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. Steam of this disinfectant may stimulate the respiratory tract and eyes.

Glutaraldehyde (GA)	Level: $\geq 2\%$ (alkaline)	≥ 10 minutes Extend the contact period not lesser than 45 minutes if the endoscope is used by patients carrying mycobacterium tuberculosis or other Mycobacterium bacteria.	Immersion	2. 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. 3. The 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	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	<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.</p> <p>2. Flowing immersion method should be adopted for disinfection.</p> <p>3. The endoscope should be rinsed with sterile or filtered water for 30 seconds after disinfection.</p>
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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

				<p>cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. It is suitable for use in the automatic disinfection machine.</p> <p>2. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.</p>
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