

***HERizon*[®] Vista ViewPoint Endoscope Image Processing System with Single Use Hysteroscope**

Image Processor Model JY-MIP-3000

With

***HERizon*[®] Vista Single Use Hysteroscopes (“Gen 2”) Models:
SH-02A, SH-02B, SH-03C, SH-04B**

***HERizon*[®] Disposable Electronic Hysteroscopes (“Gen 1”) Models:
JY-DEH-001, JY-DEH-002, JY-DEH-003**

Prescriptive Information

Refer to the device directions for use for complete instructions on the device.

Indications

The *HERizon* 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 people 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

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.
	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.

Warnings/Cautions	
	DO NOT USE IF PACKAGE IS OPENED OR DAMAGED. DO NOT USE IF LABELING IS INCOMPLETE OR ILLEGIBLE
	<i>HERizon</i> ® Vista Single-Use 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.
	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.
	This device is intended to be used on patients weighing more than 10 kg.
	Do not look straight into the hysteroscope lens as it may cause eye damage from the light source.
	The single-use hysteroscope are ethylene oxide (EO) sterilized and for single-use only.
	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.
	Do not use the device during CT examination, as it may affect imaging.
	Do not use the device in areas with excessive radiation fields.

Warnings/Cautions	
	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.
	Do not place the <i>HERizon</i> ® Vista ViewPoint Endoscopic Video Image Processor in environments with high temperatures, humidity, dust, direct sunlight or corrosive gases and/or moisture
	Always ensure the device is powered off before cleaning.
	The <i>HERizon</i> ® Vista ViewPoint Endoscopic Video 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 Image Processor and other equipment should be observed to ensure that they can operate normally under the selected configuration.
	The electromagnetic compatibility of the 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 Image Processor is being started, incidental electromagnetic coupling may interfere with other equipment.
	When the Image Processor is being used, if any interference occurs on other equipment, relocating the 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.

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

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. The physician using the system must be trained in diagnostic hysteroscopy. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*



**Manufactured and packaged for Axora Medical, Inc.
by Jiangsu Jiyuan Medical Technology Co.,Ltd.**
1000 Hamlin Ct
Sunnyvale, CA 94089
axoramedical.com