VIDEO-CYSTOSCOPE

Model: DR060380B-2

USER MANUAL

MANUAL P/N: IA-MN-213-3(Version 3.1)

Hangzhou Hawk Optical Electronic Instruments Co., Ltd.

Introduction

Thank you for your purchasing the HAWK's equipment for endoscopy. This device has been scientifically designed and manufactured to meet the international standards required in the application related to endoscopic diagnosis and surgery. In order to use the device easily, please read the user manual carefully before using this device. Operate the device according to the specific procedures.

The engineer at Hawk is always prepared to assist in answering any of your questions or in meeting your specific requirements. We also welcome any comments you may have concerning about our equipment. Your comments and questions will receive immediate attention. You can contact us via phone, mail, Fax and E-mail: hawk@chinahawk.cn. Please see Customer Service for details or visit our Homepage http://www.hawkendoscopes.com to learn about more information.







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Conformance Standards

1. The following classifications are in accordance with the IEC/EN 60601-1:6.8.1:

- 1) According to 93/42/EEC Medical Device Directive, this is Class IIa medical Device.
- 2) According to IEC/EN 60601-1.
- Equipment is Class I, BF Part.
- 3) According to IEC 60529:2001-02.

The protection level of monitor is IPX0.

The protection level of endoscope is IPX7.

2. Certification

The general electrical medical system is CE, ISO9002, ISO9001 certified.

3. Original Documentation

The original document is written in English.



DISASSEMBLY AND REPAIR BY THE CUSTOMER ITSELF IS NOT PERMITTED, IF THIS LEAD TO SOME DAMAGE, THE CUSTOMER SHOULD TAKE RESPONSIBILITY OF IT.

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1. Safety

1.1 Introduction

Safety is everyone's responsibility. The safe use of this equipment is largely depend upon the installers, users, operators, and maintainers. It is imperative that personnel study and familiar with this entire manual before attempting to install, use, clean, service or adjust this equipment and affiliated accessories. It is paramount that the instructions contained in this manual are fully understood and followed to enhance safety to the patient and the user/operator. It is for this reason that the following safety notices have been places appropriately within the text of this manual to highlight safety related information or information requiring special emphasis. All users, operators, and maintainers must be familiar with and pay more attention to all Warnings and Notes incorporated herein(as Table1).

Table1:Warning and attention label meaning			
Signal	Meaning		
٨	"Warning "indicates in case of neglect of attention the presence		
! Warning	of a hazard that could result in severe personal injury, death or		
Z	substantial property damage.		
٨	"Note" indicates informs the user in case of neglect of attention		
<u> </u>	to be improper installation, operation or maintenance, such		
Zivote	behavior can lead to device damage.		

1.2 About Safety

Please study this manual carefully before using this equipment. You must following the proper steps in training yourself for use of this equipment. Otherwise, there may be detrimental consequence to patients or the operator. Furthermore, you should carefully study the operating manuals of any other equipment and accessories that will be used in combination with this equipment.

Safety issue is discussed in comprehensive details in Chapter 1 SAFETY.

Any concern that may cause bodily harm in connection with the observation, diagnosis using the endoscope will be set out in the " Warning" symbol. Please study the content of each warning carefully and follow the instruction set out in each warning. Furthermore, any concern that may damage the endoscope will be set in the " Note" symbol.



- Incorrect use or operation of endoscope is dangerous and may cause harm to the patient, the operator or anybody in the vicinity.
- Please study this manual carefully before using this endoscope.

1.2.1 Safety Precaution

This equipment has been developed and tested according to safety standards as well as national and international standards. This guarantees a very high degree of safety for this device. The legislator expects us to inform the user expressively about the safety aspects in dealing with the device. The correct operating this equipment is imperative for its safety. Therefore, please read carefully all instructions before switching on this device. For more detailed information, please contact our Customer Service Department or one of our authorized representatives.



- The operators who will do the endoscopic surgery with medical pressurizer must be trained and qualified. Forbid unqualified personnel to use this equipment.
- This device must be installed, used, operated and maintained by or under supervision the person who is properly trained and qualified.
- It should has reliable grounding with the power supply socket to control unit. The power grid connected to the operating room must be grounded reliably, or doctors and patients would result in injury.



- Keep the User's Manual in a place easily accessible at all times for persons operating and maintaining the equipment.
- The manufacturer is only responsible of the safety, reliability and performance of the device:
- 1) Electrical installation should be done in accordance with the provisions described in this user manual.
- 2) This device should be installed, used, operated and maintained in accordance with this user manual.
- Please do not use this device if it is suspected to have problems. Please contact HAWK designated service providers and check the device before use. If any deficiency is suspected or confirmed in the device, do not use the device until it has been checked by the authorized service.
- Do not disassemble other parts by unauthorized person except the parts permitted by this operation manual. The maintenance of this device should be done in accordance with this user manual. Any additional maintenance and modification should be done only by HAWK service technicians or authorized personnel.
- Do not modify this device without any authorization. The manufacturer is not liable for damage caused by unauthorized tampering with the device(s). Such tampering will make customer forfeit any rights to claim under warranty.
- This equipment may only be used together with accessories supplied by HAWK. If the customer makes use of other brand accessories, use them only if their safe usability under technical safety aspects has been proved and confirmed by HAWK or the manufacturer of the accessory.
- •Before insert plug into socket, it should check the plug is match the socket, do not force to insert the plug into the socket. Do not pull the cable when turn off the power supply, it should hold the plug and pull it out.
- Do not force cable connections. If a cable does not connect easily, be sure that the connector (plug) is appropriate for the receptacle(socket). If you cause any damage to a cable connector(s) or receptacle(s), let the damage(s) be repaired by an authorized service technician.
- Don't plug the AC power cord into the outlet before the connection between devices of the equipment is completed which can generate the defect.
- Before every operation, visually check the equipment for exterior mechanical damaged(s) and for proper function.

• Immediately turn off and unplug any equipment that gives off smoke, sparks, strange noises, or odors .

1.2.2 Environment requirements

1.2.2.1 Avoid the following environments for operation or storage:



Where the device is exposed to water vapor. Don't operate a device with a wet hand.



Where the device is exposed to direct sunlight.



Where the temperature exchanges extremely. Normal operating temperature range is from 10° C to 40° C. Humidity is from 30% to 75%.



Where it is near the heat equipment.



Where the device is subject to excessive shocks or vibrations.



Where device is exposed to chemical material or explosive gas



Be careful not to be inserted dust, especially metal.



Where the humidity is extremely high or there is a ventilation problem.



Be careful not to close the fan located on the lateral or be opposite of the equipment.



- This equipment must not be used in such areas:
 - 1) An area that is in danger of explosions.
- 2) An area that in the presence of flammable, explosive, or volatile solvent such as alcohol, benzene or similar chemicals.



• Do not put or use this device in humid rooms. Humidity should be kept between 30% and 75% for normal operation. Do not expose the device to water splashes, dripping water, or sprayed water. Do not place containers containing fluids, liquids, or gases on

top of any electrical equipment or devices.

- 1.2.2.2 Avoid places where the ambient temperature falls below $+10^{\circ}$ C or above 40° C for normal operation;
- 1.2.2.3 Avoid environments where the equipment is exposed to excessive shocks or vibrations;
- 1.2.2.4 Storage envirement:
- Ambient temperature $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$
- Humidity will not exceed 95%
- Atmosphere pressure 500hpa~1060hpa
- None corrosive air
- Keep ventilation



• Common injuries that may happen during use of the endoscope are: irritation to mucosal, bleeding, infection, or others. If you do not follow the operating procedure in this manual, then injury or damage to the equipment may result.

1.3 Clinical operation

The device must be operated by trained and qualified person, and operator must have skilled clinical technology. This manual does not explain or discuss clinical technique, the operator should consult the professionals about clinical endoscopic operating skills.

1.4 Pre-use inspection

To ensure proper use, before you use the product, please read the 4.2 Pre-use Inspection of user manual, and check each function.

1.5 Using with other accessories

To use other accessories together with this videoscope. When using a controller or a display, in order to prevent electric shock, use a properly grounded electrical outlet to power or charge.

1.6 Maintenance

After long-term use, the endoscope may be damaged, please be sure to regularly check. Even a slight abnormality was found, please be cautious, careful examination. Be sure not to disassemble or modify this videoscope.

1.7 Cleaning and disinfection

In the operation, endoscope will touch upon the patient's mucous membranes, in order to minimize the risk of virus infection between patients, before and after each using, the videoscope is required to be thoroughly disinfected or sterilized. Before disinfection or sterilization, the videoscope should be cleaned carefully, thoroughly cleaned and microbe and the organic matter, the existence of these substances may limit the effectiveness of disinfection or sterilization. Please read these instructions carefully and strictly follow the cleaning, disinfection and sterilization rules.

1.8 Compatibility

The safety using of videoscope not only depends on videoscope itself, but also depends on other devices and accessories which use with this videoscope. To ensure compatibility with these devices and accessories, we recommend that the company uses only HAWK videoscope and accessories.

1.9 Complete Set

A complete endoscope system includes an videoscope, monitors and accessories Customers who bought this product, please open the packaging carefully and follow the packing list to check each of the sets. Please keep all packing materials in case there is any damage to the claimant's use transportation. If found damaged or missing parts, contact with the company or distributor.

1.10 Label and Symbol description

The Label Symbol Description is listed as below.

Table2:Label and Symbol

Label Icon	Meaning
~	AC Power
Ф	Power supply
0	Turn on (Main power)
I	Turn off(Main Power)
†	Type BF Applied Part
\triangle	"Note"
<u>^</u>	"Warning"
	Fuse
M	Manufacture Date
	Manufacturer and Address
EC REP	European Union representative and Address
	Do not throw into wastebin
$\left(\left(\begin{smallmatrix} \bullet \\ \bullet \end{smallmatrix}\right)\right)$	Non-Ionizing Radiation
5	Back / Convert
MENU	MENU
•	Left
•	Right

	Video
ि	Picture
	Follow instructions for use

1.11 EMC (Electromagnetic compatibility)

1.11.1 Product classification

The device is an engineering medical device, classify according to the standard EN55011 "industrial, scientific and medical (I SM) radio frequency electromagnetic equipment harassment the limits and the method of measurement" standard classification, it is belonging to one group Classification A engineering medical equipment. The meaning of this classification as follows:

- a) One set of equipment is defined as all engineering medical equipment intend to produce coupled RF energy due to play to their own function.
- b) Classification A equipment is defined as the equipment is not used at home and not connected low-voltage power net.

1.11.2 Declaration of conformity

The device is made by Hawk company meet the requirements of EN60601-1-2: 2007.

Table 3:Guidance	and manufacturers dec	laration	- Electromaç	gnetic E	missions
The device is intended for a	use in the eietromagnetic	environmen	nt specified b	elow. Th	e customer or the
user of the Irrigation Aspiration Unit should assure that it is used in such an environment.					
			_	_	

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energrgy only for its internal runction. Therfore its RF enissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The equipment is suitable for use in all facilities, including home and connected
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	directly to the household residential public low-voltage power supply network

Table 4: Guidance and manufacturers declaration: Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment

IMMUNITY test	test level	Compliance level	Electromag etic environmemt - guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kv contact ±8 kv air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile If floors are covered with synthetic material, the relative

Electrical fast transient/burst transient/burst lEC 61000-4-4 supply lines supply lines ± 1 kv for input/output lines ± 1 kV line (s) to line(s) ± 2 kV line(s) to earth ± 2 kV common mode ± 2 kV line(s) to earth ± 2 kV common mode ± 2 kV line(s) to earth ± 2 kV common mode ± 3 kV line(s) to earth ± 4 kV differential mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV common mode ± 4 kV line(s) to earth ± 4 kV differential mode ± 4 kV line(s) to for 0,5 cycle ± 4 kV for power fixed in the fixed of a typical commercial of hospital environment ± 4 kV for input lines ± 4 kV for				humidity should be at least 30%
Voltage dips,shot interruptions and voltage variations on power supply input lines IEC 61000-4-11 $\begin{pmatrix} 0.95\% & \text{dip in } U_{\text{T}} \\ 0.95\% & \text{dip in } U_{$	transient/burst IEC 61000-4-4 Surge	supply lines ±1 kv for input/output lines ±1 kV line (s)to line(s) ±2 kV line(s) to	supply lines ±1 kV for input/output lines ±1 kV differential mode ±2 kV common	Mains power quality should be that of a typical commerdial or hospital environment Mains power quality should be that of a typical commercial of hospital
Power frequency (50/60Hz) magnetic field IEC 61000-4-8 be necessary to position the Ele Pneumatic Lithotriptor image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding The power frequency magnetic field should be measured in the intended installation	interruptions and voltage variations on power supply input lines	$(>95\% \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	$(>95\% \text{ dip in } U_{\text{T}})$ for 0,5 cycle 40% U_{T} (60% dip in U_{T}) for 5 cycles $<70\% \ U_{\text{T}}$ (30% dip in U_{T}) for 25 cycles $<5\% \ U_{\text{T}}$ (>95% dip in U_{T})	a typical commercial of hospital environment If the user of the Ele Pneumatic Lithotriptor image intensifier requires continued operation during power mains interruptions it is recommended that the Ele Pneumatic Lithotriptor Image Intensifier be powered from an uninterruptible power supply or a
NOTE U_T is the a,c,mains voltage prior to application of the test level.	(50/60Hz) magnetic field IEC 61000-4-8	3A/m		be necessary to position the Ele Pneumatic Lithotriptor image intensifier further from sources of power frequency magnetic fields or to install magnetic shielding The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low

Table 5:Guida	Table 5:Guidance and manufacturers declaration Electromagnetic Interference Resistance				
	The Model is intended for use in the electromagnetic environment specified below The customer should assure that it is used in such an environment.				
IMMUNITY test	TEST LEVEL	Compliance level	Electromagnetic environment guidance		

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 3v/m 80 MHz to 2.5 GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of Model 006,including cables,than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $80MHz\sim800MHz$ $d=2.3\sqrt{P}$ $800Hz\sim2.5GHz$ where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufactuer and a is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters,as deter-mined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: $\left(\left(\frac{a}{a}\right)\right)$
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile radios, amateur radio, AM and FM radio bradcast and TV broadcast cannot be predicted theoretically with accuracy To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measuraed field strength in the location in which the Model 006 is used exceeds the applicable RF compliance level above, the Model 006 shold be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 006.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.



- It should need special preventive measures to this device, install and service according to explanation of "EMC".
- Portable and movable RF communication equipment can influent medical electronic equipment.
- In addition to the transducer and cables as spare parts of the internal components sold by manufacturers, it will probably increase eradiation or decrease the interference if using other unspecified accessories, transducer and cable.
- This equipment or system can not be closed or piled up other equipment. If it must

close or piled up to other equipment, it should observe and test the system can be run normally.

• Although the device has been designed to interfere with the protection of such electromagnetic radiation. When it connects with RF surgical set, you should restart the device as soon as electromagnetic interference occurs. Furthermore, If it is still unresolved, please increase the distance with the RF.

1.12 WEEE

The following description conforms to the stipulation of 2002/96/CE which stipulate the measures to deal with such electronic products . Please comply with the WEEE standards when deal with such equipment including it's parts and material.



This label is printed on products, package or instructor manual. This label means this products enters into the market after August 13th,2005. You should deal with each component separately according to local stipulation of waste disposal.

- Mishandling or throwing away this equipment will be harmful to environment or human healthy because this equipment contains special material.
- According to WEEE standard, it must not deal with this equipment like domestic waste, it should be divided and disposaled.
- You can contact local waste disposal collecting department to get detailed information.
- Illegal disposal of waste will be subject to legal sanctions.

2 Products description

2.1 Products list

- 1) Flexible Video- cystoscope
- 2) 3.5" monitor or 8" monitor
- 3) Leakage tester, Cover for gas sterilization, SD card, Cable, AC connector.
- * Our company can configure the instruments according to customers' requirements.
- * The equipment which produced by our company only can use with our original parts and accessories.

2.2 Intended use

An endoscope with a flexible inserted portion intended for the visual examination and treatment of the bladder and the urinary tract. It is inserted into the urethra (the tube that carries urine from the bladder to the outside of the body) through the natural urinary orifice during cystoscopy. Anatomical images are transmitted to the user by a video system with a charge-coupled device (CCD) chip at the distal end of the endoscope and the images showing on a monitor. It is used to examine/diagnose incontinence, the inability to pass urine (retention), recurrent urinary tract infections, and to remove tissue samples/stones/small tumours from the bladder. This is a reusable device.

2.3 Scope of use

This equipment may be used for examination, diagnosis and operation. Do not use this equipment for any other purposes or in any other settings.

2.4 Feature

- 2.4.1 The videoscope has a unique waterproof function, it can be cleaned thoroughly and disinfected. The instrument channel can be cleaned in whole course, so that minimize the risk of infection among patients with each other.
- 2.4.2 There are two directions, up and down direction are controlled by bending wheel.
- 2.4.3 Biopsy forceps, brush can be used.
- 2.4.4 It has fixed focus, large depth of field, wide angle, and get clean image within the range of $3 \sim 50$ mm.



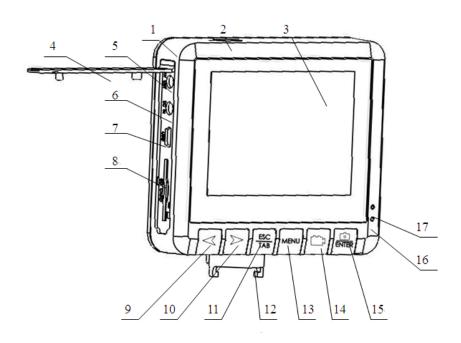
- This equipment is according to the requirement of Application Part of Type BF, it possess Type F isolation suspension application part, and B Type equipment have a specific protective level for shock.
- And protective liquid level is IPX0.
- Clean, disinfect and sterilize this equipment in accordance with the manual.
- This equipment must not be used in setting where gaseous mixture of inflammable anesthesia or nitrous oxide is in use.

2.5 Electrical connections

The input power supply is 100V-240V ~ 50Hz, only connect with a reliable grounding socket.

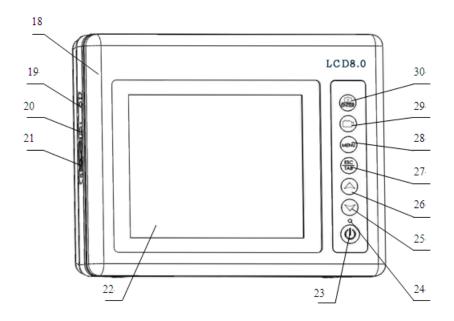
3. INSTRUCTION OF PRODUCT

3.1 3.5" LCD

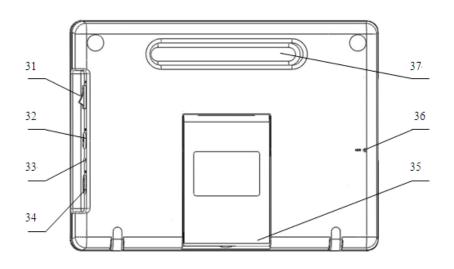


- 1. Housing 2. Power Switch 3. Screen 4. Soft Protect Cover 5. AV output connector
- 6. Power input connector 7. USB connector 8. SD Slot 9. Decrease button
- 10. Increase button 11. Back / switch button 12. Scope Lock 13. MENU
- 14. Video button 15. Photo button 16. Power Indicator 17. Charging Indicator

3.2 8" LCD

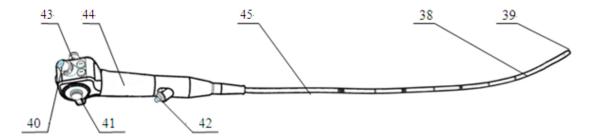


- 18. Housing 19. AV output connector 20. USB connector 21. SD Slot 22. Screen 23. Standby button 24. Power Indicator 25. Decrease button 26. increase button
- 27. Back / switch button 28. Manu 29. Video button 30. photo button



- 34. Power switch 32. DC input connector 33. Charging Indicator
- 34、AV input connector 35、Support 36、Reset hole 37、Handle

3.3 Videoscope



- (43) Leakage connector (44) Operating part (45) Insertion part (38) Bending part
- (39) Distal part: (40) Connector (41) Bending wheel (42)Instruments connector

3.4 Instruction

- 1) Housing
- 2) Power switch: I=ON、O=OFF, Power lamp lights up when the power switch turned on.
- 3) Screen
- 4) Soft protection cover: Protection cover for dust.
- 5) AV output connector: connect AV output cable and output image to TV and monitor.
- 6) Power inpout connector: charge the monitor
- 7) USD connector: transfer image to computer
- 8) SD Slot: insert SD card
- 9) Decrease button: Decrease the parameter and up the menu, review the picture.
- 10) Increase button: Increase the parameter and down the menu, review the picture.
- 11) Back / switch button: switch contrast, brightness, saturation when in adjustment of parameter,

And back function in sub menu display

- 12) Scope Lock: connect and fix videosocope,
- 13) Menu: Display menu, out of menu, delete file
- 14) Video button: start and stop video
- 15) Photo/ confirm button: Take picture and confirm in menu
- 16) Power indicator: Indicator on means working, Indicator off means turn off the device
- 17) Charging indicator: Indicator on means charging, indicator off means full charged

- 18) Housing
- 19) AV output connector: connect AV output cable and output image to TV and monitor.
- 20) USD connector: transfer image to computer
- 21) SD Slot: insert SD card
- 22) Screen
- 23) Standby button: press this button for turn on the device
- 24) Power indicator: indicator on means switch on the device, indicator off means switch off the device
- 25) Decrease button: Decrease the parameter and up the menu, review the picture.
- 26) Increase button: Increase the parameter and down the menu, review the picture.
- 27) Back / switch button: switch contrast, brightness, saturation when in adjustment of parameter,

And back function in sub menu display

- 28) Menu: Display menu, out of menu, delete file
- 29) Video: start and stop video
- 30) Photo/ confirm button: Take picture and confirm in menu
- 31) Power switch: I=ON、O=OFF, Power lamp lights up when the power switch turned on.
- 32) Power input connector: charge the monitor
- 33) Charging indicator: Indicator on means charging, indicator off means full charged
- 34) AV output connector: connect AV output cable and output image to TV and monitor.
- 35) Support
- 36) Reset button: For reset
- 37) Holder: hold monitor
- 38) Bending part: Up and down direction
- 39) Distal part: imager senor and fiber equipped in the device, for provide image and light
- 40) Connector: connect with 3.5' and 8' monitor, transfer power and signal
- 41) Bending wheel: operating bending part
- 42) Instruments connector: for insert instruments
- 43) Leakage connector: leakage test for videoscope when connect with leakage
- 44) Operating part: holder part, include bending wheel, light source and bending system
- 45) Insertion part: insert to human body

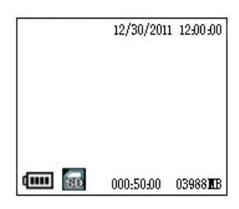
3.5 DVR

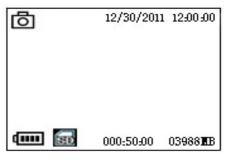
3.5.1 Image display: Turn on the power, the LCD will show our logo

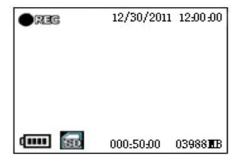
and green indicator in the low right is light. This process takes a few seconds, please wait patiently. After power on, entering the preview mode to show the current image. If shows on the low left of screen, it can take photos and videos. Date and time will show on the top right, video time and capacity show on the low right, electricity capacity and show on the low left.

3.5.2 Take photos: Press enter can take picture and will show on the top left of LCD screen. After about 2 seconds, the icon disappears, the photo files will be saved automatically. The photo resolution can be chosen in the menu as JPG format.

3.5.3 Take videos: Press can take videos and will show on the top left of LCD screen and flashing. Press the button again to stop take video, the video files will be saved automatically. The movie resolution can be chosen in the menu as AVI format.







NOTE

10 minutes, 20 minutes, 30 minutes is supported when capturing video, when the capacity of single file is full, recording will be stopped automatically and record next video file until press video button to stop recording and enter into the preview mode.

- 3.5.4 Adjust parameters of screen: Press back / switch button TAB, there are three optional items: saturation, chromo, brightness, press ➤ and ≺ to decrease and increase value.
- 3.5.5 Main menu: Press the Menu button to enter the main menu in preview mode. There are three sub-menus: Camera, My Files, Setup, press ➤ and ◀ to move yellow strip and select, then press Photo/confirm button ENTER to confirm and enter into sub-menus, press menu button to back main menu and back to preview mode.
- 3.5.6 My Files: After enter into sub-menu of My Files, files name and number of SD card will be showed, press ➤and ≺ button to select,





then press photo/confirm button ENTER to enter into the file, press menu button to back.

3.5.7 Setup: After enter into sub-menu of Setup, There are 6 sub-menus: Video time, storage, Date time, Memory Info,
 LCD Brightness, Language, press ➤and button to select,
 then press photo/confirm

button ENTER to confirm.

1) Video Time: 10Mins, 20Mins, 30Mins can be selected.





2) Storage: Flash, SD Card, we recommend you store photos And videos in SD Card.



Date Time: Date Time stampand Date Time Setup can be selected.



Date time stamp can be selected.



Time can be set, use left and right button to set, and use photo/ confirm button to confirm.



 Memory Info: To record inside memory and SD Memory capacity.



5) Brightness LCD: Seven steps can be selected, use ➤ and ≺ to decrease and increase the brightness.



6) Language: English and Chinese.

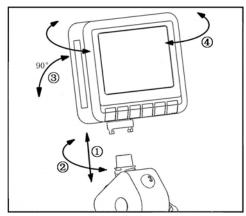


- 3.5.8 Review: In the preview mode, press menu and check photo files and Video file according to 5.i, Press the Menu button to enter the main menu in preview mode, press Photo/confirm button to confirm and play video, press Photo/confirm button or back/switch button to stop playing.
- 3.5.9 Naming Rule: Folder named according to the date, a file named according to the time.
- 3.5.10. Delete Files: Press Menu button to enter into delete menu when single file is displayed, 3 options can be selected: delete all of this, current and cancel, press left and right button to selected. System will inform if file delete or not, select YES means delete all files or current files, if select No, it will back to current file condition. Note: please delete all file before delete this folder. is back single file state. Note: when deleted all files in the folder to delete the folder.

4. OPERATING INSTRUCTIONS

4.1. Preparation before Operation

Aim at red dot of LCD Screen and Video Endoscope, connect them, then screw down lock nut and fix LCD Screen.



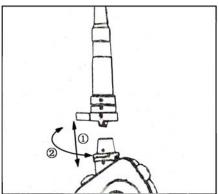


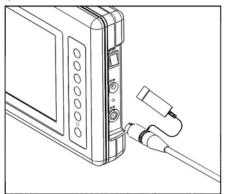
When equip and remove 3.5" monitor, be careful to prevent the fall, fall damaged!

a. Connecting LCD Screen to Video Endoscope:

Aim at red dot of LCD Screen and Video Endoscope, connect them, then screw down lock nut and fix LCD Screen.

And use the cable to connect Monitor 8" with videoscope





b. Inserting SD Card: SD cards face up, inserting SD card into the card slot. After turning on the LCD, When remove the SD card, you can push the SD card, SD card will be popped up, then unplug it.



- It cannot be used with HF hand instruments.
- It cannot be used with laser device.

Do not disconnect all joint in the working condition, otherwise it will damage the device!



NOTE

- SD Card must be inserted before turn on the power on, otherwise, no picture or video can be taken.
- SD card cannot be unplugged when it is in the working condition of videoscope, otherwise the memory files will be damaged, or even damage the SD card.
- When SD card is inserted into SD card slot, will show on LCD screen.
- The amount of photos and videos is based on SD card capacity and the time of the video can be set in the menu. If "Disk Full" shows on the screen when taking picture and capturing video, it means disk is full, files cannot be saved anymore.
- The current photo and video file will not be saved, in case the power is off.
- 4.1.4 If color is not satisfied, please aim the videoscope to the standard color, then adjust parameters of monitor. Usually color has been adjusted to the best condition before out of factory, white balance adjustment is not recommended and do not saving the white balance results. White balance: aim the videoscope at white object at 1 ~ 2CM distance, press and hold the button, observed when the screen

changes to white, and immediately release the button.

4.1.5 Please aim the videoscope at an object (such as your hand), if there is abnormal dot on the monitor screen, blurred images or striped images. If the image is not clear, check the cable connection, or wipe the objective lens with clean gauze moistened with alcohol.

4.2 Checking before Operation

- 4.2.1Inspect and confirm each connection.
- 4.2.2 Carefully wipe the insertion part, the bending part and the distal with alcohol cotton.
- 4.2.3 Check endoscopes and accessories: Before each clinical use, endoscopes and their accessories should be checked in accordance with the following procedure. If you notice a slight defect insertion tube surface, the imaging blur; or when other abnormalities, do not use vidoscope, contact with the company promptly.
- 4.2.3.1 Check the insertion tube
- a) Check if the surface of insertion tube is not smooth, damage and other defects.
- b) Chec if there are any protrusion, internal loose, rough surfaces, sharp edges and other defects.
- 4.2.3.2 Check bending part

Check if there is any damage and other defects in the surface, and check the bending part can be bent successful and also can be reach the maximum bending angle by controling the bending wheel.

- 4.2.4 Checking other parts
- 1) Check if there is any damage at the flexible tube of light guide part (such as cracks, distortion or flattened).
- 2) Please be sure the monitor in right condition



- Before each use, the outer surface of the portions of the ENDOSCOPES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.
- If any deficiency is suspected or confirmed in the device, do not use the device until it has been checked by the authorized se.
- Before each use or after a change of viewing modes / settings, the OPERATOR should check to ensure the view observed through the ENDOSCOPE provides a live image (rather than a stored one) and has the correct image orientation.
- INTERCONNECTIONS CONDITIONS require the APPLIED PARTS of other ME EQUIPMENT used within the CONFIGURATION FOR ENDOSCOPIC APPLICATION to be TYPE BF APPLIED PARTS. And the application of CF part of the equipment can not be used together, otherwise it will cause the application part of CF equipment leakage current exceeds the standard.
- Before each use, Check equipment accessories are used correctly.



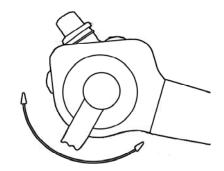
- In order to ensure smooth operation, after each operation, should first visual inspection equipment external mechanical damage and normal work can be, and as far as possible in the operation chamber spare a controller.
- CCD connector and head are vulnerable optical instruments, any curve and collision may cause the breakage of lenses or the deviation of optical axle to result in obscure image. It should pay more attention during using and cleaning this product.
- Do not use CCD camera round the equipment which has high power, or it will interfere with the image.
- Do not face the head of CCD to strong light when operating CCD camera, or it will impair the image quality.

4.3 OPERATION METHOD

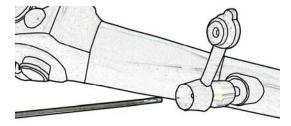


The videoscope operator should study the various clinical factors involved in the process, and to the correctness of the technical details of the program are fully prepared. Examinee should be fully prepared to ensure a smooth check. Inspectors impose appropriate guidance, such as psychological comfort, location and other clinical subjects. Operate the endoscope and all devices work properly.

- 4.3.1 Anesthetized patient: operation can be done after the full functioning of narcotic drugs.
- 4.3.2 Rotate back or forward the handwheel for bending the distal of videoscope



- 4.3.3 Observe the displayed image, at the same time insert videoscope to the body slowly.
- 4.3.4 Fix the forceps connector, then insert biopsy forceps gently.



- 4.3.5 If you need to record the examination or treatment process, you can take pictures or video. Press the photo button on the monitor, confirm or button 1 on the endoscope can take pictures./
 Press video recording button or press the button 2 on video can record video.
- 4.3.6 After each use, turn off the power switch, unplug the monitor cable and remove the endoscope.
- 4.3.7 When the display power is low, use DC5V / 3A power adapter, charging time is approximately5-7 hours after full charge, indicator turn off. After charging, please disconnect the power adapter.Or remove the battery alone charge the battery



Warning

- The operator and assistant should wear rubber gloves.
- Do not look directly at the light emitted by the device, to avoid hurt the eyes.
- Do not operate videoscope for a long time. Since the light emitting lead to high temperatures and light, the patient or operator may hurt, in order to prevent injury, it should not take long observation time of videoscope tip near the mucosa or mucous membrane
- If the device in question is running, the power switch must be turned off immediately, unplug the cable, interrupt the operation. And readjust the device by the technician, if it still have problems, please contact HAWK service department for repair.



Do not bend too hard, if the operator feel the resistance is too large, bending is not in place or cannot bend, the videoscope should be returned for repair.

- Do not adjust the wheel when insertion part in coil condition, to avoid damage the internal parts.
- Do not over force when insert the forceps, if you found large resistance, do not force please identify the reasons or return to factory for repair.
- Do not insert forceps when distal part in coil condition, to avoid damage the internal parts.
- Do not use non-DC5V power adapter to charge the display, otherwise it will damage the monitor.
- Fixed cover for gas sterilization when in long-term storage, and do not bend the insertion part.

5 Reprcessing

5.1 Reprcessing

- a) Please refer to HAWK's REPROCESSING MANUAL as attached-
- b) information if product need special treatment before reprocessing.

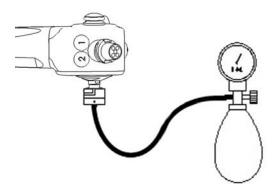
5.2 Checking

5.2.1 Leakage Test

Connect the connector of leak detector to connector of endoscope, aiming red point of connector of leak detector to red point of connector of endoscope, and then press the connector down, the leak detector is fixed on the endoscope. Adjust pressure gage to 22Kpa and last 30 seconds, if the change of index of pressure gage is not significant, only change in the two grid, that means tightness of endoscope is good. If the connection is bad, it will not generate pressure inside of the endoscope, thus it is impossible to test leakage. Please do not use the device and contact with us. See picture 11. After leakage, please release the pressure and take off the leakage measure, if not, may damage the inner parts.



- Please test leakage before using this product. Please do not use this device if the airproof is not good.
- Please check if any parts is damaged before using this products



5.2.2 About device

A regular annual inspection of equipment is proposed. The device should be checked by the designated or trained qualified personnel. If the device needs to be calibrated, it must be calibrated by the designated or trained qualified personnel.

- Check indicator of the power of monitor works normally.
- Check if output of image works normally
- Check if the adjustment of other function works normally.
- Check if the wheel can control the bending effectively.

5.2.3 Maintenance Interval

For the safety of patients, users and third-party, follow the correct maintenance interval is very important. Recommendation of maintenance intervals of the device are:

Monitor: one time in one year Videoscope: one time in one year



- If in your countries and regions have legal provisions for maintenance interval, you should comply with this requirement.
- If you try to open it, the product warranty will be canceled.

5.3 Malfunction and solution

If you have a problem with this machine, first check the power cable and all other cable connections. Then go through the following list before you call for service. If the problems still exit, turn off the device and move monitor from the videoscope, and contact local service technician or appointed HAWK service facility.

5.3.1 Monitor

Phenomenon	Reason	Corrective actions
Indicator of power light off	Power supply does not turn on	Turn on power supply
The output image	The connector of monitor is loose	Fix monitor again
is not clear.	Cable is loose	Fix cable again
	Power supply does not turn on	Turn on power supply
No image and	Cable is loose	Fix cable again
light	Power of monitor is not enough	Try again after charging
	SD card does not inserted	Insert again
Can not take picture and video	SD card is full	Use new card and delete file
	SD card is locked	Unlock SD card
	Button does not work	Please contact service department.

5.3.2 Videoscope

Phenomenon	Reason	Corrective actions
The output image	Objective lens is fuzzy	Clean the mucous membranes and other attachments on the objective lens by water or cotton
is not clear.	Water droplets or color bar is found in the Field	Stop use; please send it to service department.
Bending is not	The value of bending angle under than standard value Pull rod bending the Clearance in bending wheel Resistance of bending wheel is normal	Stop use; please send it to service department.

If the device doesn't work after you do above corrective actions, please hand this device to HAWK service and the device must conform to the following requirements.

- It should clean and sterilize the device before packing it.
- This device is a precision device, please use strong and shock-proof package to avoid the damage in the conveyance.
- Please writing the Symptoms of malfunction. If you have any other requirements, please contact HAWK service.

6. Appendix

6.1 Technical Specifications

Monitor 3.5"	
Resolution	960×240
Storage	SD Card
Inner power supply	3.7V / 3600mAh battery
Continuous working time	≥4 hours
Size	100×89×28 (mm)
Monitor 8"	
Resolution	800×600
Storage	SD Card
Inner power supply	4 pieces battery (18650) Recommended capacity 2200mAh one battery
Continuous use	≥4 hours
Size	280×210×50(mm)
Videoscope	
Image sensor	1/10" CMOS

View of filed	110°
Diameter of distal part	Fr 17.3
Diameter of insertion part	Ф5.7mm
Instruments channel	Ф2.2mm
Working length	380mm
Depth	3——50mm
Bending angle	Up 210° / down120°
Running environment	Temperature: +10°C to +40°C Humidity: 30 - 75% Pressure: 700 - 1060hPa.
Storage and transportation environment	Temperature: -40°C to +55°C Humidity: ≤ 95% Pressure: 500 - 1060hPa