HERizon™

Vista Viewpoint

Endoscope Image Processing System with Single Use Hysteroscope

Operator's Manual

Rx only

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

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About this Manual

This manual provides information on how to operate and maintain the *HER*izon Vista ViewPoint Endoscope Image Processing System and associated hysteroscopes. 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.

Warnings and Cautions Symbols Definition

	General Warning symbol – Indicates hazards that, if not avoided, could result in serious injury, device breakdown, or severe property loss.
	Caution Symbol – Indicates hazards, that, if not avoided, could cause minor or moderate injury, device malfunction or damage, or property damage
NOTE	Note symbol – Indicates additional helpful information for device operation but is not safety related

Refer to complete symbols glossary in Symbol Glossary.

Device Description

The *HER*izon Vista ViewPoint Endoscope Image Processing System is composed of the *HER*izon Vista ViewPoint Medical Endoscope Image Processor, *HER*izon Single-Use Hysteroscope, power cord, power adapter, hysteroscope cable, and HDMI cable (optional).

The complete list of components is detailed in the Table 1 below:

The *HER*izon Vista Viewpoint Endoscopic Video Image Processor is designed to process and display images transmitted from the hysteroscope during clinical procedures. The *HER*izon Vista Viewpoint Endoscopic Image Processor and Single Use Hysteroscope function as image transmission devices. They capture visual data from the intrauterine operative area and relay it to the *HER*izon Vista Viewpoint Endoscopic Video Image Processor for real-time image processing and display.

The Single-Use Hysteroscope insertion tubes are applied parts, as it comes into direct contact with the patient during use.

TABLE 1: COMPONENT LIST OF *HER*IZON VISTA VIEWPOINT ENDOSCOPE IMAGE PROCESSING SYSTEM

SN	Component	Model	Sterility and Reusability	Manufacturer
A	*HER*izon Vista ViewPoint Medical Endoscope Image Processing System	JY-MIP-3000	Non-sterile, Reusable	Jiangsu Jiyuan Medical Technology Co., Ltd.
B	*HER*izon Single-Use Hysteroscope	SH-02A, SH-02B, SH-04B, SH-03C	Sterilized w/Ethylene oxide, single use	Jiangsu Jiyuan Medical Technology Co., Ltd.
C	Disposable Electronic Hysteroscope "Gen 1" hysteroscopes which are compatible with the *HER*izon Vista ViewPoint Image Processor	JY-DEH-001 JY-DEH-002 JY-DEH-003	Sterilized w/Ethylene oxide, single use	Jiangsu Jiyuan Medical Technology Co., Ltd. (K210270)
1	Power cord (for processor)	3*16AWG, 12 A, 125 V	Non-sterile, reuseable	NA
2	Power adapter	1.2 m	Non-sterile, reuseable	NA
3	Hysteroscope cable	/	Non-sterile, reuseable	Jiangsu Jiyuan Medical Technology Co., Ltd.
4	HDMI cable (optional)	1.5 m	Non-sterile, reuseable (optional)	NA

Intended Use/Indications for Use

*HER*izon® Vista ViewPoint Hysteroscopy System 2.0 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

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

General Warnings/Cautions

Warnings/Cautions	
	R(x) only: Federal law (USA) restricts this device to sale by or on the order of a physician.
	All users must read and understand this Operator's Manual and any IFU (Instructions for Use) for related system accessories.
	The Image Processor may be used together with other medical electrical 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.
	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.
	Do not use the System near or in a Magnetic Resonance (MR) environment.
	Do not use in the presence of flammable gases.
	Do not attempt to disassemble, repair, or modify the Image Processor and/or Hysteroscope. Do not attempt to open, or gain access into, the Image Processor. Doing so may result in electric shock.
	This device is intended for use only by clinicians trained in hysteroscopic procedures.
	If pregnancy is suspected or cannot be ruled out, a pregnancy test is recommended before proceeding.

Warnings/Cautions	
	During normal use, the temperature of the hysteroscope should not exceed 41°C (106°F) but light generated heat may exceed 41°C so the user should not leave the tip in direct contact with tissue for extended periods.
	This system cannot be used in close proximity to high-frequency equipment or laser 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 an external storage device is used for transferring 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.
	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 system can only be used with compatible accessories as defined by the "Compatibility" section in this Operator's Manual.

Anticipated Postoperative Risks and Potential Adverse Events

Anticipated Postoperative Risks:

- Pelvic cramping, abdominal pain

Potential complications of continuous flow hysteroscopic surgery include:

- Uterine perforation
- Hyponatremia
- Hypothermia
- Pulmonary edema
- Cerebral edema
- Bleeding
- Urinary tract infections
- Infection, sepsis

Environmental Protection

The Image Processor 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

indicated by the expiration date on its label. 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 components to minimize the risk of environmental pollution.

How Supplied

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

*HER*izon Vista Viewpoint Endoscope Image Processor

The *HER*izon Vista Viewpoint Image Processor is supplied non-sterile and should not be sterilized. The Shipping Box contains:

- One (1) Image Processor
- One (1) Medical AC-DC Adapter (MEA-65A12C-6-A)
- One (1) Hysteroscope cable (2.8 m)
- One (1) HDMI Cable (1.5 m)
- One (1) Storage Case
- One (1) *HER*izon eIFU Insert

The Image Processor will need to be charged before use. See Figure 1.

*HER*izon Single Use Hysteroscope

The Single Use Hysteroscope is supplied sterile and is intended for single use. The shelf box contains:

- One (1) Single Use Hysteroscope
- One (1) *HER*izon eIFU Insert

Compatibility

The *HER*izon Endoscope Image Processor (Catalog # JY-MIP-3000) is only compatible with the *HER*izon Single Use Hysteroscope as shown in Table 2.

TABLE 2 COMPATIBLE HYSTEROSCOPES

Group[1]	Component	Model	Manufacturer
B	*HER*izon Vista Single Use Hysteroscope	SH-02A, SH-02B, SH-04B, SH-03C	Jiangsu Jiyuan Medical Technology Co., Ltd.
C	Disposable Electronic Hysteroscope	JY-DEH-001 JY-DEH-002 JY-DEH-003	Jiangsu Jiyuan Medical Technology Co., Ltd.

[1] B are Gen 2 Hysteroscopes, C are Gen 1 Hysteroscopes compatible with the *HER*izon Vista Viewpoint

The *HER*izon Vista Viewpoint System can be used in conjunction with a variety of optional accessories. The *HER*izon Single Use 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:

- *HER*izon Disposable Endoscopic Forceps – Biopsy (Catalog # JY-PK-350-18-S)
- *HER*izon Disposable Endoscopic Forceps – Foreign Body Grasper (Catalog # JY-C-350-18-S)
- *HER*izon Disposable Endoscopic Forceps – Alligator (Catalog # JY-CC-350-18-S)
- *HER*izon Disposable Endoscopic Forceps – Alligator XL (Catalog # JY-CC-450-18-S)
- *HER*izon Disposable Endoscopic Forceps - Inverted Tooth (Catalog # JY-DC-350-18-S)
- *HER*izon Disposable Endoscopic Scissors (Catalog # JY-JD-17-350-B)
- *HER*izon Disposable Endoscopic Scissors XL (Catalog # JY-JD-17-450-B)

Minimum recommended technical parameters for monitor, specifications:

- Monitor larger than 10 inches
- Screen resolution 1080p
- With HDMI interface
- Color space: sRGB 115% (range), sRGB 99% gamut (Coverage)
- Contrast: ≥ 700:1
- Meet IEC 60950-1-2013 criteria

NOTE: 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.

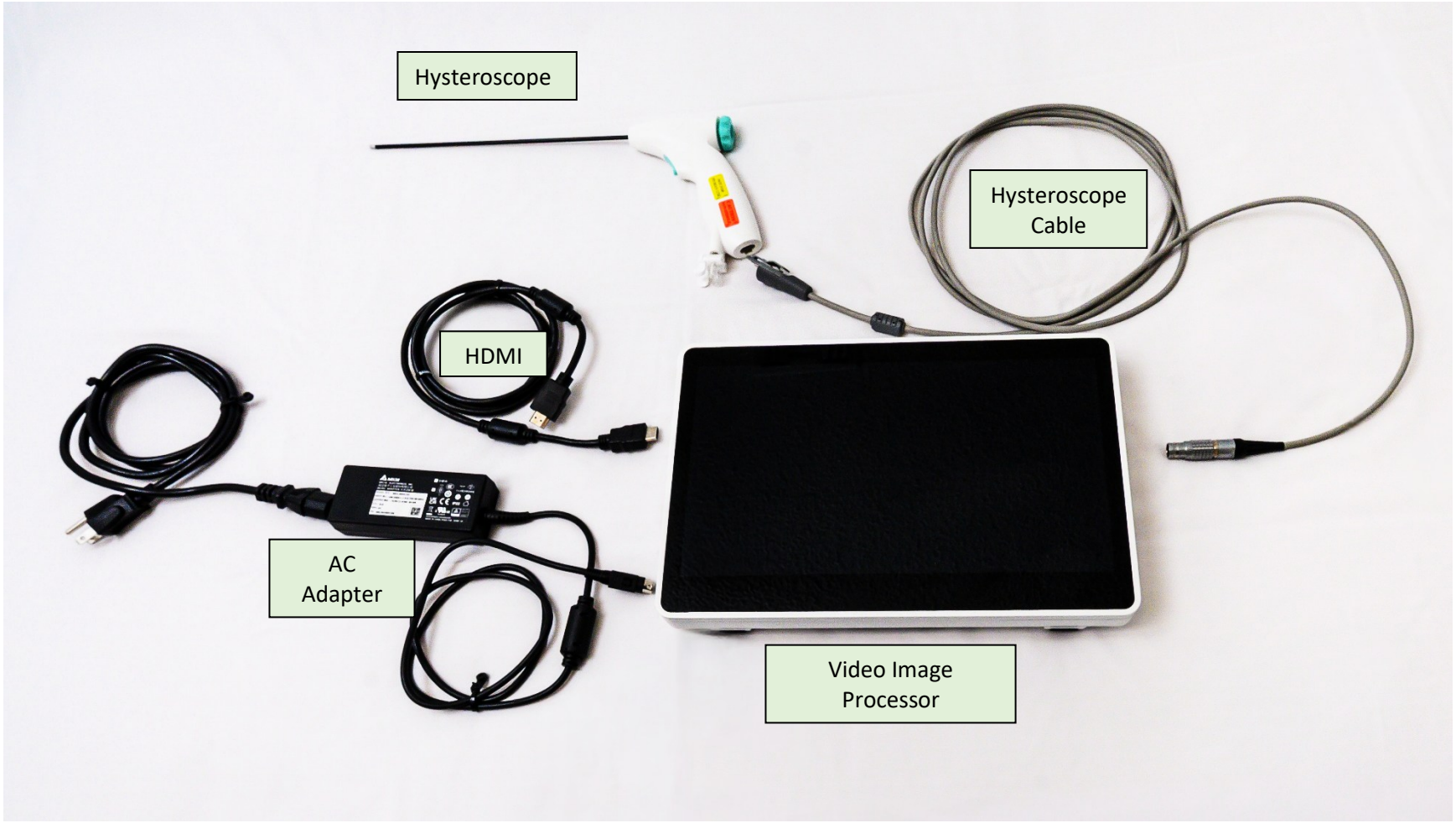
The parts of the Image Processor are shown in Figure 2.

An enlarged view of the *HER*izon Hysteroscopes is shown in Figure 3. This enlarged view shows the inlet and outlet connectors for the fluid, the control knob and the buttons to “Record Video” or to “Capture Static Images”.

Image Processor

System Components

FIGURE 1 SYSTEM COMPONENTS

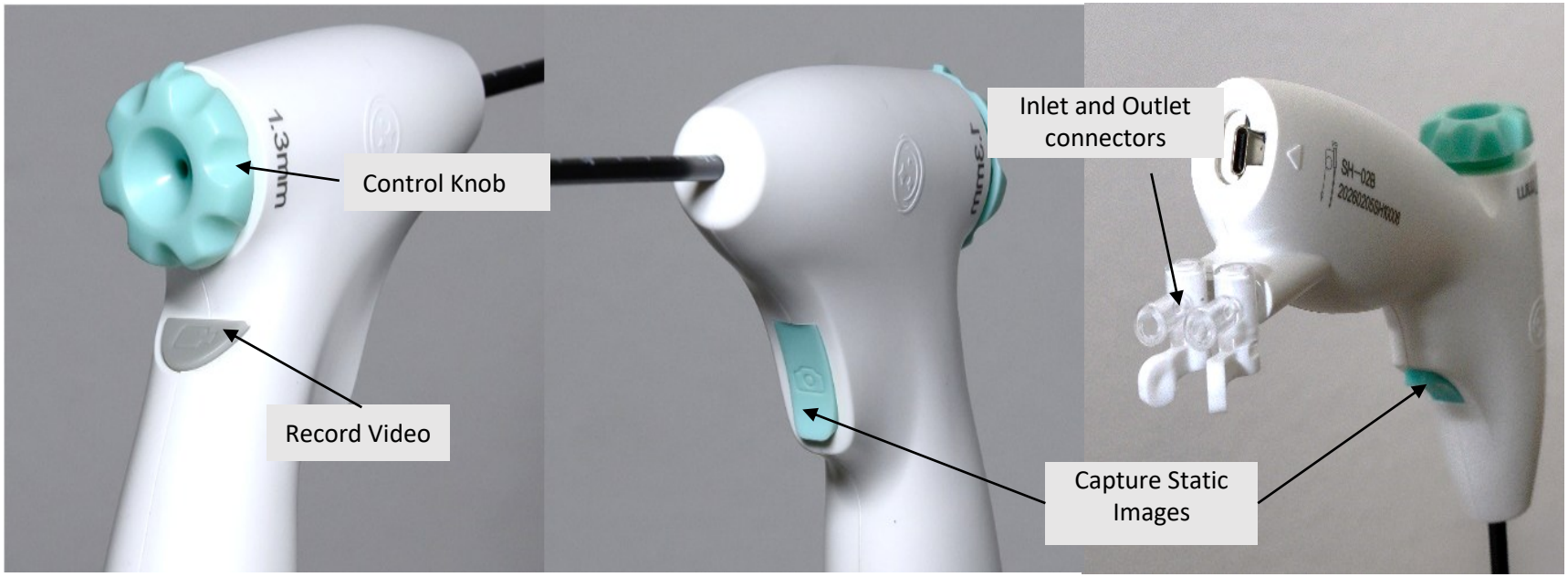


Video Image Processor

FIGURE 2 VIDEO IMAGE PROCESSOR

*HER*izon Hysteroscope Controls

FIGURE 3 *HER*IZON VISTA HYSTEROSCOPE CONTROLS



Usage Instructions – Inspection + Set Up

	This device is intended for use only by clinicians trained in hysteroscopic procedures.
	If pregnancy is suspected or cannot be ruled out, a pregnancy test is recommended before proceeding.
	For safe and effective use, please read this IFU thoroughly to familiarize yourself with all operational requirements and safety warnings and cautions.

(1) Unpacking and Inspection of the Image Processor, cables, and power supply

Carefully unpack the devices and inspect all components for any damage during transport or for missing items. Ensure that no surfaces have unintended roughness, sharp edges, or protrusions that may pose a risk of injury.

(2) Charge the Image Processor Battery

The *HER*izon Endoscopic Video Image Processor can operate on DC power supplied by its internal rechargeable battery.

Charging procedure

- When the processor is connected to an external power source, battery charging begins automatically.
- During charging, a green indicator light appears in the lower left corner of the screen.
- After the battery is fully charged, the battery status bar in the upper-right corner of the display shows 100%.

A fully charged battery supports continuous operation for up to 6 hours.

NOTE: The internal battery is designed to last for approximately 300 charge - discharge cycles. When the battery no longer functions normally, contact the manufacturer or an authorized service provider to arrange for battery replacement.

(3) Hysteroscope Inspection

The *HER*izon Single Use Hysteroscopes are supplied STERILE using Ethylene Oxide (EO). Do not use if the packaging is damaged. If damage is found, call your Axora Medical representative.

Before opening the hysteroscope package, confirm the following:

	Do not use if sterile barrier is damaged

	*HER*izon hysteroscopes are single use. Do not reuse, reprocess, or re-sterilize. 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.
	Do not use single use hysteroscopes beyond their labeled expiration date. Do not use if the expiration date has passed.

WARNINGS for Use

	Do not use the device in environments containing flammable anesthetic gases
	This device is intended for use on patients weighing more than 10 kg.
	Do not use the device during MRI or CT examinations, as it may affect imaging
	Do not use the device in areas with excessive radiation fields as it may affect imaging.

Prior to use, users should maintain and securely position the *HER*izon Vista Viewpoint Image Processor in a stable position, while ensuring proper ventilation and protection against moisture.

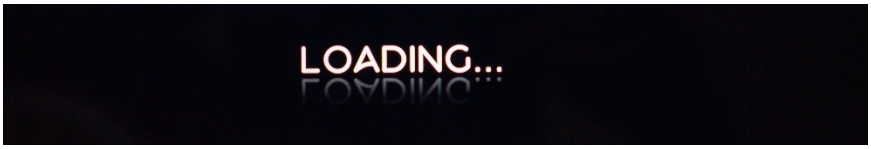
Usage Instructions –Video Image Processor – Set-up

1. Connect the power supply to the Image Processor.
2. Press and hold the power button. It is located on the top of the Image Processor.

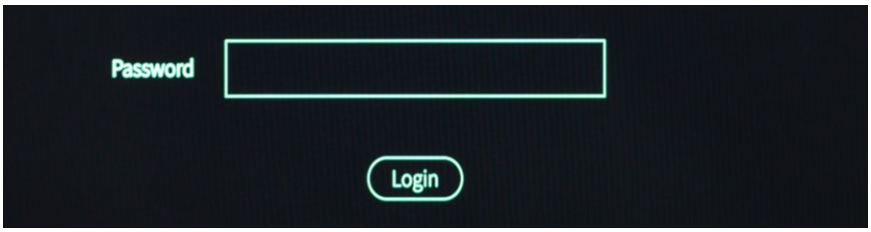
FIGURE 4 USAGE INSTRUCTIONS – VIDEO IMAGE PROCESSOR

3. A welcome screen will be displayed, automatically followed by

4. A loading screen, automatically followed by

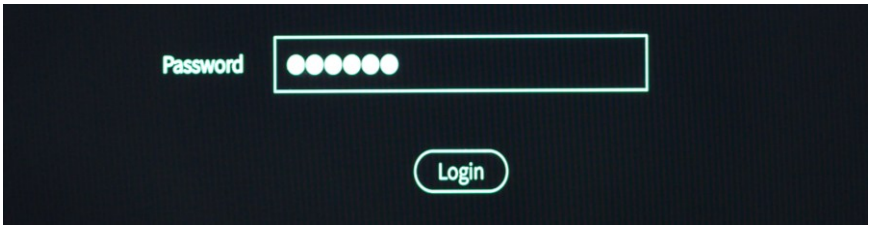


5. the login screen. Touch in the Password rectangle, which brings up the on-screen keyboard



6. Type in the system password then press the return key on the virtual keyboard. Note: The default password is 666666

7. Touch the Login button. This completes the login sequence, after which the Image Processor Screen appears.

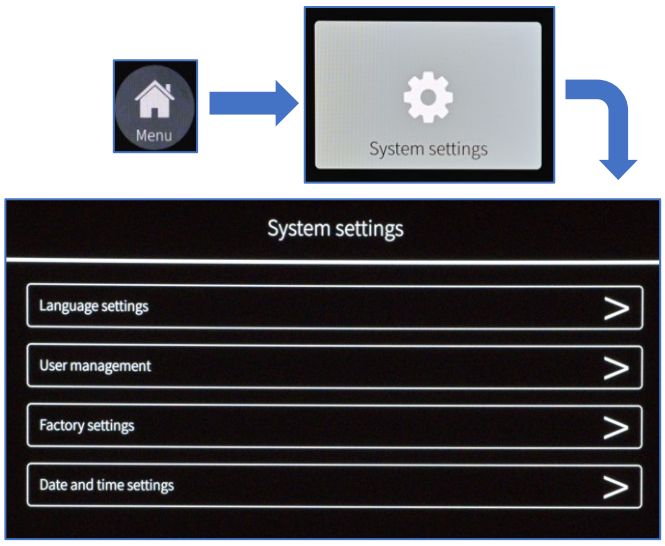


Setting Date & Time

8. The Date and Time are displayed at the top of the left panel on the main screen. If it is not correct it can be adjusted as follows:

9. Date and Time are set via the system settings menu by touching Menu, then selecting System Settings, then Date and time settings (See Figure 5)

FIGURE 5 SETTING DATE & TIME

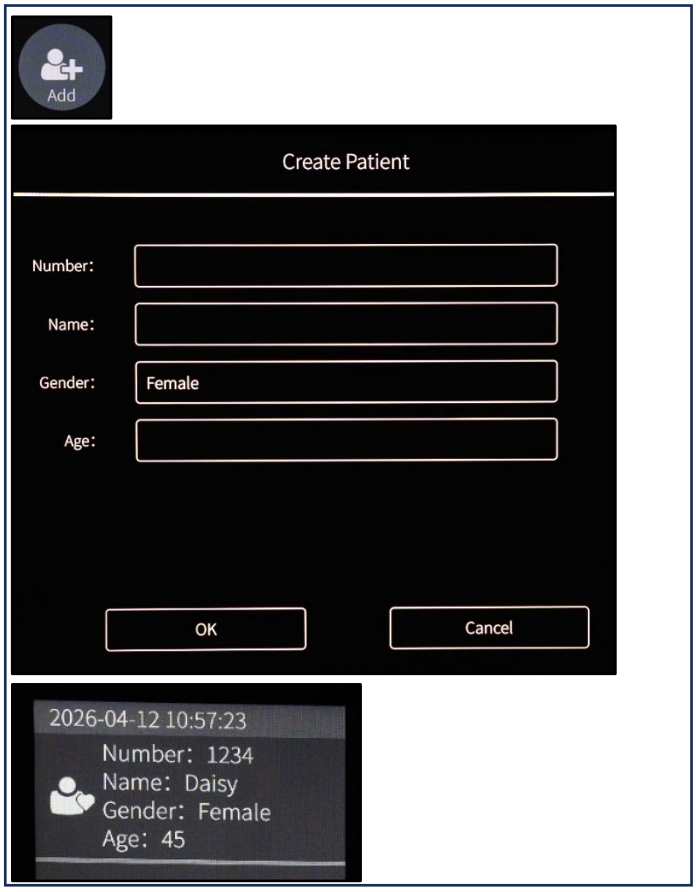


Usage Instructions – Each Use

Insert about login checking charge, check day/time. Input patient information.

Patient Input

FIGURE 6 PATIENT INPUT



10. Touch the Add Button at the top of the right display panel. The Create Patient Screen Appears. (Figure 6)

11. Touch inside of any of the rectangles. A keyboard or number pad will appear permitting completion of the selected box.

12. To hide the keypad, touch the key that represents a keyboard or keypad. This will hide the keypad so that the OK and Cancel buttons are visible.

13. When data entry is complete touch the OK button.

14. On return to the main screen the new patient data will appear at the top of the left panel.

Usage Instructions – Unpacking and connecting the Hysteroscope

FIGURE 7 HYSTEROSCOPE IN TRAY

15. Remove the *HER*izon Single-Use Hysteroscope inner package from the cardboard shelf box Figure 7.

16. Using sterile technique peel the Tyvek cover from the inner package and transfer the Hysteroscope to the sterile field.

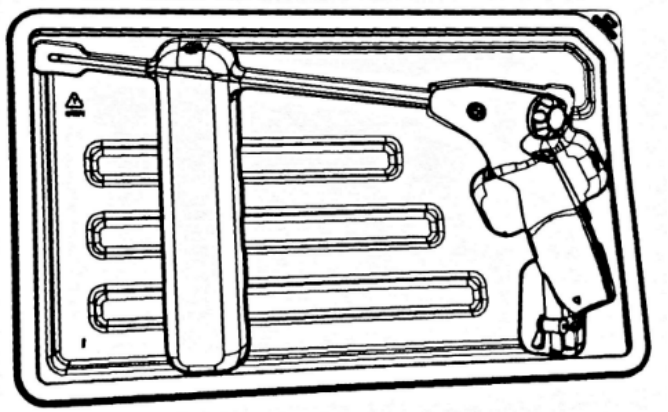
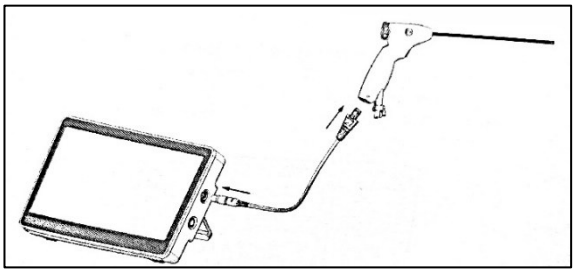


FIGURE 8 FLUID DELIVERY SYSTEM

17. Fluid Delivery System – Attach the in-flow tubing to the
in-flow port and the outflow tubing to the outflow port. Fluid
infusion is achieved by connecting either a pre-filled syringe or a pressurized bag containing distending medium to the
hysteroscope's inlet connector via an extension tube or
Tubing set.

    The valves are marked "IN" and "OUT" as shown on the left and right of Figure 8.

FIGURE 9 CONNECT HYSTEROSCOPE TO IMAGE PROCESSOR



18. Connect the Hysteroscope cable to the bottom of the handle. (See Figure 9)

19. Connect the other end of the Hysteroscope cable (metal LEMO connector) to Port 2 on the Video Processor

20. An image will appear shortly after connecting to the Video Image Processor.

⚠	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 the image orientation is correct to prevent potential injury.

White Balance

Point the tip of the Hysteroscope at a white object, such as a piece of gauze or white paper.

Touch the Automatic White Balance button on the right panel (Figure 10).

FIGURE 10 WHITE BALANCE BUTTON

In a dark or low ambient light environment, position the hysteroscope tip LED approximately 1 cm away from a white clean surface so that the Main Display Area is filled with white.

After adjustment is complete, the left pane displays the message “AWB complete”

If illumination or imaging fails, discontinue set up and replace with a new hysteroscope. (See Troubleshooting.

⚠	Only one camera port (either Camera 1 or Camera 2) may be used at a time. Simultaneous connection of both ports is not permitted and may result in malfunction or system error.

Procedure Steps

After completion of the set up steps above, these are the procedure steps

1. Run the fluid through the cannula until air bubbles are cleared.
2. With fluid flowing, gently insert the cannula through the cervical canal under visual guidance, as per standard hysteroscopic procedures.
3. Follow the manufacturer's instructions for the fluid management system.

Refer to the Settings and Features section on the right panel controls.

After the procedure is completed, carefully withdraw the *HER*izon Vista Single Use Hysteroscope.

	This device is intended to use on patients weighing more than 10 kg.
	Do no look straight into the hysteroscope lens as it may cause eye damage from the light source.
	Do not use the device in environments containing flammable anesthetic gases.
	Do not use the device during MRI examination
	Do not use the device during CT examination, as it may affect imaging.
	Do not use the device in areas with excessive radiation fields.

Usage Instructions – Post Procedure and Storage

Video and Image Capture

Follow the instructions on capturing the videos and images during the procedure to save to the Image Processor. To export video and images captured, use a USB flash drive via the USB interface.

Power off and Storage

Press and hold the power button to turn off the Image Processor.

The *HER*izon Vista Viewpoint Image Processor is nonsterile and reusable. Ensure proper disinfection procedures are followed for the image processor and accessories between patients. It should not be sterilized or placed in the sterile field.

The Image Processor can be cleaned with a cloth with 75% ethanol to wipe the front panel, rear panel, and outer casing. Follow with a dry, absorbent cloth to remove moisture. Refer to Cleaning & Disinfection.

When not in use, it is recommended to store the *HER*izon Vista Viewpoint Image Processor in the original packaging (or carrying case).

Protect the Image Processor against any sharp or blunt force impact.

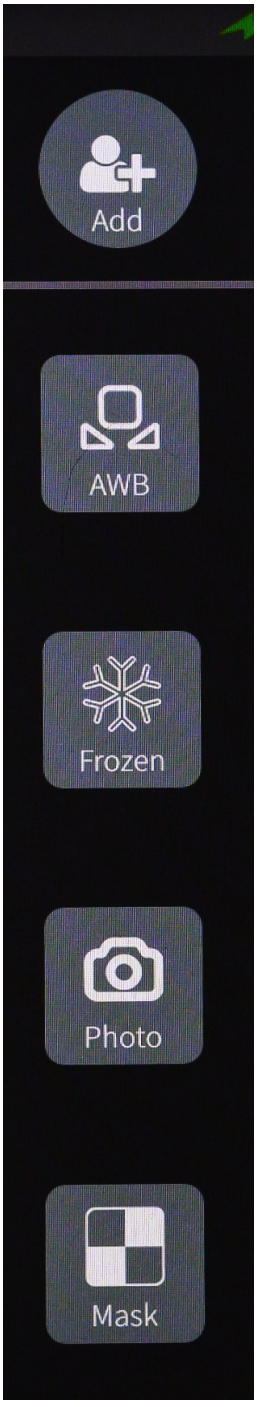
Dispose of the single use hysteroscope in the biohazard container according to the facility procedures for biohazardous waste.

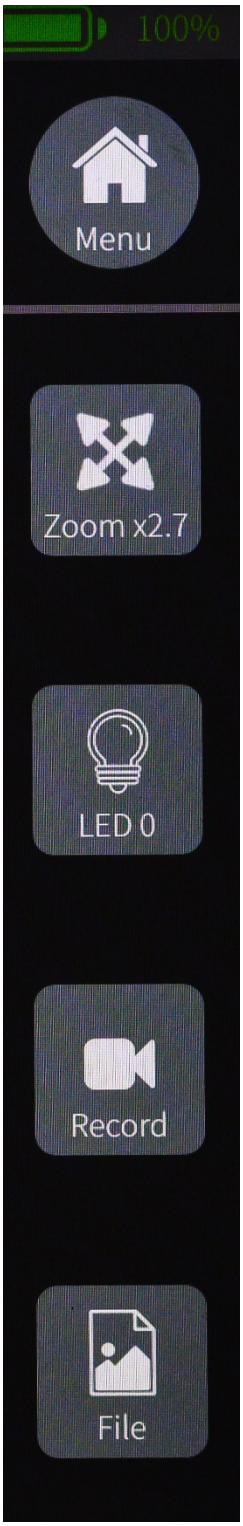
	The single use hysteroscope are ethylene oxide (EO) sterilized and for single use only. Do not reuse or resterilize hysteroscopes.
	Do not place the *HER*izon Vista Viewpoint Image Processor in environments with high temperatures, humidity, dust, direct sunlight or corrosive gases and/or moisture (See operating and storage conditions in the Appendix A- Technical Specifications.
	Always ensure the device is powered off before cleaning.

Settings and Features

The right display panel on the main screen contains two columns of controls. This section explains their functions.

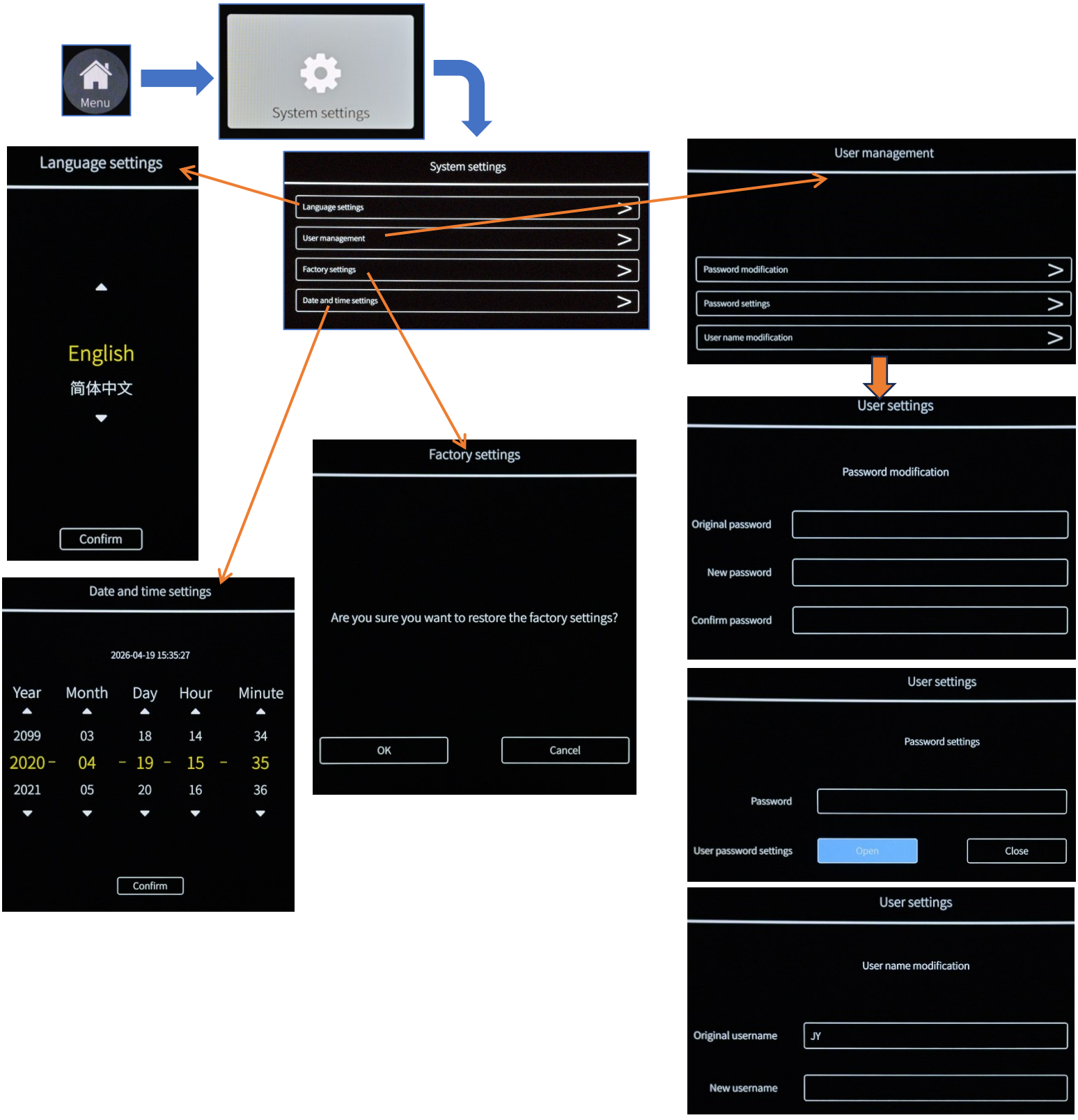
FIGURE 11 RIGHT PANEL CONTROLS

Touching the Add button brings up a screen for entering patient information, including patient number, name, gender, and age. This information is then displayed in the left display panel. The operation of that menu is shown in System Settings Menu Hierarchy Section.	
When the Hysteroscope is used, the image is displayed on the Image Processor screen. To render colors correctly the camera must first be white balanced. First, aim the distal end of the hysteroscope at a piece of white paper or gauze, then touch the "White Balance" button. "● AWB completed" will be briefly displayed on the left panel.	
Touching this button freezes the displayed image on the screen. The live image is then simultaneously displayed in a smaller window at the lower left of the display. Touching the Frozen button again causes the display to revert to the live image-only, shown in the center of the screen.	
The currently displayed image may be captured by touching the Photo button or by pressing the front trigger on the Hysteroscope. The image is automatically saved. Imagers can be reviewed in by touching File. The File name will be displayed on the monitor. See File Management section for instructions on how to access saved images and video.	
Touching the Mask button changes the shape of the image. Touching this button repeatedly will cycle the image from square, to octagonal, to round.	

Touching the Menu button opens a new menu. Details are shown in System Settings Menu Hierarchy.	
Touching the Zoom button changes the size of the displayed image. Repeatedly touching this button will cycle the displayed image size, becoming smaller with each press then returning to maximum size.	
Touching the LED button will change the brightness of the Hysteroscope lighting. The brightness cycles from off (LED 0), becoming successively brighter with each successive button touch. Once the LED reaches maximum brightness it will cycle back to LED 0. The illumination brightness is shown on the button.	
Touching the Record button begins video capture. Touching Record a second time ends recording and saves the video file. Video recording may also be initiated and terminated using the thumb button on the Hysteroscope.	
Touching the File button opens the file system. This system contains captured still images and videos. The file system operation is shown in File Management. Note that if a USB memory stick is inserted into the USB port on the side of the Image Processor that images and video may be transferred from the Image Processor to the memory stick.	

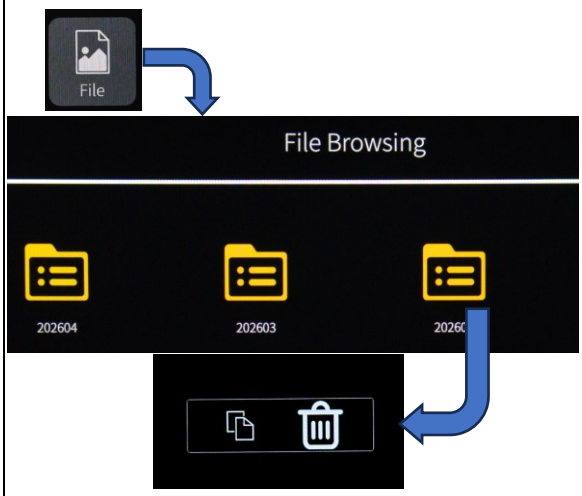
System Settings Menu Hierarchy

FIGURE 12 – SYSTEM SETTINGS MENU HIERARCHY



File Management

FIGURE 13 DELETING PICTURES AND VIDEO

Viewing, Transferring, and Deleting Pictures and Video	
Touching the File button on the main screen opens the File Browsing Menu. This opens the File Browsing screen. Folders are arranged by date and contain sub-folders of pictures and video. Touching a folder opens it, revealing subfolders, images, and video. Touching an image icon opens it. Touching a video permits playing it. To delete any folder or image/video, touch and hold on the desired item until the copy and delete menu appears. Touching the copy icon permits copying the selected item to a USB memory stick inserted into the USB port on the side of the Image Processor. If no card is present a popup indicating this appears. Touching the trash can icon deletes the selected item via a confirmation screen.	

Restore Default Settings

FIGURE 14 DEFAULT SETTING

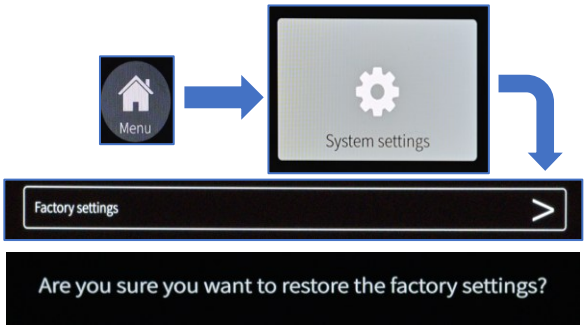
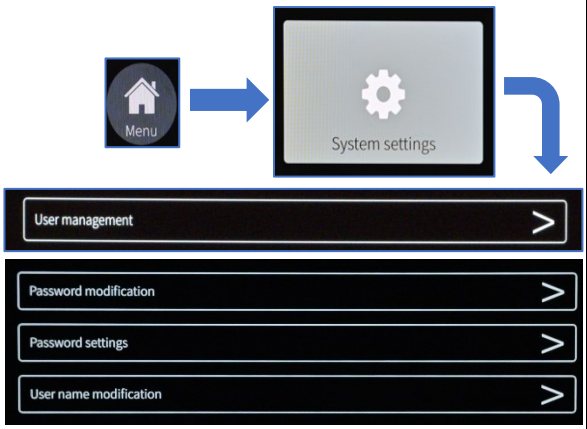
Default Setting	
To restore all settings back to the original factory settings, press the menu button on the Image Processor then System Settings and select Factory Settings. Click OK to reset to factory settings. Note: Saved images and video in File Management will not be deleted when restoring to original factory settings.	

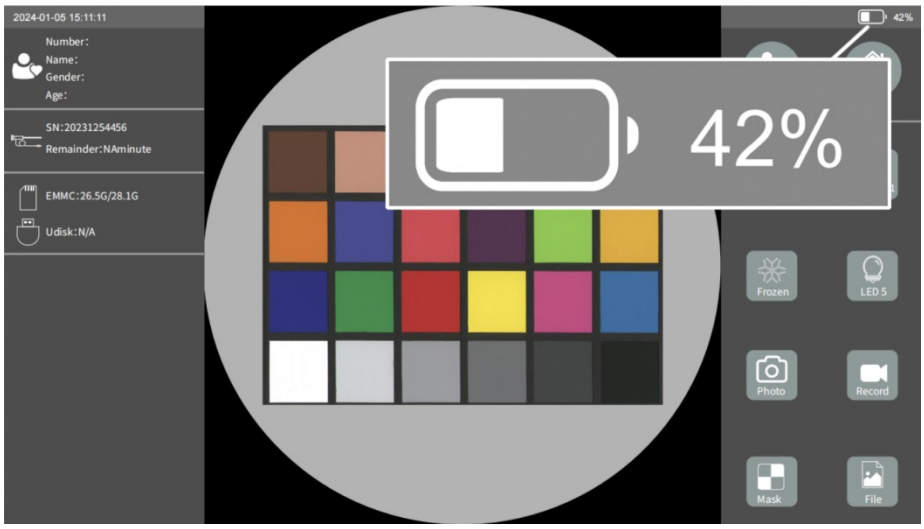
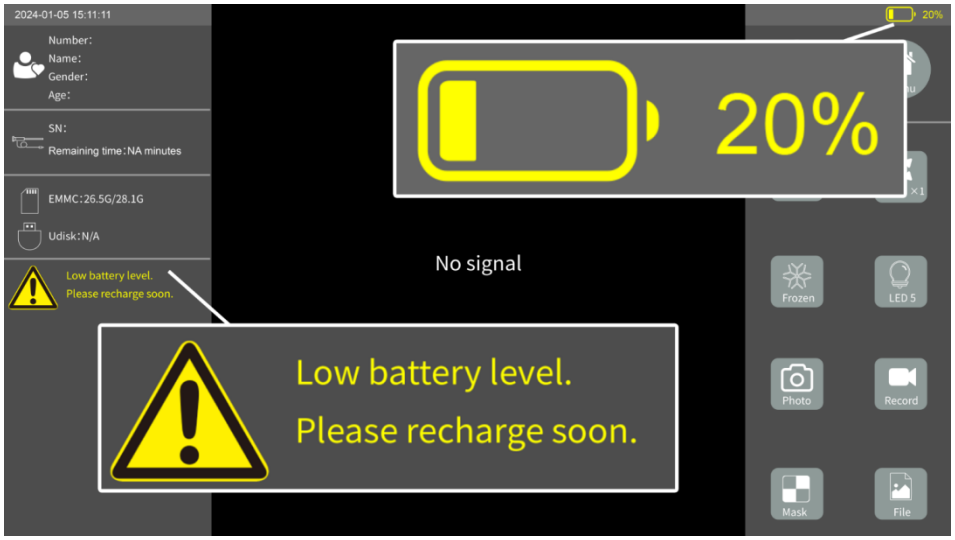
FIGURE 15 PASSWORD RESET

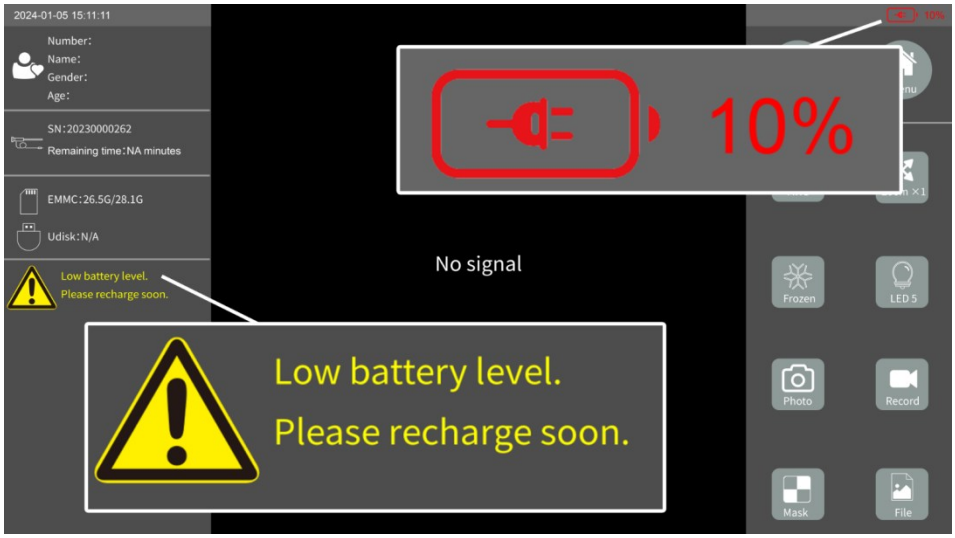
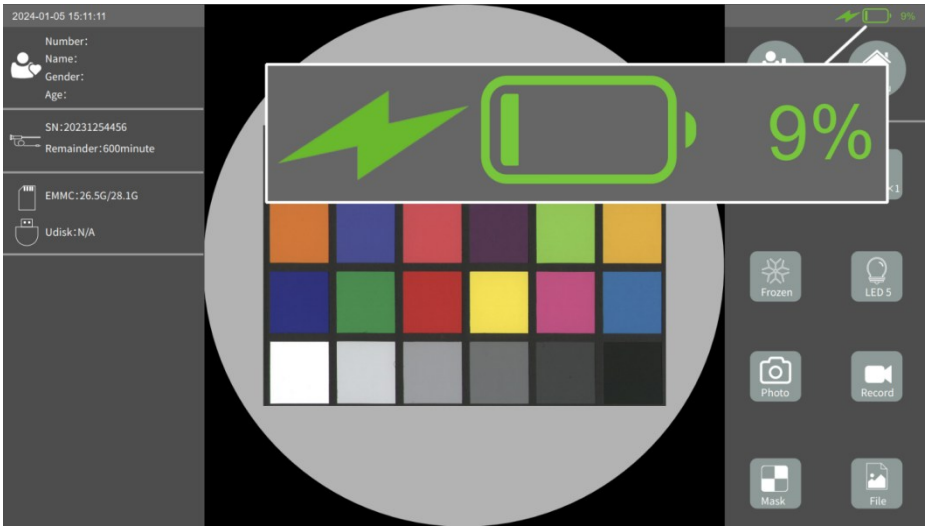
Password Reset	
To change the password, press the menu button on the Image Processor then System Settings and select User management. The three options permit: • Changing password if you remember the original password • Changing password settings enables or disables the login password at startup • User name modification changes the name and icon/image on the startup screen.	

Battery Level Screens

Table 3 has screen shots with descriptions to illustrate the battery levels of the *HER*izon Vista Viewpoint Image Processor.

TABLE 3 BATTERY LEVEL

No.	Interface and Icon	Description
1		The battery capacity is displayed in real-time as a percentage. When the battery level is between 20% and 100%, the icon color is white.
2		When the battery level drops to 10%–20%, the icon turns yellow, and a message appears in the left warning area for 5 seconds, with the prompt: "Low battery level. Please recharge soon."

No.	Interface and Icon	Description
3		When the battery level drops to 10%, the icon turns red, and the left warning area displays: "Low battery level. Please recharge soon." This warning persists until the device is connected to a mains power supply. Recharge immediately to avoid loss of function.
4		After the power adapter is connected, a green lightning icon appears to the left of the battery icon. The central capacity bar and percentage of the battery icon increase as the battery charges.

Cleaning & Disinfection

Follow Standard Hospital Procedures for cleaning the Image Processor.

The Image Processor is supplied non-sterile and is not intended to be sterilized by the user. It should be cleaned and disinfected after each use by using a clean, damp cloth moistened with a mild hospital-grade disinfectant (such as, but not limited to, isopropyl alcohol, 1.5% hydrogen peroxide or a mild 10% bleach solution), followed by wiping its surface with an absorbent dry cloth. When not in use, cleaning of the device is recommended to be performed once every 3 months.

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

Hysteroscopes are single use and should not be cleaned, disinfected or resterilized.

Storage and Handling

The *HER*izon Vista Viewpoint Endoscope Image Processor and Single Use Hysteroscope are designed to be transported and stored in an environment that is kept within the conditions as defined in Table 4 below.

TABLE 4: 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 Single Use 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 or their authorized distributor.

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 an authorized distributor 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 or their authorized distributor. Contact the distributor 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.

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Troubleshooting

TABLE 5 TROUBLESHOOTING TIPS

Symptom	Solution
The image processor cannot be turned on	Check whether the A/C Adapter is plugged into an outlet and the image processor. Check that the outlet is live.
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 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

The manufacturer warrants that the devices supplied are free from defects in materials or workmanship.

The *HER*izon Vista Viewpoint 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 Single Use Hysteroscope has a shelf life through its labeled expiration date 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 or authorized distributor. The packaging materials of devices and accessories sold are all designed to protect them from damage. Please keep the packaging materials and/or carrying case 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 the distributor surgical customer service for customer support.

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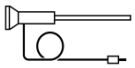
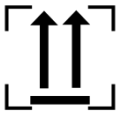
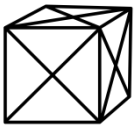
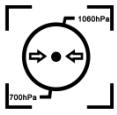
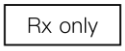
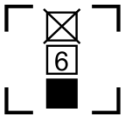
Symbol Glossary

TABLE 6 SYMBOL GLOSSARY

Symbol	Symbol Title	Standard	Description
	General Warning	IEC 60601-1 Table D.2 Symbol 2	Indicates hazards that, if not avoided, could result in serious injury, device breakdown, or severe property loss.
	Caution	ISO 15223-1	Indicates hazards, that, if not avoided, could cause minor or moderate injury, device malfunction or damage, or property damage
	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

Symbol	Symbol Title	Standard	Description
	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

Symbol	Symbol Title	Standard	Description
	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.

Symbol	Symbol Title	Standard	Description
	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.

Appendix A- Technical Specifications

TABLE 7 TECHNICAL PARAMETERS OF THE *HER*IZON VISTA VIEWPOINT IMAGE PROCESSOR

*HER*izon™ Vista Viewpoint Endoscopic Video Image Processor	
Display area's diagonal size	13.3-inch
Horizontal	325 mm*217 mm
Height	62 mm
Weight	Approx. 2100 g
Power Adapter Requirements	
Range of input power	100-240 V AC, 80 VA
Frequency	50 Hz/60 Hz
Output	DC12 V, 5 A
Length	1.2 m
Battery Specifications	
Battery type	Lithium battery
Capacity	10 Ah
Maximum voltage when fully charged	8.4 V
Minimum operating voltage	5.4 V
Full charging time	6 hours
Operating time after full charge	6 hours
Lifespan	300 charge-discharge cycles
External Monitor Requirements	
Signal input	HDMI interface
Minimum resolution requirement	1080P
Operating Environment	
Temperature	10 ℃~40 ℃
Humidity	30%~75%
Atmospheric pressure	700~1060 hPa
Transportation and Storage	
Temperature	-10 ℃~45 ℃
Humidity	30%~75%
Atmospheric pressure	700~1060 hPa

Principles of Operation

The *HER*izon™ Vista Viewpoint Endoscopic Video Image Processor is composed of three primary subsystems:

a) Image processing system

b) CMOS drive, image capture, and encoding circuit (Controls the CMOS imaging sensor, manages image acquisition, and performs signal encoding for further processing)

c) Video drive brightness control system (Regulates the brightness of the light source to optimize visualization during diagnostic and operative procedures)

Illumination (LED Source): Light-emitting diodes (LEDs) located at the distal tip of the endoscope produce bright, cool, white light. This light illuminates the internal mucosal surface of the body cavity.

Image Capture (CMOS Sensor): The light reflected off the tissue passes through an objective lens and strikes a Complementary Metal-Oxide-Semiconductor (CMOS) image sensor. This sensor immediately converts the optical image into raw digital electrical signals.

Signal Transmission: The raw electrical signals are transmitted from the tip of the endoscope through a flexible cable to the video processor.

Endoscope Image Processor: The Video Processor receives electrical signals. It performs functions such as color balancing, image sharpening, noise reduction, and enhancement of the image to ensure clear, high-resolution visualization for clinical diagnosis. The image processor contains a display that shows live video from the endoscope.

External Display: The processed signal may also be sent to a secondary monitor.

White Balance

*HER*izon™ Vista Viewpoint Endoscopic Video Image Processor is equipped with a white balance function.

Compatible Equipment Technical Parameters

*HER*izon™ Vista Viewpoint Endoscopic Video Image Processor is only compatible with the components listed in the Table 8.

*HER*izon™ Vista Hysteroscope	
Working length	245 mm
Maximum insertion diameter	For detailed parameters of each model, please refer to Table 2, Table 8 and for more details in Table 9
Minimum instrument channel	
Angled shaft proximal to tip	
Image resolution	
Single-Use Hysteroscope	
Working length	200 mm
Maximum insertion diameter	For detailed parameters of each model, please refer to Table 2, Table 8 and for more details in Table 9.
Minimum instrument channel	
Head bending angle	
Image resolution	

TABLE 8 COMPATIBLE EQUIPMENT

SN	Component	Model
A	*HER*izon™ Vista Viewpoint Endoscopic Video Image Processor	JY-MIP-3000
B	*HER*izon™ Vista Hysteroscope	SH-02A, SH-02B, SH-04B, SH-03C,
	Disposable Electronic Hysteroscope	JY-DEH-001 JY-DEH-002 JY-DEH-003
C	Monitor	With HDMI interface
1	Power cord (*HER*izon™ Vista Viewpoint Endoscopic Video Image Processor)	3*16AWG, 12 A, 125 V
2	Power adapter	1.2 m
3	Hysteroscope cable	Available with *HER*izon™ Vista Viewpoint Endoscopic Video Image Processor
4	Data cable	1.5 m

TABLE 9 SPECIFIC PARAMETERS FOR DIFFERENT MODELS OF *HER*IZON SINGLE USE HYSTEROSCOPE:

Model	Image Resolution	Angled shaft proximal to tip	Maximum Insertion Diameter (mm)	Minimum instrument channel (mm)
SH-02A	160,000 pixels	0◦	4.0	1.3
SH-02B	640,000 pixels	22◦	5.0	1.7
SH-04B	640,000 pixels	15◦	6.5	3.1
SH-03C	1,000,000 pixels	22◦	5.0	1.7

Appendix B- Electromagnetic Compatibility (EMC)

The devices or systems referred to as products in this section are all related to the *HER*izon Vista Viewpoint image processing system.

For this system, special precautions regarding electromagnetic compatibility (EMC) must be taken, and the device 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.
	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.

TABLE 10: CABLE LENGTH

Cable Name	Length
HDMI Cable	5 ft (1.5m)

Essential Performance

The essential performance is the continuous output of real-time and stable images in the correct direction in the operation mode at room temperature during surgery and examination, instead of already recorded images, without image lag, black screen or splash screen.

EMC Tables

The following tables provide information on the electromagnetic environment in which the *HER*izon 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 11: 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 assure that it is used in such an environment.		
Immunity test	IEC 60601-1-2 test level	IEC60601 Test and Compliance	Electromagnetic environment – guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± contact 8 kV ±2 kV, ±4 kV, ±8 kV, ±15kV air	± contact 8 kV ±2 kV, ±4 kV, ±8 kV, ±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 %.
Radiated RF EM Fields IEC 61000-4-3	Professional Health Care 3V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Professional Health Care 3V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARMI® Hysteroscopy System 2.0 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to Table 4	Refer to Table 4	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Grid power should be of the quality typically used in a commercial or hospital environment.

	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	IEC 60601-1-2 test level	IEC60601 Test and Compliance	Electromagnetic environment – guidance
Surge IEC 61000-4-5	AC power: Line to Line: ±0.5kV, ±1kV Line to Ground:±0.5kV, ±1kV, ±2kV	AC power: Line to Line: ±0.5kV, ±1kV Line to Ground:±0.5kV, ±1kV, ±2kV	Grid power should be of the quality typically used in a commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	Professional Health Care 3V 0.15-80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	Professional Health Care 3V 0.15-80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips:0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° Voltage Interruptions:0% UT; 250cycle at 0°	Voltage dips:0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°,225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° Voltage Interruptions:0% UT; 250cycle at 0°	Grid power should be of the quality typically used in a commercial or hospital environment. If the user of the equipment requires continuous operation during power outages, it is recommended that the equipment be powered by an uninterruptible power supply or battery.
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m 50Hz and 60Hz	30A/m 50Hz and 60Hz	The power frequency magnetic field should have the horizontal characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment.
Proximity magnetic Fields IEC 61000-4-39	Refer to Table 5	Refer to Table 5	/
	NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

TABLE 12 IMMUNITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1kHz sine	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

TABLE 13 IMMUNITY TO PROXIMITY MAGNETIC FIELDS (ACCORDING TO IEC 61000-4-39)

Test frequency Modulation	Modulation	Immunity test level (A/m)
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

TABLE 14: 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% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) 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 15: 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

Product manufactured and packaged for Minerva Surgical, Inc.

By Jiangsu Jiyuan Medical Technology Co, Ltd.

4255 Burton Drive Santa Clara, CA 95054 USA

Customer Service: 855-464-7874

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