

































SYMBOL GLOSSARY









APPLICABLE TO SYMPHION CONTROLLER SOFTWARE VERSION 2.0.19, 2.1.1, 3.0.0, RESECTING DEVICE, INFINITY AND EXPRESS FLUID MANAGEMENT ACCESSORIES, AND OPTIONAL FLUID DEFICIT READOUT ACCESSORY










USER INTERFACE SYMBOLS GLOSSARY





	On		Off
	Equipotentiality		Aspirate
	Coagulation		Resection
	Decrease Cavity Set Pressure		Increase Cavity Set Pressure
	Mode Change to RESECTION		Pressure Warning
	Volume Control		Set Pressure Arrow
	Infusion Pump ON / Off		Message Screen Info
	OK button		No Button
	Do not push here while saline bag is mounted		RF On
	Back Button		Fuses
	Footswitch		

SYMBOLS USED ON THE SYMPHION SYSTEM AND ACCOMPANYING LABELING

Symbol	Standard	Symbol Title	Description
	ASTM F2503-20	MR Unsafe	Unsafe in magnetic resonance environment
	ISO 7010/IEC 60878	Radio Frequency (RF) Energy (non-ionizing radiation)	Device emits Radio Frequency (RF) Energy (non-ionizing radiation)
	IEC 60417	Not anesthesia proofed	Do not use in the presence of flammable anesthetics
	IEC 60417	Type BF (body floating) Applied Part	Applied Parts that make direct electrical contact with the patient, except not directly to the heart
	ISO 7010	Un-insulated High voltage	Risk of Electrical Shock
	BS EN 50419	Separate Collection	Separate Collection
	NA	Contents	Package content
	NA	ETL Certification Mark	NA
	NA	Handle with Care	Fragile equipment requiring care in handling

IPN ₁ N ₂	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).	<p>Manufacturer-determined degree of particle and water ingress protection, where...</p> <p>N1= degree of protection from particulates (scale of 0-6); and</p> <p>N2 = degree of protection from water (scale of 0-8)</p>
	<p>ISO 15223-1:2021</p> <p>Medical devices — Symbols to be used with information to be supplied by the manufacturer</p>	Non-Sterile	Device not provided sterile
		Unique device Identifier	Indicates a carrier that contains unique device identifier information
		Manufacturer	Indicates the medical device manufacturer
		Date of manufacture	Indicates the date when the medical device was manufactured
		Use-by date	Indicates the date after which the medical device is not to be used
		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
		Catalogue number	Indicates the manufacturer's catalog number so that the medical device can be identified
		Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified

		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
		Do not resterilize	Indicates a medical device that is not to be resterilized
		Do not use if package is damaged and consult instructions for use	Indicates that a medical device that 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	Indicates a medical device that needs protection from light sources
		Keep dry	Indicates a medical device that needs to be protected from moisture
		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
		Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
		Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
		Biological risks	Indicates that there are potential biological risks associated with the medical device

		Do not re-use	Indicates a medical device that is intended for one single use only
		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
		Caution	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
		Not made with natural latex	Not made with natural latex

Refer to the Instructions-For-Use document for additional information on the Symphion Operative Hysteroscopy System.

The Symphion® Operative Hysteroscopy System is intended to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device.

CONTRAINDICATIONS: Pregnancy, genital tract infections, and known uterine cancer are contraindications to hysteroscopy. Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

POTENTIAL ADVERSE EFFECTS: Pregnancy, genital tract infections, and known uterine cancer are contraindications to hysteroscopy. Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

WARNINGS: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. The Symphion® Operative Hysteroscopy System should only be used by physicians trained in hysteroscopy and hysteroscopic surgery using powered instruments. Healthy tissue can be injured, e.g., perforation by improper use of the Resecting Device. Use every available means to avoid such injury.

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 hysteroscopy. www.minervasurgical.com/safety

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Legal Manufacturer

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