

REV	ECN	Revision History	Date	Editor
A01	DHF18948	First Release	2024-5-21	Guo Yulan
Title		EC-X20R/RL Series 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 SONOSCAPE MEDICAL CORP.		Document Number		Distribution Number
		901-21946		
		Version	Effective	Page
		A01	2024/5/24	Page 1 of 9
		Date		

EC-X20R/RL Series Technical Specifications



开立医疗

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. Specifications.....	5
8. Packing List	错误!未定义书签。
9. Application Range.....	错误!未定义书签。
10. Compatible Devices	5
11. Safety Standards.....	5
12. Environment Requirements	5
13. Appendix	7

1. General Description

The EC-X20R/RL series video colonoscope is a medical device tailored for the examination and diagnosis of the human lower digestive tract. The EC-X20R/RL series video colonoscope includes two models, EC-X20R and EC-X20RL.

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

With fully-sealed design, the endoscope can be directly immersed for cleaning without waterproof cap, thus to avoid water inflow and damage to the endoscope caused by incorrect operation.

The product complies with the relevant international and national standards.

The CMOS image sensor is used for signal transmission of optical fiber cable to enhance the image SNR and signal output frames.

2. Advanced Technologies

- High-definition CMOS imaging technology (2 million pixels)
- Micro-optical lens technology
- Super large field of view imaging lens technology

- Auxiliary water-feeding
- High conductive section hardness insertion tube with finer diameter
- Quick switch between air-feeding and water-feeding
- High polymer engineering materials with higher disinfectant tolerance
- Convenient operation with a new generation handle
- Safer with fully-sealed design
- Simple and quick connection and disconnection

3. Connector Section

- Light guide
- Air pipe
- Electrical contacts
- Suction port
- Leakage detector port
- Auxiliary water-feeding port
- Cap for auxiliary water-feeding port
- Air/water-feeding port (including water-feeding port and air-feeding port)

4. Control Section and Insertion Section

- Left/right angulation lock
- Left/right angulation control knob
- Up/down angulation control knob
- Up/down angulation lock
- Adjustable vary stiffness knob
- Remote buttons (0 - 3)

- Customize the function of every remote button by using the image processor.
- The customizable functions include freeze, zoom, illumination mode, IRIS, image enhancement, color enhancement, CHb pseudo-color image, contrast, AGC, screenshot, video recording, VIST, SFI, EWL.
- Instrument channel
 - Used for feeding liquid to the distal end;
 - Used for the endotherapy accessory operation;
 - Used as a part of the suction channel being covered firmly with the biopsy valve cap..
- Insertion limit mark
- Suction valve
- Air/water valve
 - Cover the hole on the valve with a finger to feed air.
 - Press the valve to feed water to clean the objective lens.
 - Air-feeding or water-feeding can remove the blood, debris or mucous membrane adhering to the objective lens.

5. Distal End

- Objective lens
- Air/water nozzle

- Light guide lenses
- Auxiliary water-feeding outlet
- Instrument channel outlet

6. Auxiliary Examination

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

7. Specifications

Refer to Appendix A.

(Net weight: 1.5 kg)

Main video:

Resolution: 1920*1080

Video edge shape: circle;

Real-time image frame rate: 60fps;

8. Compatible Devices

- Image processor : X-2600, X-2600S, X-2600A, X-2600B, X-2500, X-2500S, X-2500A, X-2500B, X-2400, X-2400S, X-2400A, X-2400B, X-2300, X-2300S, X-2300A, X-2300B

9. Safety Standards

- IEC 60601-1:2005+A1:2012+A2: 2020
- IEC 60601-2-18:2009
- IEC 60601-1-2:2014+A1:2020

10. 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

开立内部文件，禁止外传

11. Appendix

Appendix A Specifications

No.	Model		
	Parameter	EC-X20R	EC-X20RL
1	Direction of view	Front viewing	
2	Field of view	160°± 15%	
3	Resolution	1. Working distance: 10 mm: Center resolution: ≥ 11.31 lp/mm; Edge resolution: ≥ 5.56 lp/mm; 2. Working distance: 2 mm: Center resolution: ≥ 10.08 lp/mm; 3. Working distance: 100 mm: Center resolution: ≥ 1.12 lp/mm;	
4	Depth of field	2 - 100 mm	
5	Outer diameter of the distal end	Φ 9.8 mm Allowance: +5%, not considering the lower limit	
6	Outer diameter of the bending section	Φ 10.5 mm Allowance: +10% not considering the lower limit	
7	Bending angle	Up 180 °, down 180 °, left 160 °, right 160 ° Allowance: -10%, not considering upper limit	
8	Min. inner diameter of the instrument channel	≤ Φ 3.8 mm	
9	Working length	1350 mm±10%	1700 mm±10%

EC-X20 Series Technical Specifications

10	Total length	1700 mm±10%	2050 mm±10%
11	Minimum visible distance of the instrument channel	2 mm	
12	Illuminance	≥ 20000 Lx (working distance: 10 mm)	
13	Aspirated amount	≥ 400 mL/min	
14	Water/air feeding	- Amount of fed water: ≥ 50 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 Disinfection

Disinfectant			Concentration	Temperature	Contact Time	Using Method
MetriCide 28 Long-life Activated Dialdehyde Solution			2.5%	25°C	90 min	Manual disinfection
Dr. Weigert neodisher® Septo DN			10 mL/L (1%)	55°C	5 min	Automatic disinfection

Appendix C Recommended Automated Endoscope Reprocessor

Equipment Name	Model	Manufacturer
Endoscope WD BHT INNOVA® E3 CMS DC	Innova E3-CMS DC-1000	BHT Disinfection Technology

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 the local distributor for more information

Manufacturer: 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

变更单号: DHF18948

流程类型: 文档发布/变更流程V1

流程状态: 发布

最终完成日期: 2024-05-24 14:39:35

封面

精卫II英文技术规格书文档发布:

变更描述: 901-23072-A01 X-2600 Series Video System Center Technical Specifications
901-21945-A01 EG-X20 Technical Specifications
901-21946-A01 EC-X20 Series Technical Specifications

工作流: [Sono]文档发布/变更流程V1

创建日期: 2024-05-21 13:45:35

变更类别: /

所属项目: PJ191101-EUS 精卫;PJ200106-EUM 精卫镜体

精卫II英文技术规格书文档发布:

变更原因/问题分析: 901-23072-A01 X-2600 Series Video System Center Technical Specifications
901-21945-A01 EG-X20 Technical Specifications
901-21946-A01 EC-X20 Series Technical Specifications

发起人: 临床与产品规划部, 郭育兰 (107622)

发放日期: 2024-05-24 14:39:35

组织: 深圳开立

第二页

所属部门: 临床与产品规划部

产品线:

受影响物件

物件编号	所属项目	物件描述	旧版本	新版本	旧的生命周期阶段	生命周期阶段	发放方式	纸质档发放范围	电子档发放范围	发放范围备注	生效日期	物件类型	是否培训	培训记录表单号
901-21945	PJ200106-EUM 精卫镜体	901-21945[A01 EG-X20 Technical Specifications 产品技术规格书/Technical Specifications		A01		发行	电子档		51-市场管理部		2024-05-24 14:39:35	901-设计及技术说明	否	
901-21946	PJ200106-EUM 精卫镜体	901-21946[A01 EC-X20 Series Technical Specifications 产品技术规格书/Technical Specifications		A01		发行	电子档		51-市场管理部		2024-05-24 14:39:35	901-设计及技术说明	否	
901-23072	PJ191101-EUS 精卫	901-23072[A01 X-2600 Series Video System Center Technical Specifications 产品技术规格书		A01		发行	电子档		51-市场管理部		2024-05-24 14:39:35	901-设计及技术说明	否	

工作流

状态代码	workflow状态	审阅者	操作	签署注解	签署持续时间	审阅者工作职能	本地客户端时间	用户操作时间	必需	签署用户	状态变更者	工作流
当前流程	发布											[Sono]文档发布/变更流程 V1
流程已前移	文控处理						2024-05-24 06:39:35	2024-05-24 14:39:35			项目管理办公室, 李赞 (103026)	[Sono]文档发布/变更流程 V1
流程已前移	文控处理	项目管理办公室, 李赞 (103026)	已批准		0		2024-05-24 06:39:35	2024-05-24 14:39:35	是	项目管理办公室, 李赞 (103026)		[Sono]文档发布/变更流程 V1
流程已前移	培训检查						2024-05-24 06:20:42	2024-05-24 14:20:42			内窥镜产品发展规划部, 廖征 (101561)	[Sono]文档发布/变更流程 V1
流程已前移	培训实施						2024-05-24 06:20:42	2024-05-24 14:20:42			内窥镜产品发展规划部, 廖征 (101561)	[Sono]文档发布/变更流程 V1
流程已前移	批准						2024-05-24 06:20:42	2024-05-24 14:20:42			内窥镜产品发展规划部, 廖征 (101561)	[Sono]文档发布/变更流程 V1
流程已前移	批准	内窥镜产品发展规划部, 廖征 (101561)	已批准		0		2024-05-24 06:20:42	2024-05-24 14:20:42	是	内窥镜产品发展规划部, 廖征 (101561)		[Sono]文档发布/变更流程 V1
流程已前移	审核						2024-05-24 01:48:22	2024-05-23 18:48:22			技术法规部, 胡素敏 (107960)	[Sono]文档发布/变更流程 V1
流程已前移	审核	内窥镜产品发展规划部, 苏慧洁 (105111)	已批准		0		2024-05-23 09:36:10	2024-05-23 17:36:10	是	内窥镜产品发展规划部, 苏慧洁 (105111)		[Sono]文档发布/变更流程 V1
流程已前移	审核	内窥镜硬件部, 刘学民 (105640)	已批准		0		2024-05-24 01:05:42	2024-05-24 09:05:42	是	内窥镜硬件部, 刘学民 (105640)		[Sono]文档发布/变更流程 V1
流程已前移	审核	技术法规部, 张欣悦 (106168)	已批准		0		2024-05-23 08:16:59	2024-05-23 16:16:59	是	技术法规部, 张欣悦 (106168)		[Sono]文档发布/变更流程 V1
流程已前移	审核	技术法规部, 胡素敏 (107960)	已批准		0		2024-05-24 01:48:21	2024-05-23 18:48:21	是	技术法规部, 胡素敏 (107960)		[Sono]文档发布/变更流程 V1
流程已前移	审核	镜体结构技术部, 谭宝瑜 (104882)	已批准		0		2024-05-23 08:27:09	2024-05-23 16:27:09	是	镜体结构技术部, 谭宝瑜 (104882)		[Sono]文档发布/变更流程 V1
流程已前移	标准化						2024-05-23 07:47:33	2024-05-23 15:47:33			项目管理办公室, 李赞 (103026)	[Sono]文档发布/变更流程 V1
流程已前移	标准化	项目管理办公室, 李赞 (103026)	已批准		0		2024-05-23 07:47:32	2024-05-23 15:47:32	是	项目管理办公室, 李赞 (103026)		[Sono]文档发布/变更流程 V1
流程已前移	拟制						2024-05-23 07:24:17	2024-05-23 00:24:17			临床与产品规划部, 郭育兰 (107622)	[Sono]文档发布/变更流程 V1
流程已后移	标准化						2024-05-23 02:52:13	2024-05-23 10:52:13			项目管理办公室, 李赞 (103026)	[Sono]文档发布/变更流程 V1
流程已后移	标准化	项目管理办公室, 李赞 (103026)	已拒绝	1、文件的发放范	0		2024-05-23 02:52:13	2024-05-23 10:52:13	是	项目管理办公室, 李赞 (103026)		[Sono]文档发布/变更流程 V1
流程已前移	拟制						2024-05-22 11:22:35	2024-05-22 04:22:35			临床与产品规划部, 郭育兰 (107622)	[Sono]文档发布/变更流程 V1

文件名	文件描述	文件大小	文件类型	文件夹编号	文件夹描述	文件夹版本	签出用户	签出日期	修改日期	最后一次查看日期	附件类型	签入用户	标签
DHF18948流程审批页.pdf		132225	pdf	FOLDER 00708967		1			2024-05-24 06:39:36	2024-05-24 06:39:35		项目管理办公室, 李赞 (103026)	