HERizon™

Medical Endoscope Image Processing System with Disposable Electronic Hysteroscope

Operator's Manual

minerva®
The Uterine Health Company

Table of Contents

About this Manual

This manual provides information on how to operate and maintain the HERizon Medical Endoscope Image Processing System. It is essential to read and understand all the information in this manual before using the system. Pay attention to all warnings, contraindications, precautions and adverse events in this manual and other related materials. Failure to thoroughly understand and follow all instructions may result in harm to the patient or user of the system.

Reuse Warning

The HERizon Disposable Electronic Hysteroscope is supplied STERILE using Ethylene Oxide. Do not use if sterile barrier is damaged. If damage is found, call your Minerva Surgical representative.

The HERizon Disposable Electronic Hysteroscopes are for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may result in patient injury, illness or death.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Device Description

The HERizon Medical Endoscope Image Processing System consists of the following procedural components:

- HERizon Medical Endoscope Image Processor (Catalog # JY-MIP-1000)
    - HDMI Cable
    - Power Cord
- HERizon Disposable Electronic Hysteroscope (Catalog # JY-DEH-001)

Intended Use/Indications for Use

The HERizon Medical Endoscope Image Processing System with HERizon Disposable Electronic Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

Recognized indications for diagnostic hysteroscopy include:

- Abnormal uterine bleeding
- Infertility
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain
- Retained products of conception
- Other

Contraindications

This product is not suitable for use in patients with the following conditions:

- acute pelvic inflammatory disease
- known or suspected pregnancy

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- inability to distend the uterus
- cervical stenosis
- cervical/vaginal infection
- uterine bleeding or menses
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication or intolerance to anesthesia

Warnings/Precautions

- Do not attempt to disassemble the Image Processor and/or Hysteroscope. Do not attempt to open, or gain access into, the Image Processor. Doing so may result in electronic shock.
- Handle the image processor and Hysteroscope with care.
- This system cannot be used with high frequency equipment or laser equipment.
- The system does not interfere with other electromagnetic equipment in normal use. If the operating frequency of other equipment is similar to that of the system, it is recommended to maintain a large separation distance.
- If the hysteroscope does not function properly, replace it with another properly functioning hysteroscope.
- The hysteroscope and accessories must be checked for rough surfaces, sharp edges or protrusions that may cause injury before each use.
- During normal use, the temperature of the hysteroscope should not exceed 41℃. If an abnormally high temperature is suspected, dispose of the hysteroscope and replace it with another one.
- Do not look straight into the hysteroscope lens as it may cause eye damage from the light source.
- Before each use or after changing the viewing settings, the operator should check to ensure that the view observed through the endoscope provides a real-time image (instead of a stored image) and that the image orientation is correct to prevent potential patient injury.
- During normal use, the medical endoscope image processor does not produce waste or residue. When the product reaches the end of its service life, dispose of the device in accordance with medical device waste regulations. This is to prevent any potential reuse of the materials and to minimize the risk of environmental pollution.
- The Image Processor may be used together with other medical electronic equipment. To avoid potential safety hazards, it is recommended to follow the surgical operation guidelines, use and precautions for safe use of other medical surgical equipment.
- it is recommended to use read-write protection software when using an external storage device (UDisk. USB flash drive, etc.) to copy data, in order to prevent the external storage device's data from being accessed without consent.
- When the external storage device is used for obtaining data from the image processor, an appropriate antivirus software program should be used to check for and remove any potential software virus prior to use with the Image Processor.
- Before use, perform a white balance and make the proper adjustments to the image on the screen.

- Before each use or after changing the viewing settings, the operator should check to ensure that the view observed through the endoscope provides a real-time image (instead of a stored image) and that the image orientation is correct to prevent potential patient injury.
- Users should maintain and securely position the Medical Endoscope Image Processor in a stable position, while also ensuring proper ventilation and protection against moisture and dampness.
- When not in use, it is recommended to store the Medical Endoscope Image Processor in the original packaging.
- The Medical Endoscope Image Processor should not be subjected to any sharp or blunt force impact.
- Do not place the Medical Endoscope Image Processor and the Disposable Electronic Hysteroscope in environments with high temperatures, humidity, dust, direct sunlight or corrosive gases and/or fluids.
- Only personnel who have been trained or whose knowledge and practical experience are sufficient to ensure correct operation should operate and use this system.
- Only those who have read the appropriate Operator's Manuals and/or IFUs (Instructions for Use) and know the correct use of the system and accessories can operate it.
- If this system is to be used with other equipment, the user should consult applicable IFUs and receive appropriate training on the use of the equipment and use it strictly in accordance with its IFU.
- This product is by prescription only.
- The Image Processor is nonsterile and reusable.
- The disposable electronic hysteroscope is ethylene oxide (EO) sterilized and for single use only.
- This system can only be used with compatible accessories as defined by the manufacturer.
- Do not use the System near or in a Magnetic Resonance (MR) environment.
- Ensure that this system is checked for safety before use each time.

Adverse Events

Potential complications of continuous flow hysteroscopic surgery include:

- Anesthesia-related; adverse reaction or over-medication
- Uterine perforation
- Damage to Adjacent Organs
- Cervical tear/injury
- Bleeding
- Endometritis
- Urinary tract infections
- Infection, sepsis
- Nausea, vomiting
- Pelvic cramping, abdominal pain
- Cervical stenosis
- Hematometra
- Dysmenorrhea
- Dyspareunia
- Uterine synechiae (Asherman's syndrome)
- Vaginal discharge
- Fluid overload
- Electrolytic imbalance
- Rupture/obstruction of the fallopian tube
- Hyponatremia

- Hypothermia
- Pulmonary edema
- Cerebral edema
- Idiosyncratic reactions
- Dehydration
- Over-pressurization/over-fill the cavity
- Biohazard exposure to tissue, blood, fluid
- Under-filled cavity
- Loss of visualization
- Incorrect distention media used
- Kinked tubing, leaks in tubing/system
- Inability toseal the uterine cavity
- Air embolism
- Damage to healthy tissue

Environmental Protection

Follow local governing ordinances and hospital practice regarding the disposal of the HERizon Disposable Electronic Hysteroscope.

The System contains an electronic printed circuit assembly. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional policy relating to obsolete electronic equipment.

The Service Life of the Image Processor is 5 years. The Shelf Life of the Disposable Hysteroscope is 3 years.

How Supplied

DO NOT USE IF PACKAGE IS OPENED OR DAMAGED. **DO NOT** USE IF LABELING IS INCOMPLETE OR ILLEGIBLE.

HERizon Medical Endoscope Image Processor

The Image Processor is supplied in a semi-ready-to-use state. The Shipping Box contains:

- One (1) Image Processor
- One (1) Power Cord
- One (1) HDMI Cable
- One (1) Storage Case
- One (1) HERizon eIFU Insert

HERizon Disposable Electronic Hysteroscope

The Disposable Electronic Hysteroscope is supplied sterile and is intended for single use. The shelf box contains:

- One (1) Disposable Electronic Hysteroscope
- One (1) HERizon eIFU Insert

Compatibility

The HERizon Medical Endoscope Image Processor (Catalog # JY-MIP-1000) is only compatible with the HERizon Disposable Electronic Hysteroscope (Catalog # JY-DEH-001).

The HERizon System can be used in conjunction with a variety of optional accessories. The HERizon Disposable Hysteroscope working diameter has an inner diameter of 6 Fr. Additional accessories may be used which are compatible with this size of a working channel, such as:

- HERizon Disposable Endoscopic Forceps – Biopsy (Catalog # JY-PK-350-18-S)
- HERizon Disposable Endoscopic Forceps – Foreign Body Grasper (Catalog # JY-C-350-18-S)
- HERizon Disposable Endoscopic Forceps – Alligator (Catalog # JY-CC-350-18-S)
- HERizon Disposable Endoscopic Forceps – Alligator XL (Catalog # JY-CC-450-18-S)
- HERizon Disposable Endoscopic Forceps - Inverted Tooth (Catalog # JY-DC-350-18-S)
- HERizon Disposable Endoscopic Scissors (Catalog # JY-JD-17-350-B)
- HERizon Disposable Endoscopic Scissors XL (Catalog # JY-JD-17-450-B)
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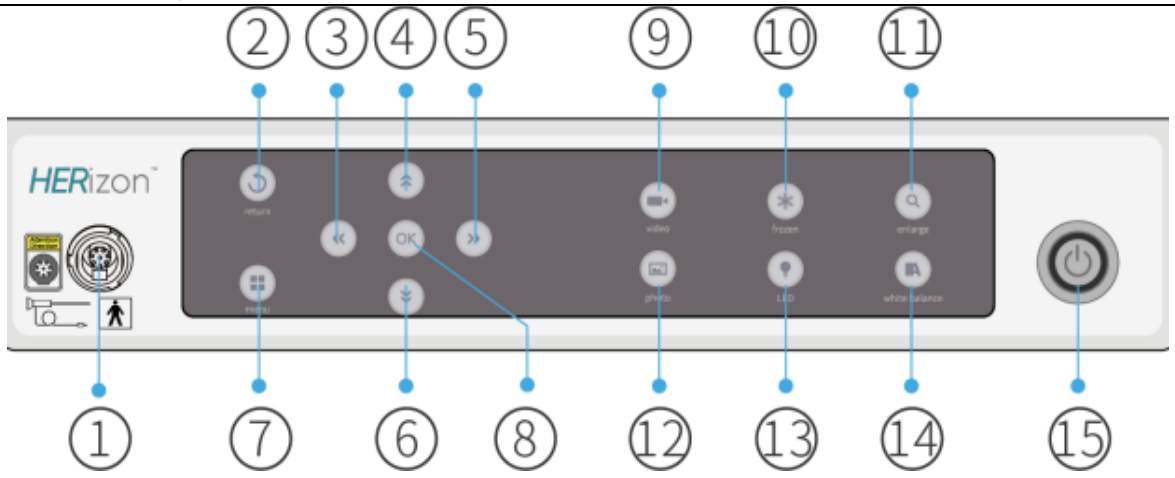
Recommended technical parameters for monitor, minimum requirements:

- Monitor larger than 10 inches
- Screen resolution 720p
- With CVBS or HDMI interface
- Color space: sRGB 115% (range), sRGB 99% gamut (Coverage)
- Contrast: ≥ 700:1
- Meet IEC 60950-1-2013 criteria

IMPORTANT: In addition to these instructions, follow the instruction manuals or IFUs of the products used in conjunction with this product. Refer to the accessory specific Instructions for Use. See www.minervasurgical.com/IFU_Symbol-Glossary for additional information.

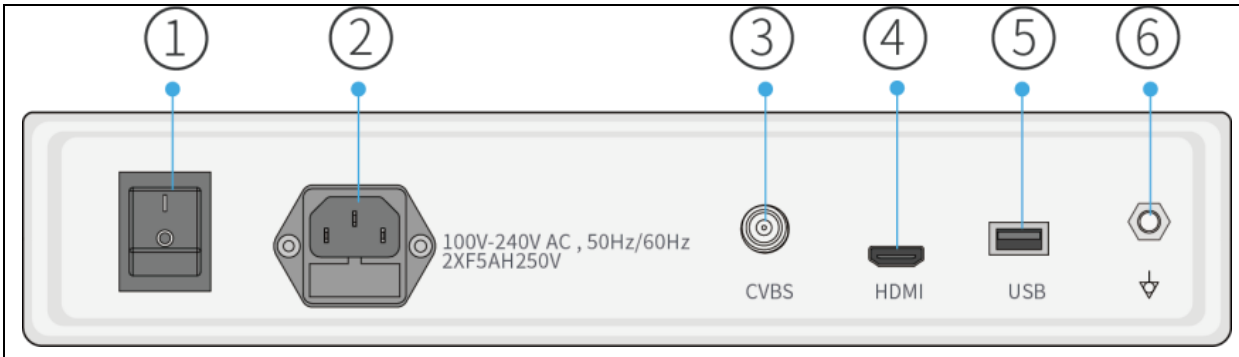
System Components



Item Descriptions		8	OK Button
1	Signal Input Interface	9	Video

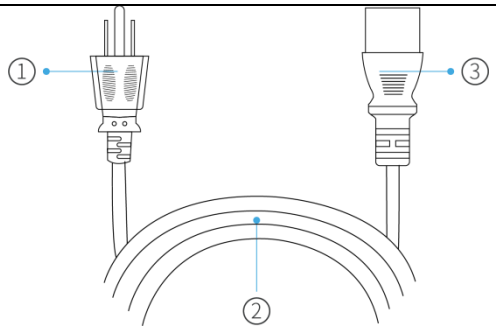
2	“Return” Menu Return Key	10	”Frozen” - Still Frame Feature
3	Direction Key – Left	11	“Enlarge” - Zoom In/Out
4	Direction Key – Up	12	“Photo” - Image Capture
5	Direction Key – Right	13	“LED” - Brightness
6	Direction Key – Down	14	White Balance
7	Menu	15	Stand-by Button

FIGURE 1:IMAGE PROCESSOR FRONT PANEL



Item Descriptions			
1	Power Switch	4	HDMI Output Interface
2	Power Input	5	USB Storage Interface
3	CVBS Output Interface	6	Equipotential Grounding

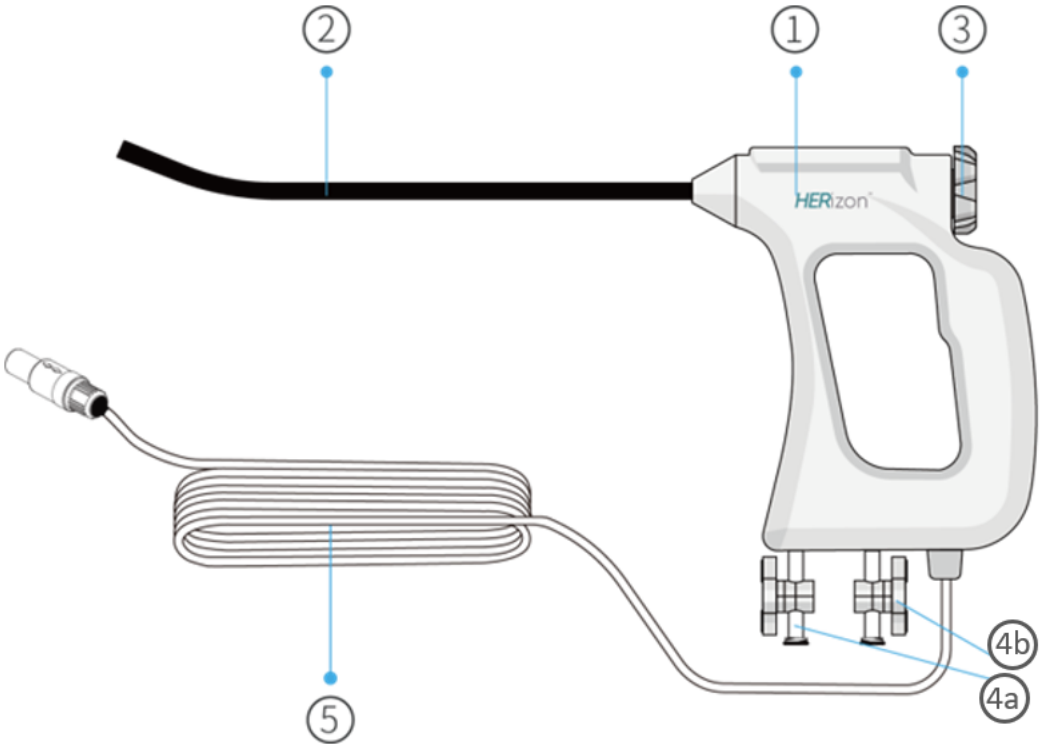
FIGURE 2: IMAGE PROCESSOR REAR PANEL



If lost or damaged, please use an equivalent medical grade power cord. Replacement power cord should have withstand voltage 300V, 3 core 1m²-16 AWG, length 5 ft, in line with UL 62:2018 certification.

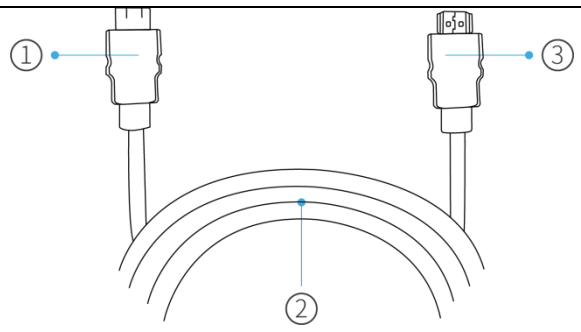
Item Descriptions	
1	NEMA 5-15P Connector
2	5 Ft (1.5 m) Power Cord
3	IEC 60320 C13 Connector

FIGURE 3: IMAGE PROCESSOR POWER CORD



Item Descriptions			
1	Handle	4a	In-flow Valve
2	Insertion part	4b	Out-flow Valve
3	Operation port	5	Endoscope power cord

FIGURE 4: HERIZON DISPOSABLE ELECTRONIC HYSTEROSCOPE



ID	Item Description
1	HDMI Connector (male)
2	5 Ft (1.5 m) Length
3	HDMI Connector (male)

FIGURE 5: HDMI CABLE

System Set Up

Note: Before use, remove the Disposable Electronic Hysteroscope from the packaging.
Note 2: Set date and time on the image processor to local time zone. Refer to Settings and Features section below.

1. With the supplied power cord, connect the IEC 60320 C13 Connector (Figure 3, ID 3) into the power input port (Figure 2, ID 2) on the rear of the image processor. Plug in the unit into the mains supply.
2. Connect the Image Processor (Figure 2, ID 4 or ID 3) to the monitor with a HDMI (or CVBS) cable. Turn on monitor.
3. Turn the power switch (Figure 2, ID 1) on the back of the image processor to ON (the standby button (Figure 1, ID 15) on the front of the image processor will be blue).
   Press the standby button (Figure 1, ID 15) on the front panel of the imager processor and it will turn green.
4. Following standard sterile practices, open the Tyvek lid of the Hysteroscope packaging. Remove and discard protective packaging insert holding hysteroscope in place.
5. Remove the hysteroscope from tray packaging. Insert the hysteroscope cable into the signal input interface (Figure 1, ID 1) on the front panel of the image processor as depicted in Figure 6. **Ensure that the notch on the connector is oriented in the 6 o'clock position, notch is downward.**

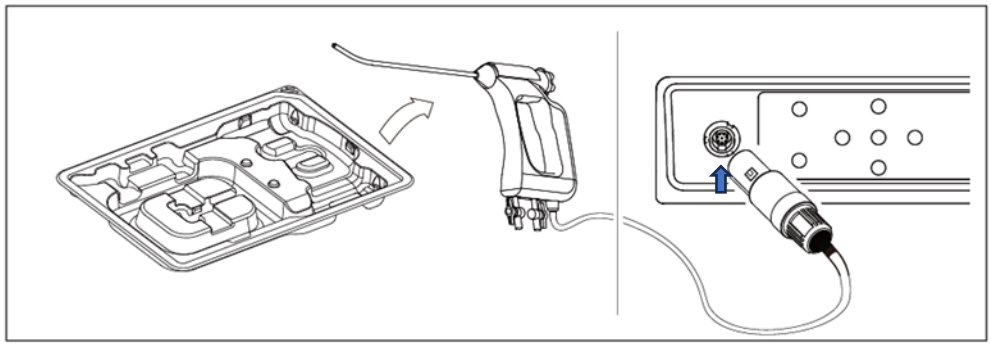


FIGURE 6: DISPOSABLE ELECTRONIC HYSTEROSCOPE CONNECTION TO IMAGE PROCESSOR

6. Connect the distal tip of the distention fluid tubing to the inflow port (Figure 2, ID 4a).
7. Connect the distal tip of the outflow fluid tubing to the outflow port (Figure 2, ID 4b).
8. Close the inflow and out flow valves (Figure 4, ID 4a and 4b) by rotating each valve 90 degrees so it's perpendicular to the tube.

FIGURE 7: IN-FLOW AND OUT-FLOW IN CLOSED POSITION

System Operation

Note: Before use, remove the Disposable Electronic Hysteroscope from the packaging. Note: When finished, turn off the powers supply and then disconnect the hysteroscope cable from the Image Processor. Failure to follow this sequence may cause an error.

1. Once powered on, the home screen should appear on the Monitor, Figure 8, and then the password screen will appear immediately after.

FIGURE 8: IMAGE PROCESSOR HOME SCREEN

2. The default password, 123456, will be prepopulated into the password field (Figure 9) on the password screen. NOTE: To change password, refer to Settings and Features section below.
3. Confirm the "Remember Password" is checked, if its preferred not to reenter the password upon next system start up. To check and uncheck the "Remember Password", select the "Enlarge" button (Figure 1, ID 11)  on the image processor. Navigate through the numerical pad using the Direction Keys (Figure 1, ID 3, 4, 5 and 6) to select the" Enter" button  , press OK on the image processor.

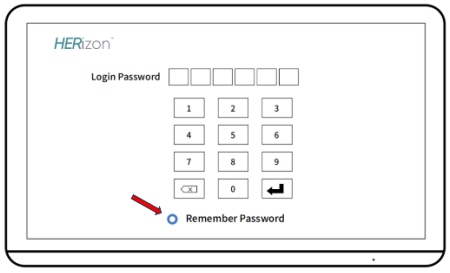


FIGURE 9: PASSWORD SCREEN

4. With the Distention Fluid and Outflow Tubing attached to the inflow and outflow port, respectively; turn open the in-flow valve (Figure 4, ID 4a) to initiate the distention media flow.
5. With the distention media flowing and under direct visualization, gently insert the tip of the hysteroscope into the endocervical canal and advance into the uterine cavity.
6. Obtain adequate distention of the uterine cavity.
   NOTE: Distention pressure and visualization may be adjusted by toggling the inflow and outflow valves (Figure 4, ID 4a and 4b), as needed.
7. Assure adequate clarity of the uterine cavity by opening the out-flow valve.

8. Maintain adequate distention of the uterine cavity by keeping the outflow valve in the semi-closed position.
9. Evaluate the uterine cavity for pathology, take images as/if needed according to the steps described in this document. If removal of polyps, endometrial biopsy or other procedures are considered, insert the appropriate instruments through the working channel of the hysteroscope.
   NOTE: Refer to the Settings and Features section below for instructions on capturing images and videos.

   NOTE : All procedures should be performed under adequate visualization. Do not perform if not achieved.

   NOTE: If the size of the removed tissue is too large to fit through the working channel of the hysteroscope, pull the tip of the device (i.e. grasper, other) to the distal tip of the hysteroscope, and while maintaining it in this position, withdraw the hysteroscope and the device simultaneously from the uterine cavity.

10. The distal end of the insertion portion of the hysteroscope can be rotated by adjusting the operation port (Figure 4, ID 3) up to 180 degrees clockwise or counterclockwise. When the neutral indicator line on the operation port is positioned at the 12 o'clock position, the scope tip is also facing towards the 12 o'clock position (Figure 10).

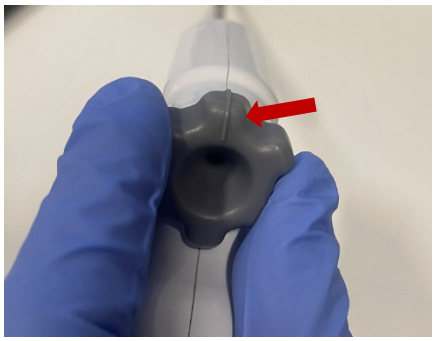


FIGURE 10: OPERATION PORT IN THE NEUTRAL POSITION

11. Upon completion of the procedure, remove the hysteroscope from the uterine cavity, turn off the power supply and then disconnect the hysteroscope cable from the Image Processor. Failure to follow this sequence may cause an error.
    NOTE: Do not remove the Hysteroscope cable from the image processor by pulling on the cord. The Hysteroscope connector locks in place and may only be removed if the gray portion of the connector is pulled.

Settings and Features

White Balance Feature

When the Hysteroscope is used, the image can be displayed by the Image Processor onto the monitor. First, aim the distal end of the hysteroscope at a piece of white paper or gauze (Figure 11) and press the "White Balance" button on the image processor (Figure 1, ID 14) to adjust the color. 'AWB OK' will appear in the upper right corner on the screen (Figure 12).

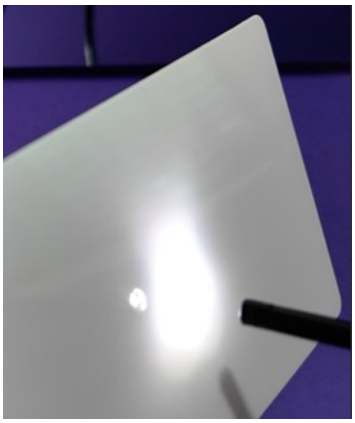


FIGURE 11:ADJUSTING THE WHITE BALANCE WITH WHITE PAPER

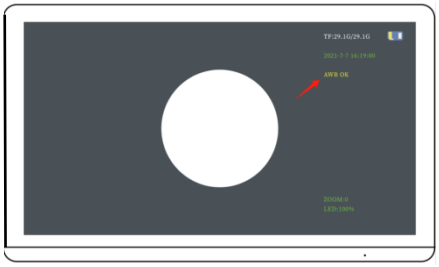


FIGURE 12: ADJUSTING THE WHITE BALANCE WITH WHITE PAPER

Enlarge (Zoom) Feature

The image size can be controlled with the "Enlarge" button on the image processor (Figure 1, ID 11). Select the Enlarge button until the desired magnification is achieved. There are 4 modes: ZOOM0 (Default), ZOOM1, ZOOM2, ZOOM3, in which the image progressively zooms in to increase the size. The current zoom mode is displayed on the monitor (Figure 13).

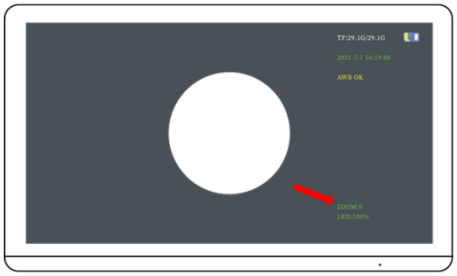


FIGURE 13: ZOOM

LED (Brightness) Feature

The brightness of the image can be adjusted by pressing the LED button on the image processor (Figure 1, ID 13). Press the LED button until desired brightness is achieved. There are five brightness levels in which the image gradually decreases in brightness: 100% (Default), 75%, 50%, 25%, and 0%. The Brightness level is displayed on the monitor (Figure 14).

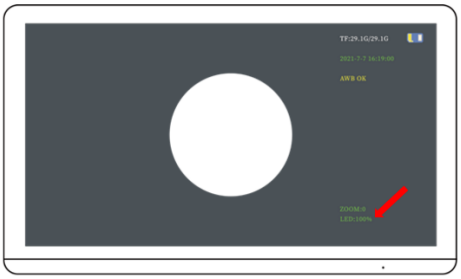


FIGURE 14: LED BRIGHTNESS

Frozen (Still-Frame) Feature

A snapshot or a still-frame of the image can be obtained by pressing the Frozen button on the Image Processor (Figure 1, ID 10). The frozen image will appear on the monitor (Figure 15). To remove the frozen image from the monitor, press the Frozen button again.

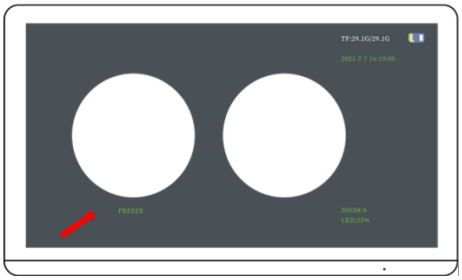


FIGURE 15: STILL FRAME IMAGE

Photo (Image Capture) Feature

The image may be captured by pressing the Photo button on the image processor (Figure 1, ID 12). The image is automatically saved in File Management. File name will be displayed on the monitor (Figure 16). See *File Management* section for instructions on how to access saved images and video.

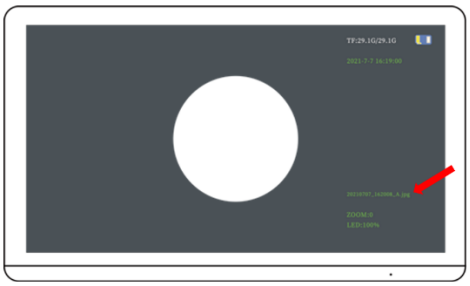


FIGURE 16: IMAGE CAPTURE

Video Feature

A recording of the image being observed on the monitor will start by pressing the Video button on the Image Processor (Figure 1, ID 9). Stop the recording by pressing the video button a second time. The image is automatically saved in File Management. File name and video duration will be displayed on the monitor (Figure 17). See *File Management* section for instructions on how to access saved images and video.

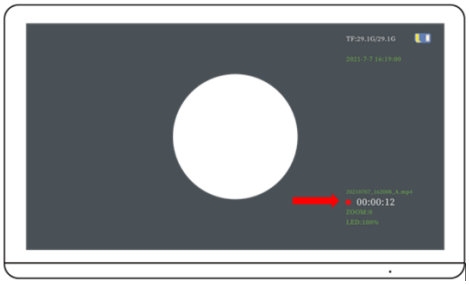


FIGURE 17: VIDEO RECORDING

Cut Type (Display Window)

To change the shape of the displayed image, press the menu button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select the Cut Type option (Figure 18) by pressing OK on Image Processor (Figure 1, ID 8). Select from either a Round (Default) (Figure 19) or Octangle (Figure 20) display window shape and press OK.

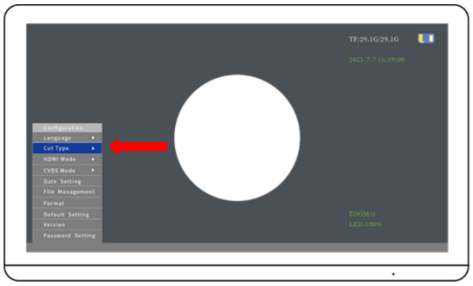


FIGURE 18: CUT TYPE SETTING

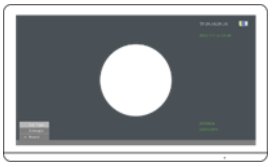


FIGURE 19: ROUND

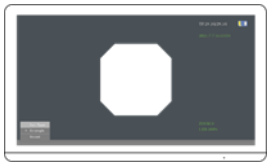


FIGURE 20: OCTANGLE

HDMI Mode

To change the HDMI mode (image resolution), press the Menu Button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select the HDMI Mode option (Figure 21) by pressing OK on Image Processor (Figure 1, ID 8). Select from the following modes by pressing OK:

- 1080@60Hz
- 1080@50Hz

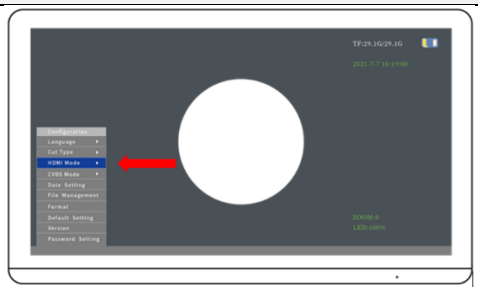


FIGURE 21: HDMI SETTING

- 720P@60Hz (Default)
- 720P@50Hz

Date Setting

To adjust the date and time, Press the Menu button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select the Date Setting option (Figure 22) by pressing OK on Image Processor (Figure 1, ID 8). Using the Directional Keys on the Image Processor, adjust the date and time as desired (Figure 23). Press OK when the desired Date/Time is set.

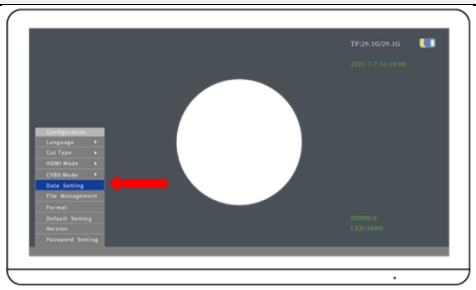


FIGURE 22: DATE SETTING

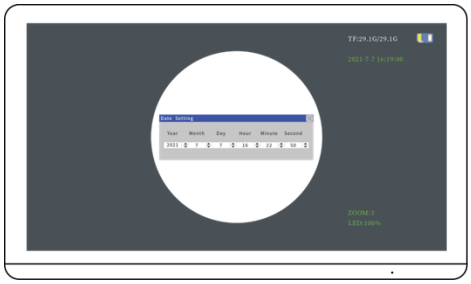


FIGURE 23: DATE/TIME TABLE

Format

To format the saved images (to delete all files), press the menu button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select Format option (Figure 24). Confirm the action by selecting YES in prompt. Cancel by selecting the Cancel button in prompt. See Figure 25. Note: TF Card is the File Storage Card.

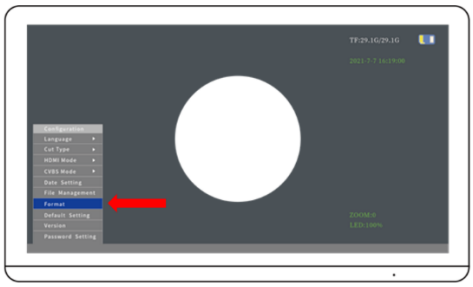


FIGURE 24: FORMAT SETTING

FIGURE 25: FORMAT PROMPT

Default Setting

To restore all settings back to the original factory settings, press the menu button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select Default Settings (Figure 26). Password screen will reappear. Re-enter password. Confirm the action to restore factory settings by selecting YES in prompt, press OK. Cancel by selecting the Cancel button in prompt, press OK. See Figure 27. Password screen will appear. If you selected "Remember Password" during the initial logging in, click OK Button (Figure 1 ID 8) . If you didn't select "Remember password", you'll need to enter your password.

Note 1: When resetting the image processor to original factory settings, enter the default password (123456). To check and uncheck the "Remember Password", select the "Enlarge" button (Figure 1, ID 11) on the image processor. Navigate through the numerical pad using the Direction Key (Figure 1, ID 3, 4, 5 and 6) to select the" Enter" button , press OK.

Note 2: Saved files in File Management will not be deleted when restoring to original factory settings.

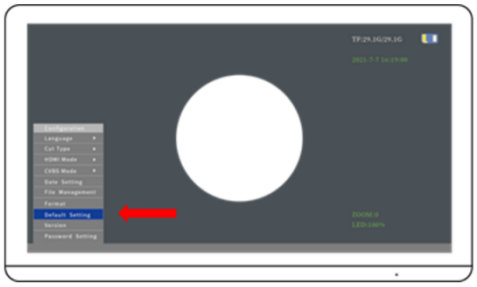


FIGURE 26: DEFAULT SETTING

FIGURE 27: DEFAULT SETTING PROMPT

Password Reset

To change the password, press the menu button on the Image Processor (Figure 1, ID 7). Navigate through the menu options using the Direction Key Up and Down (Figure 1, ID 4 and 6). Select Password Setting option (Figure 28) by pressing OK. The change password screen will appear (Figure 29). Using the Directional Keys (Figure 1, ID 3, 4, 5, and 6), Enter the current password. If current password is unknown, the default password may be entered. Select the enter button on

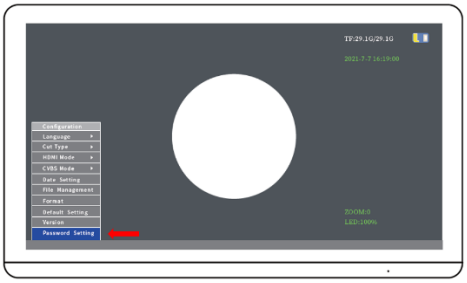
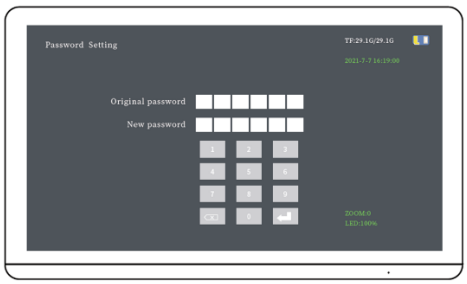


FIGURE 28: PASSWORD SETTING

the numerical pad, press OK. Enter the new Password. Select the enter button on the numerical pad, press OK. Note: The default password (123456) cannot be entered as the “New Password”.	 FIGURE 29: CHANGE PASSWORD SCREEN

File Management

File Management stores images and videos for export to an external storage device through the USB Connection.
To access File Management, press the Menu button on the Image Processor (Figure 1, ID 7).
Navigate through the Menu Options using the direction Key Up and Down (Figure 1, ID 4 and 6).
Select File Management (Figure 30), press OK (Figure 1, ID 8).

Password screen will appear. If you selected "Remember Password" during the initial logging in, click OK Button (Figure 1 ID 8) to go directly to File Management. If you didn’t select "Remember password", you'll need to enter your password.

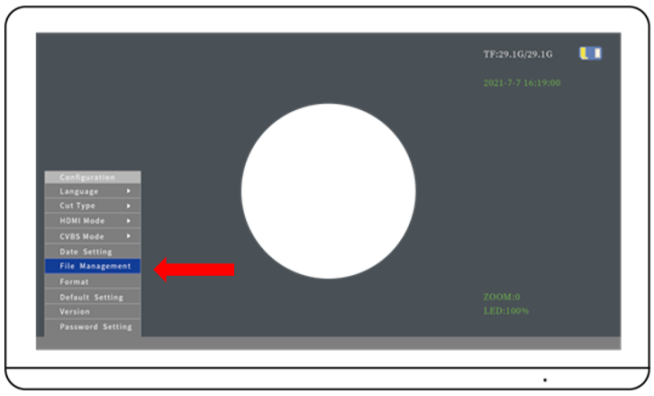


FIGURE 30: FILE MANAGEMENT MENU OPTION

File folders in File Management are organized by date (Figure 31).

FIGURE 31: FILE FOLDER SCREEN

Each image/video (Figure 32) saved in file management will be contained within the folder labeled with the date the image/video was captured. Navigate through the subfolder/files using the Direction Keys (Figure 1, ID 3, 4, 5 and 6). Each file will be automatically labeled with the date and time (YYYYMMDD_HHMMSS) in jpg and mp4 formats. Select the desired image/video to be exported to external storage drive (UDisk, USB flash drive, etc.) by pressing OK (Figure 1, ID 8).

FIGURE 32: FILE SCREEN

To delete or export (copy) file, press Menu button (Figure 1, ID 7). The Image Processor will provide a prompt (Figure 33) to user with the following options:

- Delete this file, Yes
- Copy this file to udisk (external storage device with USB connection), Yes
- Cancel

Navigate through the options using the Direction Keys (Figure 1, ID 3, 4, 5 and 6). Press OK (Figure 1, ID 8).

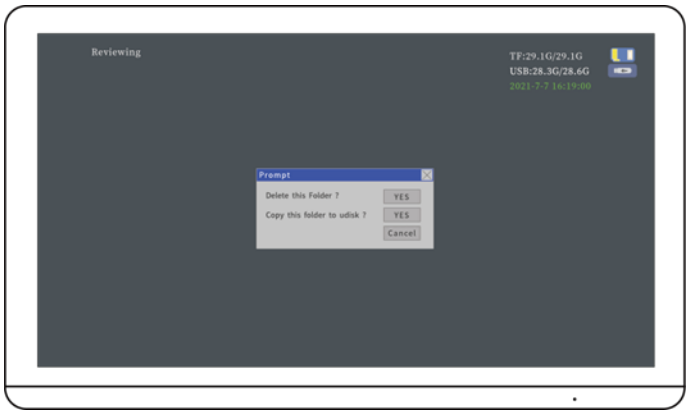


FIGURE 33: FILE ACTION PROMPT

Cleaning

Follow Standard Hospital Procedures for Cleaning.

The Medical Endoscope Image Processor is supplied non-sterile and is not intended to be sterilized by the user. It should be cleaned after each use by using a clean, damp cloth moistened with a mild hospital-grade disinfectant (such as, isopropyl alcohol, 1.5% hydrogen peroxide or a mild bleach solution), followed by wiping its surface with a well-absorbent dry cloth. When not in use, cleaning of the device is recommended to be performed once every 3 months.

Do not use diluent, alcohol, gasoline or other chemical reagents to clean the device.

Storage and Handling

The HERizon Medical Endoscope Image Processor and Disposable Electronic Hysteroscope are designed to be transported and stored in an environment that is kept within the conditions as defined in Table 1 below.

TABLE 1: STORAGE CONDITIONS

Temperature	14°F to 113°F (-10°C to 45°C)
Relative Humidity	30% to 75% RH non-condensing
Atmospheric Pressure	70 to 106 kPa
Other	In a dry and low-dust room without corrosive substances

Maintenance, Repair, and Troubleshooting

Routine Maintenance

There is no required maintenance of the Disposable Electronic Hysteroscope. It is supplied as a single-use sterile device.

There is no required maintenance of the image processor.

The user should examine all connection interfaces and accessories of the image processor for excessive wear or damage.

The power and video cables are detachable components. If these components are damaged and require replacement, only use matching and qualified products.

NOTE: Field Service is not available; all repairs are done at the manufacturer.

Replacing a Fuse in the Image Processor

In the event of a blown fuse, only F5ah250v Fuse should be used as replacements. Even if the image processor has no fault, the fuse may blow after long-term use. When the device is turned on but does not respond, there is the potential that the fuse is damaged. Fuse replacement must be completed by qualified personnel. Contact a Minerva Surgical Sales Representative or Customer Service for additional support.

Turn the power off and disconnect the power cord from the Electrical outlet. The fuse holder can be opened with a slotted screwdriver. Remove the fuse from the fuse holder and replace with new fuse. Push the fuse holder back to its original position, see Figure 32.

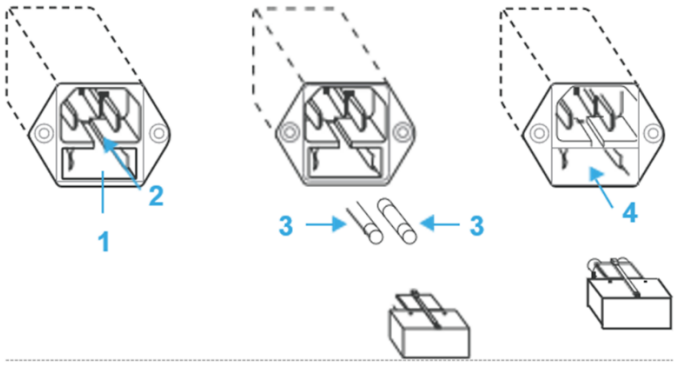


FIGURE 34: REPLACING THE FUSE

Software Security

- The Image Processor has no network connectivity ability, wired or wireless.
- If an applicable software update is available, you will be contacted by a Minerva Surgical representative. Software updates are to be performed on site at the manufacturer.
- Do not attempt to access, tamper with, or otherwise make any software modifications. Doing so will void the warranty and may cause the image processor to become unresponsive.
- When the Image Processor is not in use, ensure that it is physically secured to prevent potential tampering.

Repair

Field Service is not available; all repairs are done at the manufacturer. Contact Minerva Surgical Customer Service for support. Any repairing and handling of the system by unauthorized personnel will result in the termination of warranty, which the company is not liable for.

Call +1 (855) 646-7874

Troubleshooting

Symptom	Solution
The image processor cannot be turned on	Check whether the power cord is connected properly or if the fuse needs to be replaced.
The image cannot be displayed	Check whether the Monitor and Image Processor are powered on. Check whether the endoscope cord is securely connected to the image processor and observe whether the LED at the distal tip of the hysteroscope is on. Check whether the HDMI or CVBS cord is securely connected to the Monitor and the Image Processor. Confirm the Monitor input is set to the appropriate video input port.
The images are distorted	Check to see if there is interference from nearby equipment. Relocate source of interference.

Limited Warranty

Minerva Surgical warrants that the devices supplied are free from defects in materials or workmanship.

The Medical Endoscope Image Processor includes a one-year warranty, so long as the product has been maintained in accordance with procedures documented in the IFU. The service-life of the image processor is 5 years.

The Disposable Electronic Hysteroscope has a three-year shelf life and is warranted throughout the intended shelf life, so long as the product has been maintained in accordance with procedures documented in the IFU.

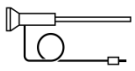
The following circumstances are not covered by the warranty and will cause all liability statements to be invalid: faults caused by non-standard or improper use, and modification or repair of device by technicians not authorized by Manufacturer. The packaging materials of devices and accessories sold by Minerva Surgical are all designed to protect them from damage. Please keep the packaging materials to store image processor when not in use, and for shipping protection of device for its return to manufacturer for repair, if necessary.

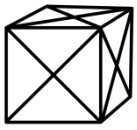
Customer Service/Technical Support

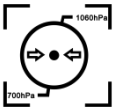
Contact Minerva Surgical Customer Service for customer support.

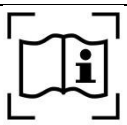
Call +1 (855) 646-7874

Symbol Glossary

Symbol	Symbol Title	Standard	Description
	Endoscope	NA	Endoscope
	Stand-by	NA	Stand-by/Power

	This Way Up	ISO 7000	Device must remain in an upward position as indicated by the arrows
	MR Unsafe	ASTM F2503-20	Unsafe in magnetic resonance environment
	Radio Frequency (RF) Energy (non-ionizing radiation)	ISO 7010/IEC 60878	Device emits Radio Frequency (RF) Energy (non-ionizing radiation)
	Not anesthesia proofed	IEC 60417	Do not use in the presence of flammable anesthetics
	Type BF (body floating) Applied Part	IEC 60417	Applied Parts that make direct Electrical contact with the patient, except not directly to the heart
	Un-insulated High voltage	ISO 7010	Risk of Electrical Shock
	Separate Collection	BS EN 50419	Separate Collection
	Contents	ISO 15223-1	Package content
	Unique device Identifier	ISO 15223-1	Indicates a carrier that contains unique device identifier information
	Manufacturer	ISO 15223-1	Indicates the medical device manufacturer

	Date of manufacture	ISO 15223-1	Indicates the date when the medical device was manufactured
	Use-by date	ISO 15223-1	Indicates the date after which the medical device is not to be used
	Batch code	ISO 15223-1	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalog number	ISO 15223-1	Indicates the manufacturer's catalog number so that the medical device can be identified
	Serial number	ISO 15223-1	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Do not resterilize	ISO 15223-1	Indicates a medical device that is not to be resterilized
	Do not use if package is damaged and consult instructions for use	ISO 15223-1	Indicates that a medical device should not be used if the package has been damaged or opened, and that the user should consult the instructions for use for additional information
	Keep away from sunlight	ISO 15223-1	Indicates a medical device that needs protection from light sources
	Keep dry	ISO 15223-1	Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation	ISO 15223-1	Indicates the range of humidity to which the medical device can be safely exposed
	Atmospheric pressure limitation	ISO 15223-1	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Do not re-use	ISO 15223-1	Indicates a medical device that is intended for one single use only

	Consult instructions for use or consult electronic instructions for use	ISO 15223-1	Indicates the need for the user to consult the instructions for use
	Equipotentiality	ISO 60417	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	Single sterile barrier system	ISO 15223-1	Indicates a single sterile barrier system that has been sterilized using ethylene oxide.
	Follow instructions for use	ISO 7010	To signify that the instruction manual/booklet must be read
	Fragile, handle with care	ISO 15223-1	Indicate the need to handle item with care.
	U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.	NA	Indicates this is a restricted device.
	Waterproof level of the insertion part ipx7	IEC 60529	Degree of particle and water ingress protection
	Stacking limit by six	ISO 7000	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Caution	ISO 15223-1	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences

Appendix A- Technical Specifications

Working Conditions

- Ambient temperature: 50°F -104°F (10℃~40℃);
- Relative humidity: 30%-75% RH (non-condensing);
- Atmospheric pressure range:70~106kPa;
- Power requirement: 100-240VAC , 50Hz/60Hz, 40VA
- Equipment noise: ≤80dB
- Equipment weight: 2.4kg (5.3 lbs)

Medical Endoscope Image Processing System primarily includes three parts:

- Image processing system;
- CMOS drive, image acquisition and coding circuit (to drive CMOS, control image acquisition and coding);
- Video driven luminance control system (to adjust the luminance of light source).

White Balance

The Medical Endoscope Image Processor has a white balance function.

Image Resolution

The minimum system image resolution is shown in Table 3:

TABLE 2: IMAGE RESOLUTION

Model/Specification	Horizontal resolution line (TV line number)	Vertical resolution line (TV line number)
JY-MIP-1000	400	400

The imaging principle of the Disposable Electronic Hysteroscope

After the light source from the LED at front end is introduced into the examined body cavity, the CMOS image sensor receives the light reflected by the mucosal surface of the body cavity and converts the light into an Electrical signal, and then transmits the signal to the Medical Endoscope Image Processor through the cable. The Medical Endoscope Image Processor stores and processes these Electrical signals and finally transmits them to the monitor to show an image of the examined body cavity.

- Field of view: 100°±10°.
- Resolution: 3.51Lp/mm, L=10mm.
- Brightness response: sRGB color coding compliant with IEC 61966-2-1.
- Effective depth of field: 3-50mm.

Appendix B- Electromagnetic Compatibility (EMC)

The devices or systems referred to as products in this section are all related to the medical endoscope image processing system.

For this system, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the electromagnetic compatibility information specified in this Operator's Manual.

EMC Warnings

- The medical endoscope image processing system should not be near to, or stacked with, other Electrical equipment. If it must be close to or stacked with other Electrical equipment, the medical endoscope image processor and other equipment should be observed to ensure that they can operate normally under the selected configuration.
- The electromagnetic compatibility of the medical endoscope image processing system is Grade A, so the system is applicable to use in non-domestic facilities and all facilities that are not directly connected to the public low-voltage power supply network that supplies residential buildings. This system is specially designed for medical use.
- Portable and mobile radio frequency communication equipment may affect medical Electrical devices.

TABLE 3: CABLE LENGTH

Cable Name	Length
Power Cord (Processor)	5 ft (1.5m)
HDMI Cable	5 ft (1.5m)

- Make sure that the cable is far away from the cables of other Electrical equipment. Other equipment may generate Electrical currents, causing unexpected results.
- Maximize the distance between the medical endoscope image processing system and other Electrical equipment (such as monitors). When the Medical Endoscope Image Processor is being started, incidental electromagnetic coupling may interfere with other equipment.
- When the Medical Endoscope Image Processor is being used, if any interference occurs on other equipment, relocating the Medical Endoscope Image Processor, connecting cables or other devices may reduce or eliminate this interference. Plugging the affected equipment into a different power supply socket may also reduce or eliminate the interference.

EMC Tables

The following tables provide information on the electromagnetic environment in which the HERizon System can operate safely. Use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the system. To ensure proper grounding reliability, the Medical Endoscope Image Processor must only be plugged into a power cord recommended by the original manufacturer or equivalent.

TABLE 4: GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSION

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The medical endoscope image processing system uses RF energy only for its internal

		function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The medical endoscope image processing system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

TABLE 5: GUIDANCE AND MANUFACTURER'S 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	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

TABLE 6: GUIDANCE AND MANUFACTURER'S 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	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: d = [1.2] P d = [1.2] P 80 MHz to 800 MHz d = [2.3] P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol: 
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 land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electro-magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

TABLE 7: RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter/m		
	150kHz - 80MHz d = 1.2 P	80MHz - 800MHz d = 1.2 P	800MHz - 2.5GHz d = 2.3 P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.			

For Additional Product Information, Scan the QR Code

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