



**SonoScape Medical**  
Caring for Life through Innovation

### HD-500 VIDEO PROCESSOR

HD video outputs	DVI, SDI, VGA
Standard video outputs	S-Video, CVBS
HD video recording	Built-in workstation, timely record and review
Zoom / PBP	Yes / Yes
Dimension (L x W x H / weight)	455mm x 370mm x 124mm / 9.5 kg

### HDL-500X LIGHT SOURCE

Main lamp	300W xenon
VIST virtual chromoendoscopy	Variable Intelligent Staining Technology
Transparency function	7 seconds maximum brightness flicker
Lifetime indicator	Yes
Hot plugging	Endoscope switch without powering off
Dimension (L x W x H / weight)	460mm x 370mm x 154mm / 15 kg

### 500 SERIES ENDOSCOPES

Parameter	Gastroscope		Colonoscope			
	EG-500	EG-500L	EC-500	EC-500T	EC-500L	EC-500L/T
Depth of view (mm)	3-100		3-100			
Field of view	140°		140°			
Distal end diameter (mm)	9.3	9.8	12	12	12.9	12.9
Bending section diameter(mm)	9.3	9.8	12.5	12.5	12.9	12.9
Instrument channel diameter (mm)	2.8	3.2	3.8		4.2	
Angulations	UP 210°/DOWN 90° LEFT 100°/RIGHT 100°		UP 180°/DOWN 180°		LEFT 160°/RIGHT 160°	
Working length (mm)	1050		1350	1700	1350	1700
Total length (mm)	1350		1700	1950	1700	1950



**HYPERION**

**HD-500**

*High Definition Video Endoscopy System*

E-HD50020170530

### SONOSCAPE MEDICAL CORP.

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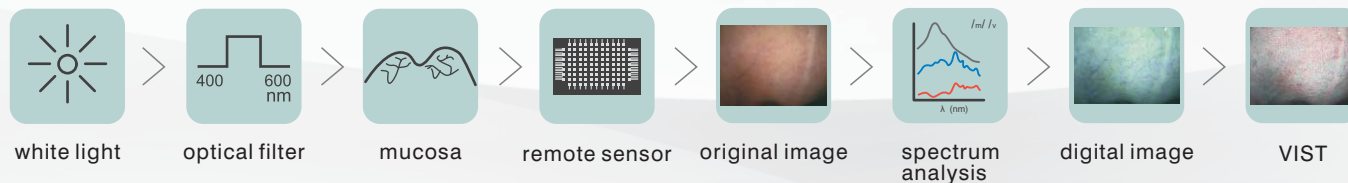
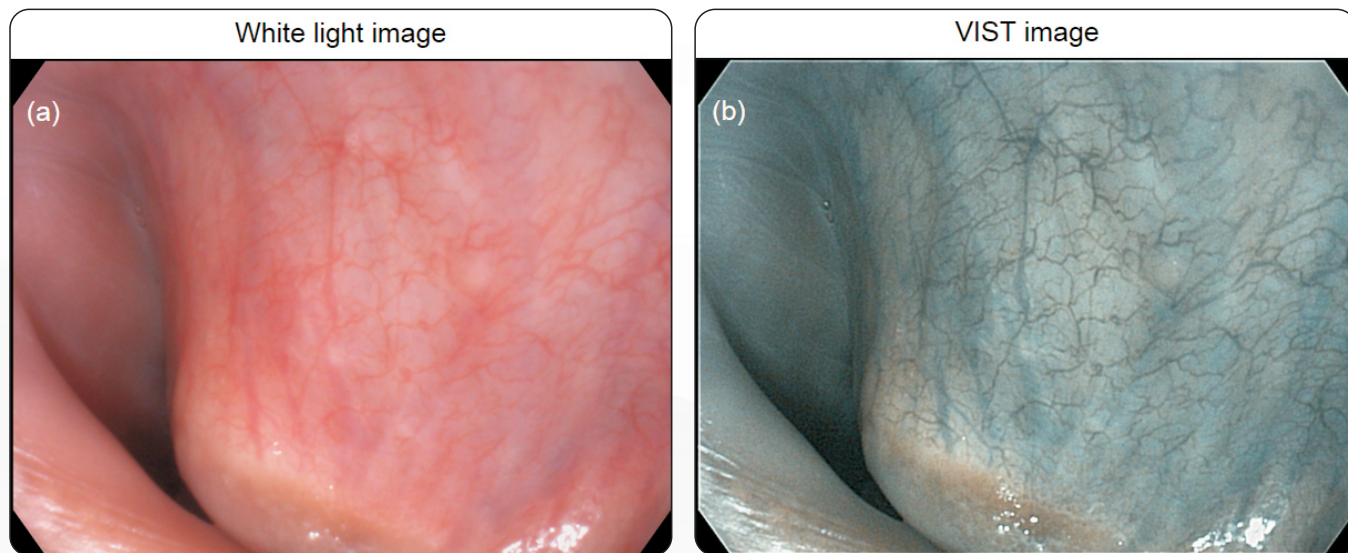
E-mail: [sonoscape@sonoscape.net](mailto:sonoscape@sonoscape.net) [www.sonoscape.net](http://www.sonoscape.net)

ISO 13485 CE<sub>0197</sub>

# Time to have a one stop, cost effective solution.

## VIST (Variable Intelligent Staining Technology)

VIST is a chromoendoscopy technology combined with optical and digital image processing, providing a clear and bright image contrast. Mucosa and blood vessels can be greatly enhanced by VIST technology in the gastric and colon.



### Unique features



Light weight handle



Water jet



Gradual stiffness design



### Brilliant workflow

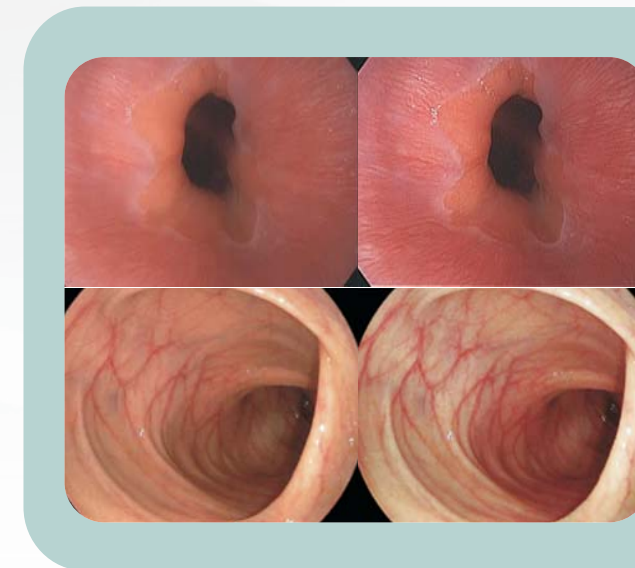
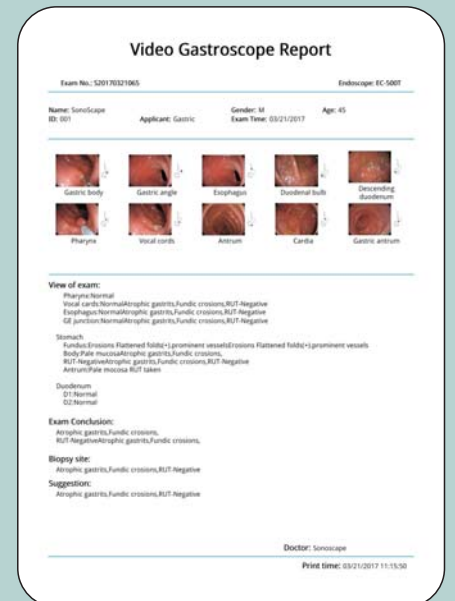


Equipped with a 500GB hard disk, the HD-500 allows you to store and archive your endoscopy images and data in one step, and to transfer it through DICOM easily.



### Ideal built-in workstation

The intelligent built-in workstation can access patient data management, report editing, image capture and HD video recording for an easier operation.



### Versatile image processing



Multistage enhancement in color, edge and structure modes can display ideal GI image through internal processing, providing you with a sharper image than ever before.

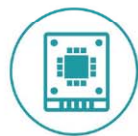
## High Definition Video Bronchoscope



High Definition



Ergonomic Design



Smart Workflow

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Zoom / PBP	Yes / Yes
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Hot plugging	Endoscope switch without powering off
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### EB-500 BRONCHOSCOPE

Depth of view (mm)	3-100
Field of view	120
Distal end diameter (mm)	5.3
Bending section diameter ( mm )	5.7
Instrument channel diameter (mm)	2
Angulations	UP 180°/DOWN 130°
Working length (mm)	600
Total length (mm)	870



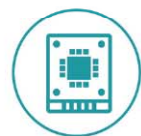
## High Definition Video Rhinolaryscope



High Definition



Ergonomic Design



Smart Workflow

### HD-500 VIDEO PROCESSOR

HD video outputs	DVI, SDI ,VGA
Standard video outputs	S-Video , CVBS
HD video recording	Built-in workstation , timely record and review
Zoom / PBP	Yes / Yes
Dimension (L x W x H / weight )	455mm x 370mm x 124mm / 9.5 kg

### HDL-500X LIGHT SOURCE

Main lamp	300W xenon
VIST virtual chromoendoscopy	Variable Intelligent Staining Technology
Transparency function	7 seconds maximum brightness flicker
Lifetime indicator	Yes
Hot plugging	Endoscope switch without powering off
Dimension (L x W x H / weight )	460mm x 370mm x 154mm / 15 kg

### ENL-500 RHINOLARYSCOPE

Depth of view (mm)	3-50
Field of view	120
Distal end diameter (mm)	5.3
Bending section diameter ( mm )	5.7
Instrument channel diameter (mm)	2
Angulations	UP 130°/DOWN 130°
Working length (mm)	350
Total length (mm)	570





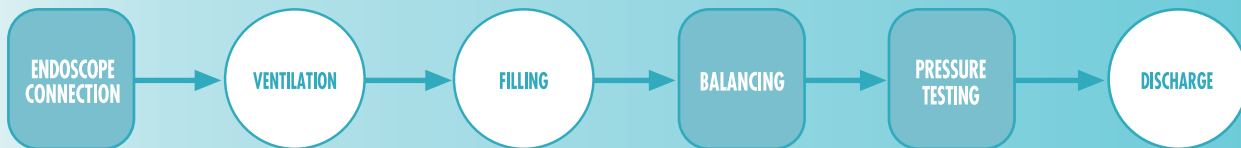
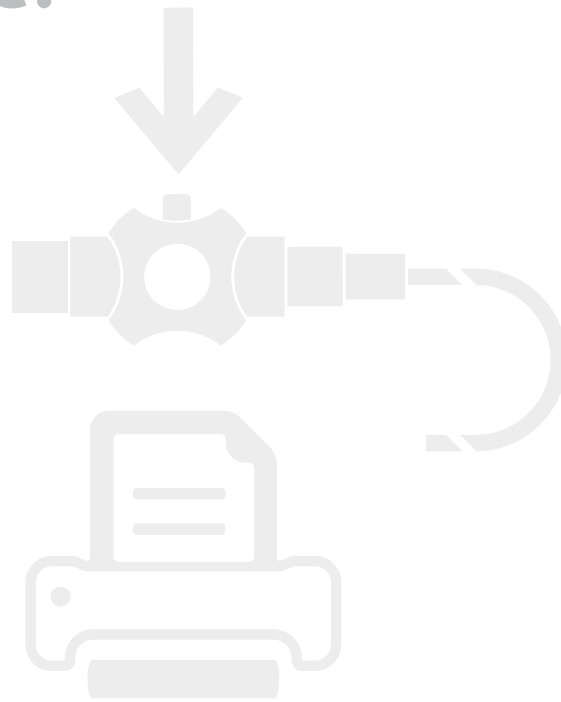
## endoLeakage endoscope leakage testing devices:

# No leakage!

The leakage testing process is very important for endoscope and patient safety.

The possible leakages should be tested with endoLeakage leakage testing device following endoscopic operations.

endoLeakage has the ability to identification operator and endoscopes with RFID. It records these information regarding the date and result of the process. It files the result of leakage testing process that lasts for about one minute by transferring it to medGate server through network system that the device is connected and a print-out can be taken from the printer above.



## Features

- It has got a leakage test connector.
- There is a hose connected to leakage test connector.
- The maximum pressure that can be applied is 440 mbars.
- It works with 220-240 V 50Hz feeder power.
- It identification endoscopes with RFID.
- It identification operator with RFID.
- The endoscopes can be identification with serial numbers.
- The operator can be determined.
- There is an information storage unit that can record information of leakage test results, endoscopes, operator, testing results and time information.
- The information in the data storage section is compatible with HBYS, EIS or medGate server management system over the network.
- It includes a start, stop and power on/off switch.
- The leakage test warns the user with successful or failed result.
- It includes RS232 port.
- It includes RJ45 network socket.



*endoLeakage endoscope  
leakage testing devices:*

```

C      endoLeakage      ]
      Endoscope Leakage Test
      version 1.2
18-08-14      13:00:01
  
```

endoLeakage is a integrated sytem which can test Endoscope leakage.

```

C      PROCESS STARTED ]
1) Pretest
   240 mBarr
18-08-14      13:00:01
  
```

An automatic pre-test stage after process initialization enables a successful start of the system. The applied pressure is always within the limits of internationally determined norms.

```

C      PROCESS STARTED ]
2) Filling Process
   --> C ]
18-08-14      13:00:01
  
```

Endoscope test channels are filled with filtered air.

```

C      PROCESS STARTED ]
3) Balancing
   --> C ] <--
18-08-14      13:00:01
  
```

Balancing of pressurized air is accomplished.

```

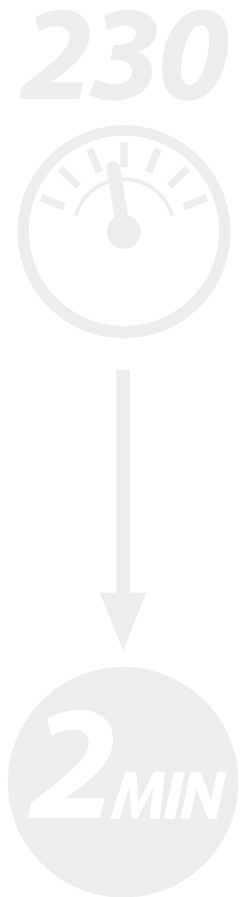
C      PROCESS STARTED ]
4) Automatic TEST
   C..]
18-08-14      13:00:01
  
```

Automatic testing process is performed for 1.5 - 2 minutes.

```

C      PROCESS STARTED ]
5) Evacuation process
   C ] <--
18-08-14      13:00:01
  
```

The inflated air is evacuated.





```

C   PROCESS COMPLETED   ]
6) RESULT
TEST SUCCESSFUL
18-08-14                13:00:01

```

Process reads SUCCESSFUL message if there is no leakage in endoscope.

```

C   PROCESS COMPLETED   ]
6) RESULT
TEST FAILED
18-08-14                13:00:01

```

Process reads FAILED message. If there is a leakage in the endoscope.

```

C   PROCESS COMPLETED   ]
E) RESULT
ERROR
18-08-14                13:00:01

```

Any errors that can come out during the process (dependent on endoscope, operator or device ) are displayed as messages.

```

C   PROCESS COMPLETED   ]
7) RESULT
SENDING RECORDING
18-08-14                13:00:01

```

The process result is recorded on the system or transferred to medGate server The displaying on the device



Figure 1 Working Rationale

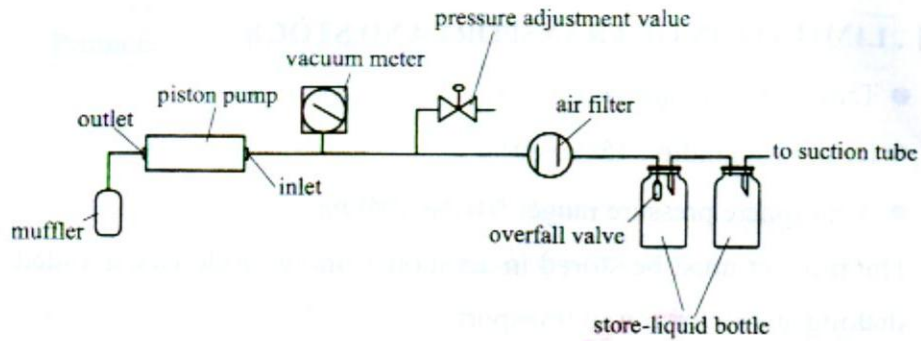
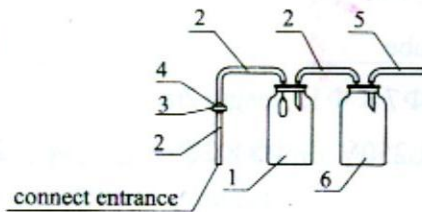


Figure 2 Connect Tubing



- 1. buffer bottle
- 2. soft tube
- 3. air filter
- 4. blue notation
- 5. soft tube
- 6. store-liquid bottle

Figure 3 Electric Rationale  
H002

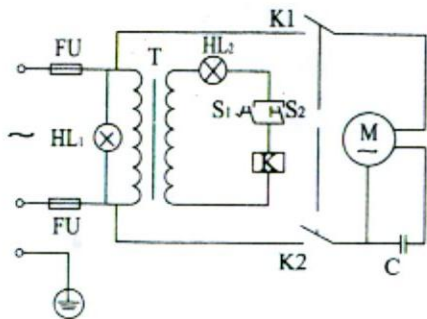
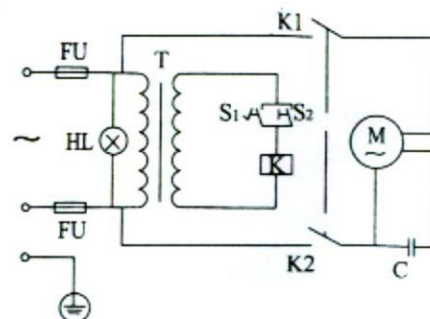


Figure 4 Electric Rationale  
H001



## ELECTRIC SUCTION APPARATUS

- H001
- H002

## OPERATIONAL MANUAL

DO NOT OPERATE THIS PRODUCT WITHOUT FIRST  
READING AND UNDERSTANDING THIS MANUAL.

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## SAFETY NOTES

### WARNING:

The product is precision-made and carefully assembled and wired. Therefore, do not disassemble or attempt to repair the product. All repairs should be done by qualified personnel at an authorized repair center.

### IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precaution should always be followed including the following:

- 1) DANGER-To reduce the risk of electrocution:
  1. Always unplug this product immediately after using.
  2. DO NOT use while bathing.
  3. DO NOT reach for product that has fallen into water. UNPLUG IMMEDIATELY.
  4. DO NOT place or store product where it can drop into water or other liquid.
  5. DO NOT come in contact with the suction apparatus while wet.
  6. DO NOT disassemble. Refer servicing to qualified service personnel.
- 2) WARNING-To reduce the risk of burns, electrocution, fire or injury to persons:

## SAFETY NOTES

1. A product should NEVER be left unattended when plugged in.
2. Close supervision is necessary when this product is used near children or physically-challenged individuals.
3. Use this product for only intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
5. Keep the cord away from HEATED or HOT surfaces.
6. NEVER block the air openings of the product. Keep the air openings free from lint, hair and the like.
7. NEVER use while sleeping or drowsy.
8. NEVER drop or insert any object into any openings.
9. Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered.

## FEATURES

### I. SUMMARY

- The type of electric suction apparatus is designed with safety and reliability in mind providing an efficient performance of vacuum aspiration for most procedures of suction environment in hospitals, nursing homes, clinics, home care, operation theatre room and ect. (Do not use for abortion suction).

### II. CHARACTERS

- Piston driven vacuum pump assures steam free and lubrication free prevents bacteria contamination.
- Hand-switch and foot-switch for operating easily.
- Vacuum adjustment system can be adjusted according to required.
- Working rationale (Figure 1).

### III. SPECIFICATIONS

1. Max vacuum:  $\geq 90$  kPa
2. Adjustable vacuum range: 20 kPa  $\sim$  Max vacuum
3. Max airflow:  $\geq 20$  L/min
4. Sound Level:  $\leq 60$  dB(A)
5. Suction bottle (glass): 2500ml/bottle, 2 bottles in a group
6. Power supply:
  - AC110V  $\pm 10\%$      AC220V  $\pm 10\%$      AC230V  $\pm 10\%$
  - 50Hz             60Hz
  - 2.0 amps
7. Input power: 150VA
8. Dimension: 350  $\times$  305  $\times$  795 (mm<sup>3</sup>) (H001)  
360  $\times$  320  $\times$  480 (mm<sup>3</sup>) (H002)

## FEATURES

9. Weight: 19.5kg(H001)      15.5kg(H002)

- Not to be used in inflammable or explosive place.
- Working system: Continuous operation with intermittent loading, maximum continuous working time is 30min, duty cycle is 50%.
- Electric classification: I class B type.

## IV. NORMAL WORKING CONDITION

- Temperature range: 5℃~40℃
- Relative humidity: 20%~60%
- Atmosphere pressure: 86kPa~106kPa

## HANDLING

### I . UNPACKING

- Check for any obvious damage to the carton or its contents. If damage is evident, please notify the carrier or local dealer.
- Remove all loose packing from the carton.
- Carefully remove all the components from the carton.

NOTE: Unless suction apparatus is to be used immediately, retain containers and packing materials for storage until use of the apparatus is required.

### II . INSPECTION

- Examine exterior of the suction apparatus for nicks, dents, scratches or other damages. Inspect all components.

### III . STORAGE

- Store the repackaged suction apparatus in a dry area.
- DO NOT place other objects on top of the repackaged suction apparatus.

## ASSEMBLY AND DEBUGGING

### I. CONNECT TUBING (Figure 2)

NOTE: The blue point face on the air filter is air entrance, which should connect with exit of store-liquid bottle.

### II. CONNECT POWER

Draw back handle, and take out power cord, then connect power.

Caution: This product should be grounded. In the event of electrical short circuit, grounding reduces the risk of electrical shock by providing an escape wire for the electric circuit. This product is equipped with a cord having a grounded wire with a grounding plug. The plug must be plugged into an outlet that is properly ground. DANGER—Improper use of the grounding plug can result in a risk of electric shock.

### III. VERIFY TUBING

- Screw pressure regulator knob clockwise, and block up air entrance with fingers or rubbers, or pinch soft tube.
- Starting the unit, without abnormal noise, the needle on the vacuum meter rise to maximum pressure immediately. Unloosening air entrance, the needle will be below 20 kPa. That is to say that tube connections are right.

### IV. ADJUST VACUUM PRESSURE

- Block up air entrance, switch on suction apparatus, and adjust pressure regulator. The readings of vacuum meter are changed in the range 20 kPa to maximum pressure.
- Control vacuum with pressure regulator in clinic.
- Pressure changes through circumvolving adjustment valve.

## ASSEMBLY AND DEBUGGING

- Reduce pressure below 20 kPa before switching off the machine.

### V. EXAMINE, TRY OVERFALL DEVICE

- Open bottle plug, clean valve mouth, and smooth the rubber valve slice on the buoy. The valve slice must be no defects such as warp, crack and so on. The valve slice should connect buoy well with buoy. The buoy should be agile on the buoy frame.
- Carry the bottle plug with hand and make buoy touch surface vertically, then move down the bottle plug and make buoy float.
- Close the bottle plug, connect soft tube, then screw pressure regulator and switch on suction apparatus.
- Make soft tube enter a pure water barrel, and inhale liquid to store liquid bottle with overfall device. The liquid site will rise with buoy.
- Loosen pressure regulator, switch off suction apparatus, open bottle plug, and empty store liquid bottle. When retightening bottle plug, buoy is at the bottom of the buoy frame, and valve mouth is open.

The overfall device that accord with aforesaid conditions can be used in clinic.

#### CAUTION:

1. After switching off the overfall device, the liquid site still rises, has two reasons:

- 1) One reason is from the remainder vacuum in the store-liquid bottle.
- 2) The valve mouth is incomplete closed up. Go through the reason of the valve mouth is invalidation.

2. When valve is shut off by buoy, the buoy could still be absorbed on the valve mouth.

## ASSEMBLY AND DEBUGGING

The reason is vacuum in the tube road. At this time, loosen pressure regulator or switch off suction apparatus to relieve vacuum in the tube road. Under the effect of gravity, buoy will fall from valve mouth. (Strictly prohibit pulling buoy with hand to avoid valve slice come over with buoy.)




3. After stopping the machine, relieving vacuum, then open the bottle plug.

4. After taking down overfall device and draught tubes, strictly prohibit using the suction apparatus.

### VI. STOPPING MACHINE

Switch off the suction apparatus first, then pull out power cord from power socket, and cut off net power supply.

### VII. SYMBOL AND SIGNIFICATION

Symbol	Signification	Symbol	Signification
	Alternating current		Consult the manual
	Earthing		

## OPERATING AND MAINTENANCE

### I. OPERATING

1. Before using apparatus, examine it by the process of assembly and debugging. After ensuring good capability, connect disinfected soft tube and abdomen suction tube to store-liquid bottle.
2. When using, adjust vacuum with pressure regulator, and pay attention to the liquid level in the store-liquid bottle.
3. When inhaled liquid is not too much once, do not to allow liquid to enter the second store-liquid bottle. When the first store-liquid bottle rises to prescribed volume ( The machine tilted through an angle of  $10^\circ$  is applicable still), you must stop inhaling. After empty and clean the store-liquid bottle, reuse it. Then the second store-liquid bottle is regarded as buffer bottle avoid liquid entering pump body.
4. When inhaled liquid is too much once, liquid will enter the second store-liquid bottle. Empty the store-liquid bottle in time, or else liquid will rise with buoy to cause to close up valve mouth and to auto-stop suction.
5. After shut off overfall device, liquid level still rise, please read "EXAMINE, TRY OVERFALL DEVICE".

### II. REPLACE AIR FILTER

If dirt or froth is haled into air filter, the color of filter velum will turn from light to deep, even induce suction power to reduce visibly or disappear, and vacuum on the meter rise beyond 40 kPa. At this time, air filter should be replaced with manufacturer in time.

Air filter should be replaced frequently, and destroyed together.

## OPERATING AND MAINTENANCE

### III. REPLACE FUSE TUBE

Fuse tube is fixed at the back of the pedestal. Before replacing it, CUT OFF power supply first. Unscrew fuse box counterclockwise, then replace the fuse tube. (Type: RF2AL250V~/Φ5×20)

### IV. MAINTENANCE

#### 1. CLEANING CABINET

WARNING: CUT OFF the power supply first. To avoid electrical shock, DO NOT remove cabinet.

Clean the cabinet with a mild household cleaner and non-abrasive cloth or sponge at least one time each month.

#### 2. CLEANING TUBING

Before stopping the machine, suggest to inhale little pure water to suction tube to clean tubing each time.

#### 3. CLEANING COLLECTION CONTAINER

(Include overfall device, and valve slice and bouy must not disconnect.)

- Clean collection container after using each time.
- After stopping the machine, empty store-liquid bottle.
- Clean the dirt on the bottle and bottle cover with soft brush, non-abrasive dishcloth or sponge.
- Rinse them with pure water thoroughly.

#### 4. DISINFECTION

- Disinfect collection container and soft tubing with a solution of ten (10) parts warm water and one (1) part vinegar.
- Disinfect metalline suction tube with  $134^{\circ}\text{C} \pm 3^{\circ}\text{C}$  saturated

## OPERATING AND MAINTENANCE

steam for 20 minutes.

### V. TROUBLESHOOTING GUIDE

Problem	Probable Cause	Solution	Remark
The maximum vacuum is below 90 kPa.	1) Leakage gas of bottle-mouth 2) Leakage gas of tubing joint 3) Pressure regulator is loose.	1) Clean dirt of bottle-mouth, tighten or replace bottle cover. 2) Tighten joints 3) Screw pressure regulator	Repairs by qualified personnel.
Vacuum is beyond 40 kPa, but suction power of tube-mouth reduce visibly or disappear.	1) Overfall device is shut off. 2) Tubing are jammed 3) Air filter is jammed	1) After stopping the machine, relieve pressure and rescrew firmly. 2) Dredge, clean or replace soft tubes 3) Replace air filter	1) Empty store liquid bottle in time
Power voltage is normal, but indicator lamp is not bright.	1) The power socket is loose. 2) Fuse tube is broken. 3) Indicator lamp is damaged.	1) Repair or exchange the power socket 2) Exchange fuse tube 3) Exchange indicator lamp.	Repairs by qualified personnel.



## OPERATING AND MAINTENANCE

Problem	Probable Cause	Solution	Remark
Fuse tube is broken	1) Voltage is gone beyond 2) Circuit breakdown 3) Relay breakdown 4) Pump body is jammed	2)Examine circuit, and exclude breakdown 3)Adjust or exchange relay 4)Examine pump body and motor.	Repairs by qualified personnel .

If you have all other problems, TURN OFF the concentrator first, and contact dealer or manufacturer immediately.

## OTHERS ATTENTION ITEMS

### I . LIMITATION OF TRANSPORT AND STOCK

- Temperature range:  $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$
- Relative humidity: 15%~95%
- Atmosphere pressure range: 50kPa~106kPa

The product must be stored in aeration without erode gas, avoided shaking and inversion in transport.

### II . ACCESSORIES LIST

- Abdomen suction tube 1PC
- Suction soft tube  $\langle \Phi 7 \times \Phi 12, \text{length } 2\text{m} \rangle$  1PC
- Fuse tube  $\langle \text{RF2AL250V} \sim / \Phi 5 \times 20 \rangle$  2PCS
- Power cord 1PC
- Foot-switch 1PC
- Air filter 2PCS
- Manual 1PC.

All specifications and product configurations are subject to change without notification.

**Business Stream Products  
Certification Department**



TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

SONOSCAPE MEDICAL CORP.  
Yuehai Subdistrict, Nanshan Distric  
Shenzhen  
518057 GUANGDONG  
CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date June 06, 2019

**Application for : Vollst. QMS, Anhang II MDD**  
Certificate No. : HD 60138552 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the  
new certificate No. HD 60138552 0001  
replacing the previous certificate.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60138552 0001

**Report No.:** 17032653 018

**Manufacturer:** SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
Shenzhen Software Park Phase II,  
1 Keji Middle 2nd Road,  
Yuehai Subdistrict, Nanshan District  
Shenzhen  
518057 Guangdong  
China

**Products:** Ultrasonic Diagnostic Systems, Medical Endoscope Systems  
(see attachment for additional sites included)

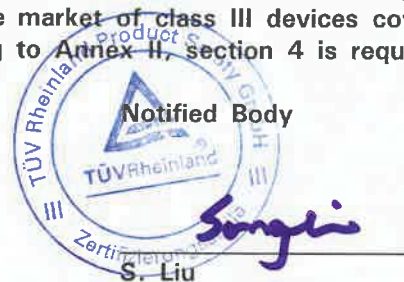
Replaces Approval, Registration No.: HD 60128046 0001

**Expiry Date:** 2023-06-18

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-06-06

**Date:** 2019-06-06



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60138552 0001  
**Report No.:** 17032653 018

**Manufacturer:** SONOSCAPE MEDICAL CORP.  
Room 201 & 202, 12th Building,  
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**Date:** 2019-06-06



**S. Liu**

**Business Stream Products  
Certification Department**



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Precisely Right.

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Date June 06, 2019

**Application for** : QMS Produktion, Anhang V MDD  
**Certificate No.** : DD 60138551 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the  
new certificate No. DD 60138551 0001  
replacing the previous certificate.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

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A02	D00056420	Adding the software function descriptions	2018-12-17	Xu Lin
A01	D00029319	First Release	2016-07-14	Shu Rong
<b>Title</b>	<b>HD-500 Series Image Processor Technical Specifications</b>			
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 SonoScape Medical Corp.	Document Number 901-02630		Distribution Number	
	Version A02	Effective Date	Page Page 1 of 18	

## HD-500 Series Image Processor Technical Specifications



**SonoScape**

SonoScape Medical Corp.

## 1. General Descriptions

The HD-500 series image processor adopts the advanced technology to provide high-quality image for the endoscopic diagnosis and treatment.

The built-in workstation of the image processor is used to edit, manage and store medical records and print reports. It can well communicate with the network information system of a hospital.

System maintenance and upgrade, and performance enhancement can be completed by updating software, thus to improve product value.

The image processor complies with the international and national standards.

## 2. Advanced Technologies

- High-definition video imaging
- Full-digital image processing

- Image denoise and enhancement
- CHb pseudo-color display
- Automatic equalization of brightness
- Hot plugging of the endoscope
- Capacitor touch control
- Intelligent medical record management
- Endoscope identification
- Multi-spectral imaging VIST

## 3. Ports

- Endoscope signal input port
- Video output port:
  - DVI port (1)
  - VGA port (1)
  - S-Video port (1)
  - CVBS port (1)
  - SDI port (1)
- High-definition video signal (DVI, SDI, VGA); the resolution of the output image is no less than 1920 × 1080.



- Video print control port
- Footswitch port
- Gigabit Ethernet network port (IEEE 802.3)
- USB ports (4)
- RS232 ports (2)
- Light source communication port
- Grounding terminal
- Power supply port

#### 4. Specifications

- Multi-spectral imaging VIST (used with the HDL-500X light source )
  - Function: used with the optical dyeing and electronic dyeing, the VIST can enhance the vessel contrast without brightness loss.
  - Triggering: press the **VIST** button on the keyboard, remote buttons/ footswitch (define the VIST features in advance) or press the **Filter** button

- on the light source.
- Hot plugging of the endoscope
- White balance memory
- Automatic white balance
- Structural enhancement
  - The structural enhancement includes structural enhancement A and structural enhancement B.
  - The structural enhancement A enhances the vessel networks and the structural enhancement B enhances the micro-vessel network.
  - There are three modes (1-3) and the enhancement level of each mode is 0-8.
- Edge enhancement
  - There are three enhancement mode (1-3) and the enhancement level of each mode is 0-8.
- Color tone adjustment
  - Red: -8 - +8

- Blue: -8 - +8
- Saturation: -8 - +8
- Color enhancement  
There are three enhancement mode (1-3) and the enhancement level of each mode is 0-8.
- IRIS
  - Automatic mode
  - Peak mode
  - Average mode
- Zoom: ×1, ×1.4, ×1.6, ×1.8
- Image freeze/ storage
  - Real time image freeze
  - Methods: the remote button, keyboard or footswitch
  - PBP functions: the image position and size can be adjusted.
- Display mode: standard/ full-screen
- CHb pseudo-color image display: on/off
- Local video recording and playback
- Endoscopic image and text reporting system

- Patient list management: bodymark marking, report templates with different typesettings , common diagnosis glossary, customizable diagnosis glossary and report headline, editable report content, report searching, selectable report fields, report preview, image video and report exporting
- The image can be acquired, archived, transmitted, displayed, searched and is compatible with DICOM standard.
- Storage capacity: 500GB (standard configuration)
- Support system version update
- Output format
  - Standard definition: PAL, NTSC
  - High-definition: Full-HD, WUXGA

## 5. Main Screen

- The patient information can be entered and modified on the main screen, including patient name (50 characters are allowed and the historical entered data can be memorized), age (range: 1-99), gender (male, female and blank), DoB, applicants (32 characters are allowed and the historical entered data can be memorized), ID (32 characters are allowed and the historical entered data can be memorized), exam number (the unique identification created by the system). More than 10000 patient information can be entered into the system.
- The patient information can be displayed on the main screen, including patient name, age, gender and the DoB, applicant, ID, exam number can be added into or delete from the main screen.
- Work modes display, including ten public modes (1-10) and private mode (P)
- Zoom level display
- Image enhancement value display
- Color enhancement value display
- Color tone adjustment value display
- The video function status switch indications include AGC, VIST, light control, contrast, white balance and timer
- Shortcut function icons displayed on the main screen: shortcut description, report edit, desktop change and desktop switch
- The hospital name can be displayed on the main switch.
- Videos can be recorded, saved and played.
- Thumbnails of the saved image and recorded video can be displayed on the main screen and pages can be turned.
- The four status of the main screen include displaying all items, displaying the video and main switch only, hiding the right frames or the left/right frames

- Main video resolution: 1280 × 960

## 6. System Settings

- Video parameters

- Resolution: 1920 × 1080, 1920 × 1200 and auto
- Video format: PAL, NTSC
- Synchronous output of high-definition signal: DVI, VGA
- Synchronous output of standard-definition signal: CVBS, S-Video
- The patient information, video parameters, system time, endoscope information, hospital name and manufacturer logo can be overlaid on the standard-definition signals.
- Two information layout styles can be selected.
- Examples of the two styles can be

reviewed.

- Selectable freeze time: 0.5, 1, 2, 3, 4, 5, 6, 7, 7, 8, 9 and non.
  - PBP: open/close
  - PBP position configuration: left up/down, right up/down
  - PBP size selection: big or small
  - Image format: jpg or bmp
  - Video format: mkv or flv
  - Check videos to print saved image
  - Video printer: close, USB and GPIO+ Video
  - Video printer drive type: auto
  - Several printer drive is available and the drive can be imported.
  - The white balance memory can be checked.
  - Contour shape: round or octagonal
- General Settings
  - The hospital name can be edited and

- displayed on the main screen and report edit screen
- Full-screen display: time, date and manufacturer logo.
- The hospital logo can be imported and displayed on the report. The image formats include jpg, bmp and png.
- Time format settings:
  - YYYY/MM/DD
  - MM/DD/YYYY
  - DD/MM/YYYY
  - YYYY/MM/DD
- Specific date/time setting
- 65 time zones can be selected.
- The time service IP can be set.
- Time synchronous with the time service IP.
- Enable the time synchronous when powering on the device.
- Languages: Chinese, English, French, German, Portuguese, Spanish and Russian
- Build-in lithium cell with 3-year lifespan
- Contextual Settings
  - The patient information can be automatically matched.
  - The report printer includes:USB printer and network printer
  - Paper size: A4 (210mm×297mm) and Carta (216mm×279mm)
  - The printer drive type can be set.
  - The printer drive type can be imported.
  - Set the network printer IP can be set and the network printer within the local area network can be researched.
  - The printer parameters can be set, including brightness and Gama (setting the visibility of the user service authority)

- The local IP can be set.
- The local Mac address can be viewed.
- DICOM settings
  - Basic setting
    - Station name
    - Local AE title
    - Timeout
    - Port
  - Storage settings
    - Enable the storage server features.
    - Upload image once it is saved
    - Server name
    - Server IP
    - Port
    - AE title
  - Commitment Storage
    - Enable the commitment storage
    - Server name
    - Server IP
    - Port

- AE title
- Worklist
  - Enable the Worklist
  - Server name
  - Server IP
  - Port
  - AE title
  - Maximum results
  - Step description
- MPPS
  - Enable the MPPS
  - Server name
  - Server IP
  - Port
  - AE title

## 7. Mode settings

- Modes include ten public modes and a private mode that can be bound with the account.

- Image enhancement includes edge, structural A and structural B.
- Structural enhancement includes three adjustable modes and the adjusting range is 0-8.
- Edge enhancement includes three adjustable modes and the adjusting range is 0-8.
- Color enhancement includes three adjustable modes and the adjusting range is 0-8.
- Color tone (R/B/C) adjustment range is -8 - +8
- ZOOM includes three modes and the adjustment ranges are level  $\times$  1 , level  $\times$  1.4 , level  $\times$  1.6 and level  $\times$  1.8.
- The customizable functions of the four remote buttons include freeze, zoom, VIST, IRIS, image enhancement, color enhancement, CHb, transparent, contrast, AGC, image size, screenshot, video print, record, timer, PBP, information display and

fast export and upload

- The functions of the left and right button can be customized by the footswitch and the customizable functions include freeze, zoom, VIST, IRIS, image enhancement, color enhancement, CHb, transparent, contrast, AGC, image size, screenshot, video print, record, timer, PBP, information display and fast export and upload
- IRIS methods: auto, average, peak
- The parameter of the present image can be saved automatically.
- Contrast: low/ medium/high

## **8. Work Order List**

- More than 10000 work orders can be created and saved in to the work order list.
- The work order list can be selected according to the exam items.
- The information in the work order list can be

re-edited, conducted or delete directly.

- The work list information can be displayed or hidden.
- Information in the work order list includes patient name, gender, age, ID, applicant, pre-exam date and status
- The work order list can be sorted according to the table title.
- The table title on the work order list can be displayed or hidden.
- The work order list can be searched according to name, gender, age, ID, applicant and application time.
- The total number of the work order can be displayed below the work order list.
- View the DICOM queue
  - All datum in the DOCIM queue list can be sorted according to descending or ascending order by clicking the table title.

- The DICOM queue can be searched through the patient name, ID, date, type and status.
- The search condition can be reset.
- The datum in the DICOM queue can be refreshed.
- Resend the datum selected in the DICOM queue if failed to send it to the DICOM queue.
- The Worklist inquiry conditions, including name, examination device, ID, accession number and pre-exam date can be set.
- Fields in the work order list can be displayed or hidden.
- The work order list includes patient information and exam information.

## **9. Patient List**

- The patient lists can be selected according to the examination items.



- The patient list information can be viewed, including video, image and report.
  - Reports for each patient list can be generate.
  - The patient information, diagnosis images, view of exam, exam conclusion and biopsy site are included in the report.
  - The specific video, images and reports can be viewed.
  - The image can be viewed and marked, and the marker types include dot, lower/upper-right arrows and lower/upper-left arrows.
  - The exam can be canceled.
  - The patient list can be exported.
  - The image and report of the patient list can be uploaded.
  - The patient list can be searched according to the following conditions: name, ID, doctor, status and exam date.
  - The patient list can be deleted.
- The information in the patient list are name, ID, exam date, doctor, endoscope mode, status and exam number.
  - The patient list statuses include printed, uploaded, examined and diagnosed.
  - The patient information is sorted according to patient name, ID, exam date, doctor, endoscope model, status and exam number.
  - View the DICOM queue
    - All datum in the DOCIM queue list can be sorted according to descending or ascending order by clicking the table title.
    - The DICOM queue can be searched through the patient name, ID, date, type and status.
    - The search condition can be reset.
    - The datum in the DICOM queue can be refreshed.
    - Resend the datum selected in the

DICOM queue if failed to send it to the DICOM queue.

- Report edit:

- The patient information can be edited.
- The report and image can be edited.(At most 10 images can be stored.)
- Bodymarks and organ names can be added into the report images in the.
- The exam type can be selected according to the present exam.
- The view of exam, exam conclusion, biopsy site and suggestions can be edited.
- Select items from the glossary directly and fill them into the view of exam and exam conclusion.
- The items in the glossary can be edited.
- The operations for the glossary

include switching items, adding, editing, copying and deleting.

- The exam items in the report can be switched.
- The presently edited view of exam and exam conclusions can be saved into the glossary as new items.
- Several report templates can be selected: 1P-1×4, 1P-2×2, 1P-2×3, 1P-4×1 and general.
- The report fields can be set.
- Individualized titles can be set in the report template.
- The report preview page has 22 page scales.

## **10.Doctor List**

- One hundred accounts can be created into the doctor list.
- Custom operations of the doctor list differ

according to different account limitations:

the admin account includes add, edit, delete, and login mode, and the doctor account includes edit and view.

- The doctor name, job ID, and title (including resident physician, physician, vice doctor and director physician), account and password, and customizable private mode (used for load private parameter settings when logging in the account) can be identified in a new account.
- The doctor list includes: job ID, name, title and account.
- The order of the doctor list datum is job ID, name, title and account.
- Custom login methods include auto and account, and the account logging has drop-down list and can also enter contents.

## 11. View the Endoscope Information

- The endoscope specifications can be viewed, including the endoscope mode, inner diameter of the instrument channel, outer diameter of the distal end, insertion tube outer diameter, biopsy entrance position icon and the endoscope specifications icons consist of all the first four items.
- The endoscope information can be viewed, including the date of manufacturer, endoscope series number, and using time.
- The custom information can be viewed, including the contract number and annotations.

## 12. Custom Service Interface

- This system can manage and control the prototypes, including the image processor management and control, as well as the assorted endoscope management and control.

- The image processor management and control includes time and endoscope match management and control.
- The endoscope control includes the endoscope using time and assorted processor management and control.
- The system can be upgraded by USB.
- The video can be imported and looped.
- The QR code including the device and manufacturer information can be displayed.
- Data restore function
- One-key restore function
- The assorted light source information can be displayed, including the series number, present main lamp service time and service time of all main lamps.
- The endoscope series number and using time can be viewed.
- The image processor series number, the rest space, video record time and picture storage

number can be viewed.

### **13. Applications**

The image processor can be used with the endoscope manufactured by SonoScape. It is used to process endoscopic image in clinical diagnosis and supply power to the endoscope.

### **14. Size & Weight of the Image Processor**

#### **Processor**

- Size: 455mm × 370mm × 124mm(L×W×H)
- Weight: 9.5kg (approx.)

### **15. Monitor (Optional)**

- LCD monitor: 24 inch color display
- Resolution: 1920×1080/1920×1200
- Video input port: S-Video (1), CVBS (1), VGA (1), DVI (1), SDI (1)
- Video output port: DVI (1), SDI (1)

## 16. Compatible Equipment

- Light source: HDL-500X/HDL-500E
- Endoscope: 500 series endoscopes
  - EG-500 series video gastroscope  
(EG-500/EG-500L)
  - EC-500 series video colonoscope  
(EC-500/EC-500T/  
EC-500L/EC-500L/T)
  - EB-500 video bronchoscope
  - ENL-500 video rhinolaryngoscope

## 17. Safety Standards

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

## 18. Environment Requirements

- Operation Environment
  - Temperature: 0°C - +40°C
  - Relative humidity: 30% - 80%

- Atmosphere pressure: 700 hPa - 1060 hPa

- Storage Environment

- Temperature: -5°C - +40°C
- Relative humidity: 30% - 80%
- Atmosphere pressure: 700 hPa - 1060 hPa

- Transportation Environment

- Temperature: -20°C - +55°C
- Relative humidity: 20% - 90%
- Atmosphere pressure: 700 hPa - 1060 hPa

- Safety Types

- Type of protection against electric shock: Class I equipment
- Degree of protection against electric shock: Type BF applied part
- Power Supply Requirements
- Input voltage: AC 100V - 240V, 50/60Hz

- Input power: 160VA

**NOTE:**

- The specifications of this product 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.

**Sonoscape Medical Corp.**

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**D00056420**

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

**完成**

**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图像处理英文技术规格书	HD-500图像处理英文技术规格书 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					

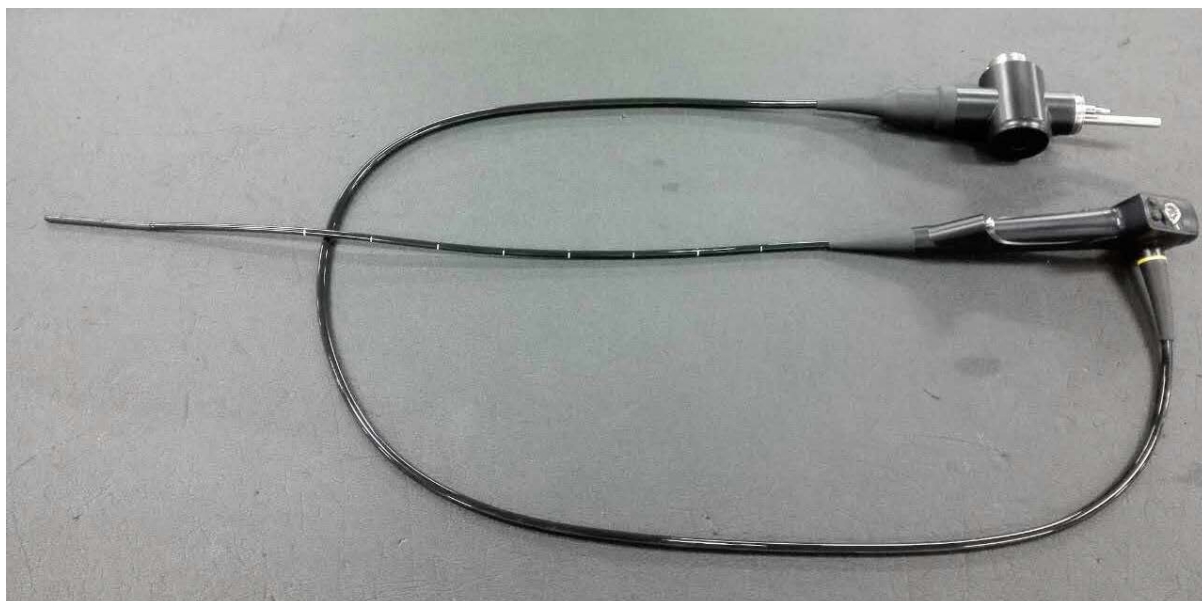
**工作流程**

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
流程已前移	批准	邱建军 (qiuji)	已批准	[Sono]文件发行/变更/报废流程	是	邱建军 (qiuji)		01/03/2019 09:47:00 上午 CST		0
流程已前移	检查			[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			[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
流程已前移	审核	李剑峰 (lijf)	已批准	[Sono]文件发行/变更/报废流程	是	李剑峰 (lijf)		12/18/2018 11:39:41 上午 CST		0
流程已前移	审核	高慧梅 (gaohm)	已批准	[Sono]文件发行/变更/报废流程	是	高慧梅 (gaohm)		01/03/2019 09:12:28 上午 CST		12
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		



REV	ECN	Date	Revision History		Editor
A01	D00036706	2017-04-27	Initial Release		Xiao Dan
<b>Title EB-500 Video Bronchoscope Technical Specifications</b>					
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 SONOSCAPE MEDICAL CORP.			Document Number 901-04496		Distribution Number
			Version A01	Effective Date 2017-04-27	Page Page 1 of 6

## Specifications for EB-500 Video Bronchoscope



**SonoScape**

SonoScape Medical Corp.

## 1 Overview

EB-500 series video bronchoscope is used for examination, diagnosis and treatment of the respiratory tract and lung. It adopts the advanced technologies of high-definition CMOS imaging, digital image processing and micro optical lens to provide high-quality image, safe diagnosis and treatment, accurate judgment and stable operation.

The device allows an operator to remotely operate such functions as real-time video collection, suction, image freezing and magnification.

The device has been designed to comply with applicable international standards and regulations, ensuring the safety and availability of this product.

## 2 Advanced Technologies

- High-definition CMOS imaging technology
- Micro optical lens technology
- Wide field of view imaging lens technology
- High-conductivity and small -diameter insertion section with different rigidity at different

segments

- Small bending radius and large bending angle
- Adoption of polymer engineering material, high durability against disinfectant

## 3 Connectors

- Electrical connector
- Light guide port
- Suction valve cylinder

## 4 Applicable Range

The device is used with the light source, image processor, monitor and other peripherals provided or approved by the manufacturer. It is intended to examine, diagnose and treat the respiratory tract and lung.

## 5 Compatible Equipment

- Light source: HDL-500X/E
- Image processor: HD-500

## 6 Safety Standards

- IEC 60601-1:1988+A1:1993+A2:1995;
- IEC 60601-2-18:1996+A1:2000

- IEC 60601-1-2:2007

## 7 Environment Requirements

- **Operating Environments**

- Temperature: +5°C ~ +40°C
- Relative humidity: 30% ~ 80%
- Atmospheric pressure: 700 – 1060hPa

- **Storage Environments**

- Temperature: -5°C ~ +40°C
- Relative humidity: 30% ~ 80%
- Atmospheric pressure: 700~1060 hPa

- **Transportation Environments**

- Temperature: -20°C ~ +55°C
- Relative humidity: 20%-90% (non-condensing)
- Atmospheric pressure: 700-1060 hPa

- **Safety Types**

- Type of protection against electric shock: Type III
- Degree of protection against electric shock: Type BF applied part
- Degree of protection against liquid: IPX7
- The device is not allowed to be used with flammable

anaesthetics (category AP) or flammable anaesthetics with oxidants (category APG).

- Operation mode: operation after connection

## 8 Appendix

<b>Item</b>	<b>Parameter</b>	<b>EB-500</b>
1	View direction	Front
2	View field	120 °
3	Resolution	Resolution $\geq$ 14.50lp/mm (if the work distance is 3mm)
4	View depth (mm)	3~100
5	Outer diameter of the distal end	$\Phi$ 5.3mm
6	Outer diameter of the bending section	$\Phi$ 5.7mm
7	Bending angle	Up 180 °, down 130 °
8	Minimum inner diameter of the instrument channel	$\Phi$ 2.0mm
9	Insertion section length	600mm
10	Total length	870mm
11	Minimum viewing distance of instrument channel	3mm
12	Illumination	$\geq$ 8000Lx (if the work distance is 7mm)
13	Aspirated amount	$\geq$ 200ml/min
14	Endoscope information storage	Support
15	Endoscope net weight	0.72 Kg

**Note:**

- The specifications of this product is subject to change without any prior notification.
- Some products or features may not be available in some countries.
- For further information, please contact your local SonoScape sales representative.

**Service Information:**


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<b>REV</b>	<b>ECN</b>	<b>Revision History</b>	<b>Date</b>	<b>Editor</b>
A02	D00059410	Update the manufacturer address	2019-06-24	Xu Lin
A01	D00056420	First Release	2018-12-17	Xu Lin
<b>Title</b>	<b>VLS-50 Series Light Source Technical Specifications</b>			
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## VLS-50 Series Light Source Technical Specifications



**SonoScape**

SONOSCAPE MEDICAL CORP.



## 1 Overview

The VLS-50 series light source system is designed to realize multispectral illumination by a white light LED and a violet LED. The white light LED is featured with high color rendering index ( $\geq 90$ ) and high luminous flux ( $\geq 600\text{lm}$ ), and the violet LED (with main wavelength of 415nm, corresponding to the maximum absorption spectra of hemoglobin) enables to highlight the superficial mucosal micro-vessels, benefiting to identification and diagnosis of the lesion parts.

## 2 Advanced Technologies

- Multispectral illumination
- Aspheric optical technique
- Capacitor touch screen
- Quick luminous flux adjustment based on current regulation
- High color rendering index and high luminous flux in the white light mode
- High brightness and specific spectra in the special light modes
- Two special light modes
- Fast light mode switch in millisecond order

## 3 Functions

- Power switch: on/off
- Powering on/off the light source:
  - Powering on: press the **LIGHT** button to enlighten the lamp and the <LIGHT> indicator illuminates.
  - Powering off: press and hold the **LIGHT** button for about 2 seconds to power off the lamp and the <LIGHT> indicator lights off.
- Brightness adjustment:
  - Modes: automatic and manual
  - Adjusting levels: 1–19
- Air-feeding pressure adjustment : low/medium/high
- Transillumination function:
  - Press the **TRANS** button to enable this function. The transillumination mode can maintain for 6–8 seconds if no button is pressed.
  - Press any button to disable the transillumination mode.
- Services time indication:
  - The elapsed time of the light source is counted every other minute and the left time is indicated when the light source is powered on.
  - The service time indicator flashes

when the elapsed time reaches 10000 hours.

- Over-heat protection
- Abnormal report and processing:  
Provide the LED flashing, buzzer alarming and so on according to the malfunction processing requirements.
- Power-down protection:  
Provide power-down protection for the light control mode, light control level, air pump powering on/off, air pump flow level and service time

#### 4 Parameters

- Light source: W-LED, 70W; violet LED, 50W; no auxiliary lamps
- Air-feeding level: four levels  
off/low/medium/high
- Light control level: level 1–19
- Total luminous flux output :  $\geq 600\text{lm}$ , allowance: -10%
- Correlated color temperature (CCT):  
5000K – 7000K
- Color rendering index (CRI):  $\geq 90$  in the white light mode
- Service time: 10000 hours (continuous use)
- Air-feeding system:
  - Air-pump flow levels: high, medium,

low

- Pressure range: 45Kpa – 65Kpa
- Maximum air flow volume:
  - High: 3.7L/min – 5.5L/min
  - Medium: 3.0L/min – 4.7L/min
  - Low: 2.0L/min – 3.7L/min

#### 5 Ports

- Endoscope port
- Light source control port
- Power supply input port
- Equipotential terminal
- Optical fiber cable port
- Water bottle connector

#### 6 Compatible Equipment

- Image processors: HD-550
- Video gastroscopes: 550 series video gastroscopes (EG-550/EG-550L)
- Video colonoscopes: 550 series video colonoscopes (EC-550/EC-550T/EC-550/ EC-550L/T)
- Trolley: HDT-330

#### 7 Size and Weight

- Size:  $473\pm 5\text{mm(L)} \times 370\pm 5\text{mm(W)} \times 154\pm 5\text{mm(H)}$
- Weight: 13kg (approx.)

- Input power: 300VA

## **8 Standards**

- IEC 60601-1:2005+A1:2012
- IEC60601-2-18:2009
- IEC 60601-1-2:2014

## **9 Environment Requirements**

- Operation environment
  - Temperature: 0°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
- Power supply requirements:
  - Input voltage: 100 – 240V AC  
50/60Hz

**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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## Termenii și condițiile de livrare

Denumirea    **“Consolidarea controlului Tuberculozei și reducerea mortalității cauzate de SIDA în Republica Moldova”**  
Cumpărător:  **Instituția Publică „Unitatea de Coordonare, Implementare și Monitorizare a Proiectelor în Domeniul Sănătății”**  
Destinatar:   **IFP - (Chișinău).**  
Pachet nr.:    **192/GD/T**

### 1.    Prețurile și Termenii de livrare

Furnizorul recunoaște că va fi, de asemenea, responsabil de:

- a) Livrarea mărfurilor la adresa destinatarului, IMSP IFP „Chiril Drăganiuc”;
- b) Instalarea echipamentului și instruirea personalului medical pentru întreținerea de rutină a echipamentului (toate instrumentele din cadrul acestui Lot).

### **LOTUL 1. “ Sistem videoendoscopic pentru videobronhoscopie, cu dispozitiv de reprocesare automată”:**

<b>Nr</b>	<b>Articol</b>	<b><u>Cantitate totala, gr</u></b>	<b>Preț per unitate Chișinău, <u>MDL</u></b>	<b>Preț total Chișinău, <u>MDL</u></b>	<b><u>Termenul de livrare</u></b>	<b><u>Destinatar</u></b>
<b>1</b>	<b>Sistem videoendoscopic pentru videobronhoscopie, cu dispozitiv de reprocesare automată</b>	<b>1</b>	<b>1064000,00</b>	<b>1064000,00</b>	<b>Maximum 60 zile calendaristice</b>	<b>IFP, Chișinău.</b>
<b><i>TOTAL:</i></b>				<b>1064000,00</b>		

**Notă:** În caz de discrepanță între prețul unitar și totalul derivat din prețul unitar, corectarea se va face conform prevederilor punctului 8 (iii) din Invitația pentru prezentarea ofertei de preț

- 2.    Prețul Fix: Prețurile indicate mai sus sunt fixe și nu fac obiectul niciunei ajustări în timpul executării contractului. Confirmăm că prețurile nu includ taxele vamale, accizele, taxele pentru efectuarea procedurilor vamale și taxa pe valoarea adăugată (TVA) din Republica Moldova.
- 3.    Țara de origine: Bunurile oferite trebuie să provină din țările membre ale Băncii Mondiale și se solicită să furnizați un certificat de origine pentru fiecare articol.
- 4.    Programul de livrare: Livrarea trebuie finalizată conform condițiilor de livrare din Termenii și condițiile de livrare din momentul semnării contractului.
- 5.    Legislația aplicabilă: Contractul va fi interpretat în conformitate cu legile din țara Cumpărătorului.
- 6.    Soluționarea litigiilor: Cumpărătorul și Furnizorul vor depune toate eforturile pentru a rezolva pe cale amiabilă, prin negocieri directe informale, orice neînțelegere sau litigiu

între ei în temeiul sau în legătură cu Contractul. În cazul unui litigiu între Cumpărător și Furnizor, litigiul va fi soluționat în conformitate cu prevederile legilor din țara Cumpărătorului.

7. Livrarea și Documentele: La expedierea bunurilor, Furnizorul va notifica Cumpărătorului prin email sau fax detaliile complete ale expedierii, inclusiv numărul contractului, descrierea bunurilor, cantitatea etc.
8. Plata facturii dvs. se va efectua la 100% contra livrării bunurilor, prin transfer bancar în favoarea Băncii Furnizorului, în termen de zece (10) zile bancare de la recepționarea bunurilor și a serviciilor conexe prevăzute de punctul 1 din acești Termeni și condiții de livrare (denumite în continuare „Serviciile conexe”), confirmate prin semnarea unui act de recepție finală pentru bunuri și servicii conexe emis de Cumpărător și confirmat de Destinatar/beneficiar final (denumit în continuare „Actul de Recepție Finală”).
9. Garanție: Bunurile oferite trebuie să fie acoperite de garanția producătorului (perioada de valabilitate) așa cum este indicat în Anexa A la Termenii și condițiile de furnizare de la data Actului de Recepție Finală. **Vă rugăm să specificați perioada de garanție și termenii în detaliu, conform cerințelor din Anexa A.**
10. Autorizația producătorului. Cumpărătorul poate solicita Furnizorului înainte de atribuirea contractului să furnizeze autorizația producătorului pentru bunurile contractate.
11. Instrucțiuni privind ambalarea și marcarea: Furnizorul va asigura ambalarea standard a bunurilor după cum este necesar, prevenind prejudicierea sau deteriorarea acestora în timpul tranzitului către destinația lor finală, așa cum este indicat în Contract.
12. Defecte: Toate defectele vor fi corectate de către Furnizor fără niciun cost pentru Cumpărător în termen de 30 de zile de la data notificării de către Cumpărător.
13. Forță majoră: Furnizorului nu îi vor fi aplicate penalități sau rezilierea contractului pentru carențe dacă și în măsura în care întârzierea sa în executare sau altă neîndeplinire a obligațiilor asumate prin Contract sunt rezultatul unui eveniment de forță majoră.

În sensul acestei clauze, „Forță Majoră” înseamnă un eveniment care nu poate fi controlat de Furnizor și care nu implică vina sau neglijența Furnizorului și care nu este previzibil. Astfel de evenimente pot include, dar fără a se limita la, actul Cumpărătorului în calitatea sa suverană, războaie sau revoluții, incendii, inundații, epidemii, restricții de carantină și embargouri de mărfuri.

Dacă apare o situație de forță majoră, Furnizorul va notifica prompt Cumpărătorul în scris despre această situație și cauza acesteia. Cu excepția cazului în care Cumpărătorul solicită altfel în scris, Furnizorul va continua să își îndeplinească obligațiile în temeiul Contractului, în măsura în care este rezonabil din punct de vedere practic, și va căuta toate mijloacele alternative rezonabile de executare care nu sunt împiedicate de evenimentul de forță majoră.

14. Specificațiile tehnice necesare

**(i) Descriere generală**

- a. Toate bunurile trebuie să fie noi, nefolosite, dintre cele mai recente și actuale modele, încorporând toate îmbunătățirile recente ale designului și materialelor, cu excepția cazului în care se prevede altfel în aceste specificații.

(ii) **Detalii specifice și standarde tehnice** - conform Anexei A la Termenii și condițiile de furnizare

**Furnizorul confirmă corespunderea cu specificațiile de mai sus (În caz de abateri furnizorul va enumera toate aceste abateri).**

15. Neexecutarea: Cumpărătorul poate anula Contractul în cazul în care Furnizorul nu livrează bunurile și nu furnizează Serviciile conexe, în conformitate cu termenii și condițiile de mai sus, în pofida unei notificări de 10 zile oferite de către Cumpărător, fără a-și asuma nicio răspundere față de Furnizor.
16. Întârzieri: În cazul în care Furnizorul nu reușește să livreze oricare sau toate bunurile până la data livrării sau să efectueze Serviciile conexe în perioada specificată în Contract (așa cum este prevăzut în Termenii de livrare de mai sus), Cumpărătorul poate, fără a afecta toate celelalte clauze în temeiul Contractului, deduce din Prețul Contractului, drept despăgubiri forfetare, o sumă echivalentă cu 0,1% din prețul oferit al bunurilor întârziate sau al serviciilor neexecutate pentru fiecare zi lucrătoare sau parte din aceasta de întârziere până la livrarea sau executarea efectivă, până la o deducere maximă de zece (10)% din Prețul Contractului.
17. Frauda și corupția: Politica Fondului Global este de a cere ca toți ofertanții, furnizorii și contractanții și agenții acestora (fie că sunt declarați sau nu), personalul, subcontractanții, sub-consultanții, furnizorii de servicii în cadrul contractelor finanțate de Fondul Global să respecte cel mai înalt standard de etică în timpul achiziției și executării unor astfel de contracte.<sup>1</sup> În aceste circumstanțe, Fondul Global a elaborat un **Cod de Conduită pentru Furnizori** care are ca scop să asigure că Furnizorii și Reprezentanții Furnizorilor vor participa la procesul de achiziții într-o manieră transparentă, echitabilă, responsabilă și onestă, inclusiv prin respectarea tuturor legilor și reglementărilor aplicabile privind concurența loială precum și a standardelor recunoscute de bune practici în achiziții. Documentul detaliat (Code of Conduct for Suppliers / Codul de Conduită pentru Furnizori) poate fi găsit și trebuie citit pe website-ul: <https://www.theglobalfund.org/en/governance-policies/>
18. În calitate de ofertant, confirmăm prin prezenta că am citit Codul de Conduită pentru Furnizori (Code of Conduct for Suppliers), așa cum este menționat în clauza 17 de mai sus și prin semnătura noastră de mai jos ne asumăm responsabilitatea pentru acțiunile întreprinse de noi în cadrul acestei achiziții.

NUMELE FURNIZORULUI ERICON SRL

Semnătura și ștampila autorizate Gheorghe Bunic

Locul: Chisinau

Data:

04 04 23

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<sup>1</sup> În acest context, orice acțiune întreprinsă de un ofertant, furnizor, contractant sau de orice al lor personal, agenți, subcontractanți, subconsultanți, furnizori de servicii, furnizori și/sau angajații acestora în vederea influențării asupra procesului de achiziție sau a executării contractului pentru un avantaj necuvenit este improprie.