SYMPHION®

Operative Hysteroscopy System

OPERATOR'S MANUAL

APPLICABLE TO SYMPHION CONTROLLER SOFTWARE VERSION 3.0.1, RESECTING DEVICE, INFINITY AND EXPRESS FLUID MANAGEMENT ACCESSORIES, AND OPTIONAL FLUID DEFICIT READOUT ACCESSORY

TABLE OF CONTENTS

1 ABOUT THIS MANUAL

This manual provides information on how to operate and maintain the Symphion® Operative Hysteroscopy System. It is essential that you read and understand all the information in this manual before using or maintaining the system. Pay attention to all warnings, contraindications, precautions, and adverse events in this manual and other related material. Failure to thoroughly understand and follow all instructions may result in harm to the patient or user of the system.

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

℞ ONLY

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

2 REUSE WARNING

The Symphion Resecting Device (RD) and Symphion Infinity and Express Fluid Management Accessories (FMA) are supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Minerva Surgical representative.

The Symphion RD and Symphion FMA 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 lead to injury, illness or death of the patient.

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

3 DEVICE DESCRIPTION

The Symphion Operative Hysteroscopy System consists of the following procedural components:

- Symphion Controller with Software (SW) v3.0.0 or higher.
    - Power Cord
    - Footswitch
    - Saline Pole
- Symphion Fluid Management Accessories:
    - INFINITY FMA (REF# FG-0204)
    - EXPRESS FMA (Currently not available for sale in the US)

  Note: Symphion FMA (REF# FG-0202) is not compatible with SW v3.0.0 or higher.
- Symphion Resecting Device (REF# FG-0201)
- Symphion 6.3 Hysteroscope (REF# FG-0703)
- Symphion Fluid Deficit Readout (Optional Accessory, REF# FG-FDR1)

The Controller provides bipolar radiofrequency outputs (resection and coagulation) and fluid management through the use of two integrated peristaltic pumps. Fluid infusion and aspiration of the uterine cavity are controlled by the Controller's peristaltic pumps in conjunction with a disposable fluid management accessory. The Controller has two distinct modes: diagnostic mode and resection mode.

Diagnostic Mode: Provides distension of the uterus during diagnostic hysteroscopy. Bipolar radio frequency energy is NOT active in this mode (no resection and coagulation). The footswitch is used to aspirate and re-circulate the saline.

Resection Mode: Bipolar radiofrequency energy is active (bipolar resection and coagulation). The footswitch is used to resect and coagulate. Aspiration is also active in this mode.

The Resecting Device is a disposable, handheld bipolar radiofrequency device configured for the resection and aspiration of uterine pathology.

The Symphion Controller, with software version 3.0.0 or higher, is designed to be used in either a recirculating (closed-loop) or non-recirculating system configuration. The Fluid Management Accessory is a disposable tubing set.. The FMA is designed to assist with the delivery, monitoring, and control of the amount of distention media delivered to the uterine cavity when used with the Symphion controller. When the controller is used with the INFINITY FMA, the system components form a closed-loop recirculating system configuration. Alternatively, when the controller is used with EXPRESS FMA (currently not available for sale in the US), the system components form an open, non-recirculating, system configuration.

The Symphion 6.3 Hysteroscope is a reusable instrument that provides access to and visualization of the uterine cavity. The Hysteroscope connects with the FMA to enable the fluid to be delivered to and returned from the uterine cavity as part of the distension fluid circulation system. The Hysteroscope contains a working channel that is compatible for use with the Resecting Device.

NOTE: Refer to the Symphion 6.3 Hysteroscope Instructions for Use (L0156). See *www.minervasurgical.com/IFU_Symbols-Glossary* for more information.

The Symphion Fluid Deficit Readout (FDR) is an optional accessory that measures the weight of the saline bag and when applicable, the weight of the recovery bag, throughout a Symphion procedure in real time. The system converts the weight measurements into fluid volume readings using the following values to automatically calculate the fluid deficit during a Symphion procedure.

- *Initial Bag Volume*: The volume of fluid in a bag at the beginning of the procedure.
- *Current Bag Volume*: The volume of fluid remaining in a bag during the procedure.

The following equation is calculated by the FDR to determine the Deficit during a Symphion procedure:

INFINITY FMA

Current Deficit = (Initial Saline Bag Volume) – (Current Saline Bag Volume)

EXPRESS FMA

(currently not available for sale in the US)

Current Deficit = (Initial Saline and Recovery Bag Volume) – (Current Saline and Recovery Bag Volume)

NOTE: The saline bag and EXPRESS FMA recovery bag are to be hung on a single hook. Monitoring the volume of the two bags will give an accurate measure of the Deficit.

The Deficit volume is displayed on the unit's Deficit Display (**Figure 8, ID 1**). The Symphion Fluid Deficit Readout will display the initial volume and then the Deficit volume once the tubing set is primed and the Fluid Deficit Limit is set to at least 50 mL.

The Fluid Deficit Limit is set by using the Up and Down buttons (**Figure 8, ID 4 and 5**). This limit establishes the threshold for audible and visual indicators that notify the user when the real-time fluid loss (or Deficit) exceeds the Deficit Limit.

The Fluid Deficit Limit can be changed in 50 mL increments with each button press or at a faster rate by continuously holding the Up or Down Button.

There is a maximum Fluid Deficit Limit allowed by the Symphion Fluid Deficit Readout is dependent on the Saline Bag. Refer to **Table 1** for the maximum fluid deficit limits.

TABLE 1: FLUID DEFICIT LIMITS

Saline Bag Size	Maximum Deficit Limit
2 Liter	1450 mL
3 Liter	2450 mL

NOTE: If the measured Deficit exceeds the applicable maximum Fluid Deficit Limit noted in Table 1, an audible indicator will be generated. The audible indicator cannot be silenced unless the user increases the fluid deficit limit to a value above the currently measured deficit as displayed (**Figure 8, ID 1**) on the FDR.

NOTE: The Symphion Fluid Deficit Readout has a system measurement accuracy of +/- 50 mL.

4 INTENDED USE/INDICATIONS FOR USE

The Symphion System is intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through either the closed loop recirculation of filtered distension fluid or non-recirculating/non-filtered distension fluid.

Refer to L0156 SYMPHION 6.3 Hysteroscope instructions for use for specific Hysteroscope Intended use. See *www.minervasurgical.com/IFU_Symbols-Glossary* for more information.

5 CONTRAINDICATIONS

Pregnancy, genital tract infections, and known uterine cancer are contraindications to hysteroscopy.
The use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated.

The Symphion System contains a large amount of metal components. Therefore it is MRI unsafe. Do not use the Symphion System in conjunction with MRI, CT or RFID.

Refer to Symphion 6.3 Hysteroscope Operators Manual for specific Hysteroscope contraindications. See *www.minervasurgical.com/IFU_Symbols-Glossary* for more information.

6 WARNINGS

6.1 SYMPHION SYSTEM GENERAL WARNING

6.1.1 The Symphion System is only intended for use as outlined in Section 4, Intended Use/Indications For Use.

6.1.2 Before using the Symphion System, please review all available product information carefully!

6.1.3 The Symphion 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.

6.1.4 Do not use the Symphion System with another fluid management system, hysteroscope, or controller. Use with another fluid management system, hysteroscope or controller may result in failure of the device to operate or lead to patient or physician injury.

6.1.5  **DANGER**: Do not operate the Symphion System in close proximity to volatile solvents such as methanol or alcohol, or in the presence of flammable anesthetics, as explosion may occur.

6.1.6 Use Resection and Coagulation modes with caution in the presence of any active implantable or body worn medical devices such as internal or external pacemakers or neurostimulators. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. The output of the Symphion device might also affect other types of active devices such as implanted neurostimulator devices. Consult the active implantable device manufacturer (for implanted pacemakers and ICDs the hospital cardiology department might also be helpful) for further information when use of myomectomy or tissue coagulation is planned in patients with active implantable devices such as cardiac pacemakers.

6.2 REUSE WARNINGS

6.2.1 The Symphion Resecting Device and Symphion Fluid Management Accessories are supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Minerva Surgical representative.

6.2.2 The Symphion Resecting Device and Symphion Fluid Management Accessories 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.

6.2.3 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 lead to injury, illness or death of the patient.

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

6.3 CONTROLLER WARNINGS

6.3.1 Known Risks Associated with use of Electrosurgical Devices:

- Potential EMC issues
  - Interference causes device failure,
  - interference causes other devices to fail,
  - RF interferes with pacemaker, defibrillator.
- Use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the system.
- The Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller should be observed to verify normal operation in the configuration in which it will be used.
- Electrical safety issues – shock, burn, device/controller overheats, incorrect power source used, water enters the controller, use of incorrect power source, arcing.
- Explosion/fire may occur if the controller is operated near volatile solvents.
- Tissue damaged during coagulation/resection.

6.3.2 Fluid Overload: There is a risk of distension fluid reaching the circulatory system of the patient by passing into the capillaries of the uterine cavity. This can be caused by distension pressure, flow rate, perforation of the uterine cavity and duration of the endoscopic procedure. It is critical to closely monitor the inflow and outflow of the saline at all times. Vital signs recording, physical examination and pulse oximetry is recommended, as it may reduce the risk of fluid overload.

6.3.3 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the Symphion Fluid Deficit Readout, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

6.3.4 Fluid Deficit: The fluid absorbed by the patient must be monitored.
The following equation should be used to estimate the fluid deficit using a single 3-liter saline bag after FMA has been primed.

INFINITY FMA

2500 mL – Remaining volume in saline bag = total fluid deficit

EXPRESS FMA

(currently not available for sale in the US)

2700 mL – Remaining volume in saline bag – Volume in recovery bag = total fluid deficit

The following equation should be used to estimate the fluid deficit using a single 2-liter saline bag after FMA has been primed:

INFINITY FMA

1500 mL – Remaining volume in bag = total fluid deficit

EXPRESS FMA

(currently not available for sale in the US)

1700 mL – Remaining volume in saline bag - Volume in recovery bag = total fluid deficit

IMPORTANT: Use a single 2-liter or 3-liter irrigation USP Saline bag* only. Do not use multiple saline bags. Use of multiple saline bags increases the chance of fluid overload.
**Take notice of the measurement tolerance of the saline bag (+/-10%)*

6.3.5 Fluid Intake: Strict monitoring of fluid intake should be maintained. Intrauterine instillation of saline exceeding 2-liter should be followed with great care due to the possibility of fluid overload.

6.3.6 Serum Sodium Concentration: As with any normal saline hysteroscopic insufflation, the possibility of fluid intravasation and subsequent electrolyte disturbances may occur. It is important that the physician monitor the patient's electrolytes if significant intravasation occurs. The Symphion System does not measure sodium or other electrolyte concentrations.

6.3.7 Rupture of the Fallopian Tube Secondary to Tubal Obstruction: Distension of the uterus may lead to a tear of the fallopian tube should there be an obstruction or permanent occlusion. The rupture could lead to saline flowing into the patient's peritoneal cavity, resulting in fluid overload. It is critical to closely monitor the input and outflow of saline at all times.

6.3.8 An air embolism can be the result of air contained in the tubing set or connected instrument reaching the patient. To prevent air from being pumped into the patient ensure that the infusion tubing set is primed prior to start of the procedure and that there is always fluid in the saline bag. If air bubbles are seen in the infusion tubing set prior to the insertion of the scope into the patient, manually prime via turning on infusion while the scope is outside of the patient until there is no longer air in the infusion tubing. If air remains in the infusion tubing following the manual prime or is noted in the infusion tubing at any point during the procedure after the scope has been inserted into the patient, remove the Hysteroscope from the uterine cavity and discontinue the procedure.

6.3.9 To prevent hypo/hypernatremia assess electrolytes before and after procedure, and observe for signs of significant electrolyte imbalance (e.g., electrocardiogram and physician examination).

6.3.10 Use of pressures higher than 100 mmHg is strongly discouraged. Intrauterine pressure should be maintained as low as possible so as to allow adequate visualization and minimize the forces potentially driving fluid, room air and/or gas into circulation. Cavity distension is usually possible with pressure values between 35 to 70 mmHg. A pressure above 75 to 80 mmHg is required only in rare cases or if the patient has unusually high blood pressure.

6.3.11 While fluids must always be monitored during use, exercise extreme caution and very close fluid monitoring in patients with severe cardiopulmonary disease.

6.3.12 The Symphion® system permits the operator to select an intrauterine pressure up to 125 mmHg. Clinicians using the Symphion System should be aware of the AAGL practice guidelines regarding uterine cavity distension pressure (i.e. lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure) when setting distension pressure on the Symphion System.

6.3.13 Testing of the Symphion System has not been confirmed in patients with hemoglobinopathies (e.g., Sickle Cell Disease, Beta Thalassemia) and therefore, the possible effects are unknown.

6.3.14 When using the Symphion INFINITY FMA, hemolysis may occur during recirculation. If significant hemolysis occurs, this may result in electrolyte (e.g., increased serum potassium) changes or decrease in hemoglobin. Hemolysis may reveal red-tinged coloring of the recirculated fluid, but may not be visually apparent. Therefore, assessment of serum electrolytes and hemoglobin level after completion of the procedure is recommended.

6.3.15 Magnetically susceptible medical devices should not be used closer than 15 cm (6 inches) to any part of the Symphion Controller. Otherwise, degradation of the performance of this equipment could result.

6.4 RESECTING DEVICE WARNINGS

6.4.1 **Do not** operate the Resecting Device without clear visualization. The device resecting window area should be in the field of view while the Resecting Device is operating. If visualization is lost at any point during the procedure, resection/coagulation must be stopped immediately.

6.4.2 Magnetically susceptible medical devices should not be used closer than 15 cm (6 inches) to any part of the Symphion Controller. Otherwise, degradation of the performance of this equipment could result.

6.5 WARNINGS APPLICABLE TO AIR/GAS EMBOLI HAZARDS

6.5.1 Gas bubbles are a normal by-product of electrosurgical procedures performed in liquids. When bubbles occur in the uterus, care should be taken to manage the removal of air/gas bubbles to minimize the inherent risk of emboli. Bubbles produced during tissue vaporization may interrupt surgery by temporarily interfering with field of view and may also result in electrode overheating, causing damage to the electrode tip.

6.5.2 Surgeons should consider the anticipated length of surgery and size of leiomyomata when selecting patients and system configuration (e.g. INFINITY FMA or EXPRESS FMA) for procedures.

6.5.3 Operating room personnel must be trained to prime fluid lines with saline prior to surgery, avoid entry of air into fluid lines, and provide constant, careful attention to fluid deficits. Avoid situations where the fluid bag is completely emptied.

6.5.4 Basic equipment should be available to fulfill the requirements for monitoring of fluid deficit, assessment and control of intrauterine pressure, and anesthesia monitoring. Intrauterine pressure should be maintained as low as possible so as to allow adequate visualization and minimize forces potentially driving air and gas into circulation.

6.5.5 Surgical team must have access to appropriate resuscitative capabilities.

6.5.6 Patients should be kept in a flat or in reverse Trendelenburg position.

6.5.7 If room air or gas embolism is suspected, surgeon should consider interrupting surgery, deflating the uterus, and removing sources of fluid and gas until the diagnosis and a management plan are clarified.

6.5.8 Surgeon should avoid entry of air into uterus by:

- Carefully priming fluid inflow lines and hysteroscopic devices prior to use.
- Following cervical dilation, care should be taken to minimize the exposure of the open cervix to room air.
- Keeping an effective cervical seal during surgery as much as possible once the cervix is dilated.
- Using active fluid outflow to effectively flush the uterus of bubbles and debris.
- Minimizing the frequency of removal and reinsertion of hysteroscopic devices.

6.6 CONSIDERATIONS FOR ANESTHESIA

6.6.1 Nitrous oxide anesthesia may enlarge the size of air bubbles and thus should be avoided, when possible, in operative hysteroscopy.

6.6.2 Patients at high risk for room air and gas embolism should be managed using controlled ventilation.

6.6.3 For high-risk patients undergoing operative hysteroscopy, one should consider intra-operative monitoring, such as end-tidal CO_2 monitoring if under general anesthesia and pre-cordial Doppler monitoring to detect room air and gas emboli early.

7 PRECAUTIONS

7.1 SYMPHION SYSTEM GENERAL PRECAUTIONS

7.1.1 **Do not** use the Symphion System in patients where anatomy does not support an endoscopic procedure (i.e. cervical stenosis, existence of an IUD, or in conditions that limit access to the target tissue).

7.1.2 Use Resection and Coagulation modes with caution in the presence of any active implantable or body worn medical devices such as internal or external pacemakers or neurostimulators. Interference produced by the use of electrosurgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. The output of the Symphion device might also affect other types of active devices such as implanted neurostimulator devices. Consult the active implantable device manufacturer (for implanted pacemakers and ICDs the hospital cardiology department might also be helpful) for further information when use of myomectomy or tissue coagulation is planned in patients with active implantable devices such as cardiac pacemakers.

7.1.3 If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing myomectomy or tissue coagulation. Electrosurgery or tissue coagulation may cause multiple activations of ICDs.

7.1.4 Small electrical arcs between the resection electrode and the tissue being resected can produce low-frequency currents that may produce local neuromuscular stimulation. Per standard of care, ensure that the patient's legs are supported and secured appropriately.

7.1.5 Prior to use, examine all system components for possible damage and ensure proper function. If any of the system components are damaged, **do not** use.

7.1.6 **Do not** use the Resecting Device or the FMA if the sterile barrier or sterility is compromised prior to or during the procedure. Failure to maintain sterile technique in the operating room could result in infection.

7.1.7 **Do not** lubricate the Resecting Device or the FMA.

7.1.8 **Do not** use the Resecting Device or the FMA after its expiration date.

7.1.9 The Resecting Device and FMA are intended for single use only. Discard the Resecting Device and FMA after use.

7.1.10 **Do not** re-use or re-sterilize the Resecting Device and FMA . Use of re-processed, single use device(s) may result in patient or physician injury.

7.2 CONTROLLER PRECAUTIONS

7.2.1 Verify the Controller is fully operational prior to starting the clinical procedure. Failure of the Controller could result in an unintended increase in output power.

7.2.2 Interference produced by the operation of high-frequency equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems.

7.2.3 **Do not** operate the Controller in a moist environment, as a shock hazard may exist. If liquids have entered the unit **do not use**. The Controller must be returned to the manufacturer for testing.

7.2.4 Use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the system.

7.2.5 Return Controller to manufacturer for servicing in the event of failure.

7.2.6 In case of Controller failure, remove the Hysteroscope and Resecting Device from the patient immediately. Switch off/ unplug the power cord to stop Controller operation.

7.2.7 Removing screws and/or opening this device will invalidate the warranty.

7.2.8 To ensure proper grounding reliability, a Hospital Grade Power Cord must be used with a receptacle marked “Hospital Grade”.

7.2.9 **Do not** sterilize the Controller. Sterilization may damage the unit.

7.2.10 Reconditioning, refurbishing, repair, or modification of the Controller other than by the manufacturer is expressly prohibited as it may result in loss of function and/or patient injury.

7.2.11 **Do not** obstruct openings on the bottom and back of the Controller, as they provide the required airflow for cooling.

7.2.12 The Controller needs special precautions regarding EMC and needs to be placed and put into service according to the EMC information provided in this document.
NOTE: Portable and mobile RF communication equipment can affect the performance of the Controller (See Appendix G).

7.2.13 If electromagnetic interference with other equipment is suspected, re-orient the device and/or remove possible sources of interference (e.g., cellular phones, radios, etc.) from the room.

7.2.14 The Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller should be observed to verify normal operation in the configuration in which it will be used.

7.2.15 If electromagnetic interference with other equipment is suspected, re-orient the device and/or remove possible sources of interference (e.g., cellular phones, radios, etc.) from the room.

7.2.16 Needle monitoring electrodes are not recommended.

7.2.17 Patient should not come into contact with grounded metal parts; the use of antistatic sheeting is recommended.

7.2.18 Cables to the surgical electrodes are recommended to be positioned such that contact with patient or other leads is avoided.

7.2.19  The lightning flash with arrowhead symbol, within an equilateral triangle, is intended to alert the user to the presence of un-insulated “dangerous voltage” within the product’s enclosure that may be of sufficient magnitude to constitute a risk of electric shock to persons.

7.2.20 Use only normal saline (sodium chloride (0.9% w/v; 150 mmol/L)) irrigation solution. The performance of the system will be adversely affected by the use of any other solution.

7.2.21 All models of the FMA are designed for use with either a SINGLE 2-liter or 3-liter Irrigation USP saline bag.

IMPORTANT: Use a single 2-liter or 3-liter irrigation USP Saline bag only. Do not use multiple saline bags. Use of multiple saline bags increases the chance of fluid overload.

7.2.22 **Do not** open the latch of pumps while hysteroscope is in the patient. This may result in a loss of visualization and/or serious patient injury.

7.2.23 **Do not** pinch, step on, kink or otherwise occlude the tubing set. Tubing restrictions can result in high pressure or poor device performance.

7.2.24 **Do not** close the latch of the pump on the indicators installed on tubing. This may result in a failure of the pump and/or tubing set.

7.2.25 Continuous, extended RF energy output may cause the Controller to overheat. If this occurs, the Controller must be allowed to cool down before further use.

7.3 RESECTING DEVICE PRECAUTIONS

7.3.1 Excessive force on the Resecting Device tip does not improve resection performance and may increase the risk of perforation or device damage.

7.3.2 Do not allow the tip of the Resecting Device to touch any hard object. If such contact does occur, inspect the tip. If there are cracks, fractures, or if there is any other reason to suspect the tip is damaged, replace the Resecting Device immediately.

7.3.3 Any monitoring electrodes are recommended to be placed as far as possible from the Resecting Device when high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.

7.3.4 Excessive force applied during insertion or removal of the Resecting Device may result in device damage or tissue injury including perforation.

7.3.5 Insertion and removal of the Resecting Device should always be under direct visualization.

7.3.6 **Do not** activate the Resecting Device unless the resecting window and tip are immersed in a saline environment. Electrodes may arc if activated in air, damaging the device.

7.3.7 **Do not** activate the Resecting Device while the resecting window section is inside the Hysteroscope. Ensure that the resecting window is outside the Hysteroscope working channel in the saline environment before activating RF resection or coagulation.

7.4 FLUID DEFICIT READOUT PRECAUTIONS

7.4.1 As an accessory to the Symphion System, all of the Symphion Operative Hysteroscopy System Warnings apply to the Symphion Fluid Deficit Readout.

7.4.2 Use of a power supply and/or cable other than those supplied as parts from Minerva Surgical, Inc. may increase electromagnetic emissions or decrease immunity of the Symphion Fluid Deficit Readout.

7.4.3 Use of this equipment adjacent to or stacked with equipment, other than a Symphion Controller, should be avoided as it could result in improper operation. If such use is necessary, the Symphion Fluid Deficit Readout and the other equipment should be observed to verify that they are operating normally.

8 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
- Cannot create seal with cavity
- Air embolism
- Damage to healthy tissue

9 ENVIRONMENTAL PROTECTION

Follow local governing ordinances and hospital practice regarding the disposal of the Resecting Device and FMA – Disposable Devices.

The Resecting Device 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.

10 HOW SUPPLIED

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

10.1 CONTROLLER WITH INTEGRATED FLUID MANAGEMENT

The Controller is supplied in a semi-ready-to-use state.
The shipping box contains:

- One (1) Controller
- One (1) Footswitch
- One (1) Detached 10 ft. Hospital Grade Power Cord
- One (1) Detached Saline Pole
- One (1) Symphion System Package Insert
- One (1) Symphion Controller Calibration Sheet

10.2 FLUID MANAGEMENT ACCESSORY

The Fluid Management Accessory is supplied sterile and is intended for single use.
The shelf box contains:

- One (1) Fluid Management tubing set.
- One (1) Biohazard Sticker
- One (1) Symphion System Package Insert

10.3 RESECTING DEVICE

The Resecting Device is supplied sterile and is intended for single use.
The shelf box contains:

- One (1) Resecting Device
- One (1) Symphion System Package Insert

10.4 FLUID DEFICIT READOUT

The FDR is supplied in a semi-ready-to-use state.
The shipping box contains:

- One (1) Fluid Deficit Readout Module
- One (1) Detachable Medical Grade Power Supply
- One (1) Detachable Locking Power Cord
- One (1) Symphion System Package Insert

11 COMPATIBILITY

The Symphion System is used in conjunction with:

- Symphion 6.3 Hysteroscope

- A single 2-liter or 3-liter Irrigation USP Saline Bag (sodium chloride (0.9% w/v; 150 mmol/L)) Irrigation Solution.
- Light Sources and Flexible Light Cables
- Endoscopic Accessory (light cable adapters, brushes)

IMPORTANT: In addition to these instructions, follow the instruction manuals or IFUs of the products used in conjunction with this product.

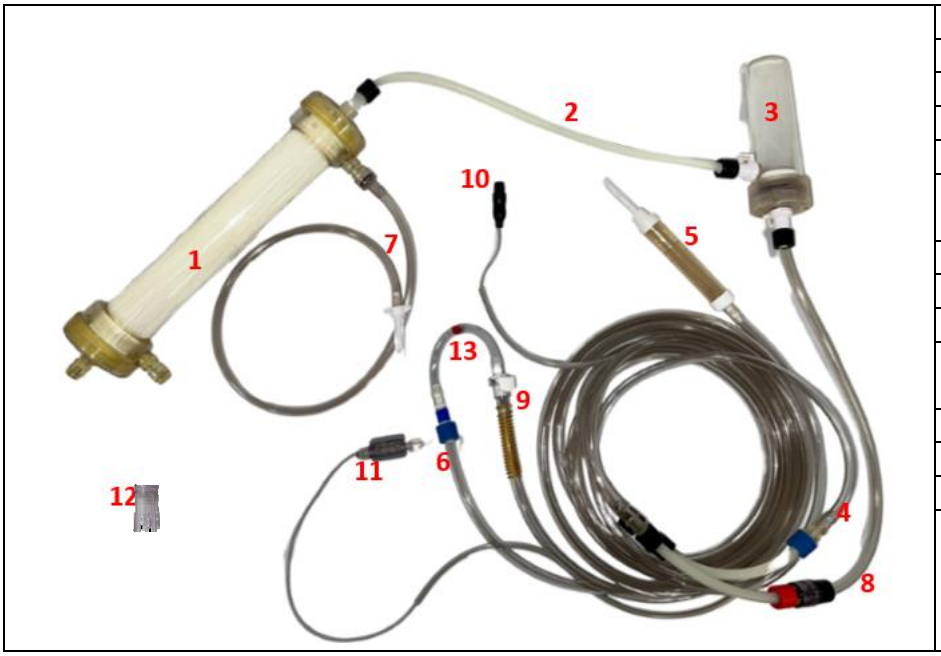
12 SYSTEM COMPONENTS

ID	Item Description
1	Footswitch Receptacle
2	Resecting Device Receptacle
3	LCD Touch Screen
4	Infusion Pump
5	Aspiration Pump
6	Pressure Sensor Receptacle
7	Power ON LED
8	Fault LED
9	RF ON LED

FIGURE 1: CONTROLLER FRONT AND ITEM DESCRIPTION

ID	Item Description
1	Saline Pole Bracket
2	Volume Control Knob
3	Equipotential Lug
4	Power Entry Module
5	Fuse Drawer
6	Power ON / OFF Switch

FIGURE 2: CONTROLLER BACK AND ITEM DESCRIPTION



ID	Item Description
1	Filter
2	Tissue Catch Tube
3	Tissue Catch
4	Infusion Tubing
5	Saline Spike – Infusion Tubing
6	Luer – Infusion Tubing
7	Filter Tube
8	Aspiration Tubing
9	Quick Connect – Aspiration Tubing
10	Pressure Sensor Connector
11	Luer – Pressure Sensor
12	Introducer
13	Bypass Connector

FIGURE 3: INFINITY FMA AND ITEM DESCRIPTION

ID	Item Description
1	RESECT (Yellow) Pedal
2	COAG (Blue) Pedal
3	Aspiration Button

FIGURE 4: FOOTSWITCH AND ITEM DESCRIPTIONS

ID	Item Description
1	Hospital Grade Power Cord- 10ft

FIGURE 5: CONTROLLER POWER CORD AND ITEM DESCRIPTION

ID	Item Description
1	Saline Hook
2	Saline Pole
3	Silicone Cap

FIGURE 6: IV POLE AND ITEM DESCRIPTION

ID	Item Description
1	Resecting Window
2	Shaft
3	Device Handle
4	Aspiration Quick Connect Fitting
5	Resecting Device Cable

FIGURE 7: RESECTING DEVICE AND ITEM DESCRIPTION

ID	Item
1	Initial Volume/Deficit Display
2	Deficit Bar Graph Indicator
3	Deficit Limit
4	Deficit Limit Adjustment - Up
5	Deficit Limit Adjustment – Down
6	Saline Bag Hook
7	Pole Mount
8	On/Off Rocker Switch
9	Recall Button
10	Power Inlet

FIGURE 8: FDR (OPTIONAL ACCESSORY) AND ITEM DESCRIPTION

ID	Item
1	DC Power Supply
2	AC Power Cord

FIGURE 9: FDR (OPTIONAL ACCESSORY) POWER CORD AND ITEM DESCRIPTION

13 SYSTEM SETUP

13.1 ASSEMBLE THE SALINE POLE

13.1.1 Remove Controller and saline pole from packaging.

NOTE: Care should be taken not to drop the Symphion Controller. Dropping the Controller can injure the user and/or the patient.

13.1.2 Place the Symphion Controller on a stable flat work surface.

13.1.3 Remove plastic cap from saline pole bracket (**Figure 10**) on the back of the Controller (**Figure 2 ID 1).**

FIGURE 10: SALINE POLE MOUNT BRACKET WITH PLASTIC CAP REMOVED

13.1.4 To attach the saline pole to the Controller slide the pole into the mount bracket on the back of the Controller.

Note: Do not use the saline pole if the IV bag hook appears damaged. Failure of the hook will prevent the proper use of the Symphion Controller.

13.1.5 Push the button on the left side of the pole mount bracket and rotate the pole until it settles to the bottom of the pole mount bracket (**Figure 11**); the saline hook on the pole will be facing away from the side of the Controller when the pole is oriented in the final position.

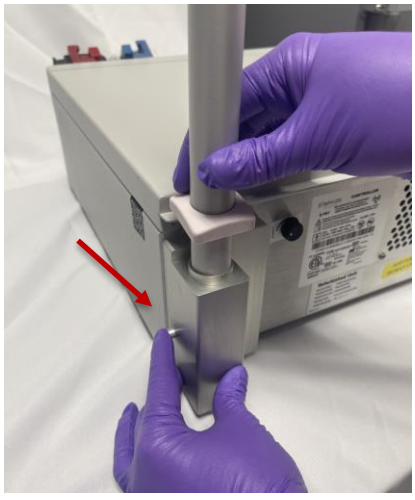


FIGURE 11: SALINE POLE MOUNT BRACKET (SIDE VIEW)

13.1.6 Pole should be in a locked position, verify by gently lifting up on the pole.

13.1.7 Slide the Silicone cap down the pole and place over the pole mount bracket to prevent ingress of liquid into the pole mount cavity (**Figure 12**).

NOTE: Maximum Saline Load of IV hook is 3.3 kg (7.2 lbs).

FIGURE 12: SALINE POLE MOUNT BRACKET WITH SILICONE CAP

13.2 FLUID DEFICIT READOUT (OPTIONAL ACCESSORY)

13.2.1 Remove the Fluid Deficit Readout Module from packaging (**Figure 13**)

FIGURE 13: FDR PACKAGING

13.2.2 Place the Symphion Fluid Deficit Readout on the Saline Pole (**Figure 14**).

FIGURE 14: FLUID DEFICIT READOUT ON SALINE POLE

13.2.3 Connect (**Figure 15**) the AC Power Cord (**Figure 9, ID 1**) to the DC Power Transformer (**Figure 9, ID 2**).

FIGURE 15: FDR POWER CORD AND TRANSFORMER

13.2.4 Plug the DC Power Transformer into the rear of the Symphion Fluid Deficit Readout (**Figure 16**).

FIGURE 16: FLUID DEFICIT READOUT (REAR VIEW)

13.2.5 Plug the AC Power Cord into power outlet.

13.3 CONTROLLER

IMPORTANT: Prior to use verify that the Controller and footswitch are decontaminated and clean and that the Hysteroscope is clean and sterilized.

13.3.1 Connect the Controller Power Cord (**Figure 17**) to the power entry module (**Figure 2, ID 4**).

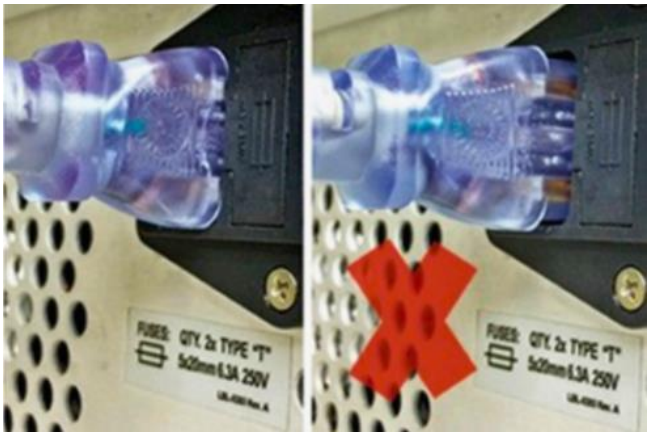


FIGURE 17: CONTROLLER POWER CORD FULLY SEATED(LEFT), NOT FULLY SEATED (RIGHT)

IMPORTANT: Ensure that the Power Cord is fully seated, plugged all the way into the power entry module.

13.3.2 Connect the power cord to power outlet.

13.3.3 Connect the footswitch cable to the footswitch receptacle (**Figure 1, ID 1**) on the left-hand side of the front panel of the Controller (**Figure 18**).

FIGURE 18: FOOTSWITCH CABLE CONNECTED TO FOOTSWITCH RECEPTACLE

IMPORTANT: ALWAYS UN-PLUG FOOTSWITCH CONNECTOR FROM CONTROLLER BY PULLING BACK ON OUTER COLLAR PRIOR TO PULLING CONNECTOR FROM CONTROLLER. FAILURE TO DO THIS MAY RESULT IN DAMAGE TO THE FOOTSWITCH CONNECTOR.

13.3.4 Turn on the Controller using the power ON/OFF switch (**Figure 2, ID 6**) on the back of the Controller.

The Software revision will appear on the screen. Verify that version 3.0.1 is displayed and then press OK to proceed (**Figure 19**).

FIGURE 19: SYMPHION CONTROLLER START UP SCREEN

IMPORTANT: If software displayed shows version 2.1.1 or prior, reference system IFU for software version 2.1.1 at *www.minervasurgical.com/IFU_Symbols-Glossary*.

13.3.5 The FMA selection screen will appear on the screen. Select INFINITY on the touch screen and Press OK to proceed (**Figure 20**). A back button will appear on screens for returning to this FMA selection screen, if needed.

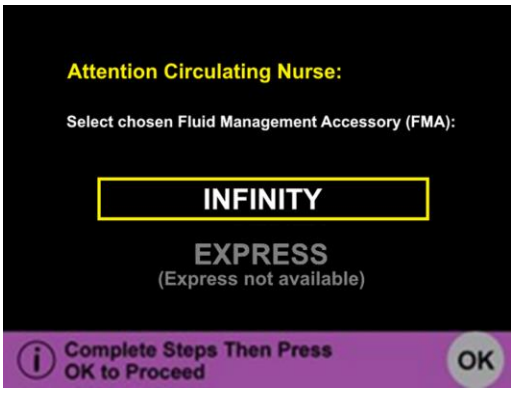


FIGURE 20: FMA CONFIGURATION SELECTION SCREEN

13.3.6 Confirm INFINITY FMA is on the affixed FMA carton label.

Note: Symphion FMA (REF# FG-0202) is not compatible with SW v3.0.0 or higher.

13.4 INFINITY FMA (REF# FG-0204)

13.4.1 **Circulating Nurse** – Confirm that a SINGLE 2-liter or 3-liter saline bag is being used, if yes, press OK (**Figure 21**).
Check the Irrigation USP saline bag (2-liter or 3-liter) for damage; do not use if damaged.
If undamaged, apply biohazard label (included in the FMA shelf box) to the saline bag or as recommended by and in accordance with applicable hospital procedures.
NOTE: Once used, the contents are considered biohazardous.

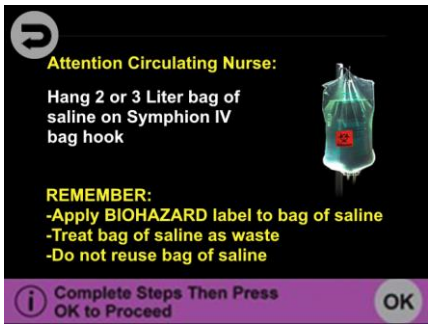


FIGURE 21: HANG BAG SCREEN

IMPORTANT: If using the optional Fluid Deficit Readout, follow the instructions in section 13.4.2 below. Otherwise, skip to section 13.4.3 for instructions to continue without the optional FDR accessory. Follow instructions in section 6.3.4 to manually calculate fluid deficit as needed.

13.4.2 **Circulating Nurse** – Prepare FDR for Bag Hanging.
Power the Symphion Fluid Deficit Readout using the rocker switch on the rear panel (**Figure 22**).

FIGURE 22: ROCKER SWITCH ON REAR FDR PANEL

Allow system to complete Power On / Self-Test sequence, wait for the “HANG BAG” prompt (**Figure 23**).

FIGURE 23: FDR FRONT, HANG BAG PROMPT

Hang the saline bag on the installed Symphion Fluid Deficit Readout device. Initial Bag Volume will then be displayed in the upper right in green in the INITIAL BAG VOLUME display and the word “Set” will be displayed in red in the DEFICIT LIMIT display in the lower left of the Fluid Deficit Readout device (**Figure 24**).

FIGURE 24: FDR DEFICIT DISPLAY

Once FDR set-up is complete and bag(s) are properly hung, press OK (**Figure 25**) on Symphion Controller.

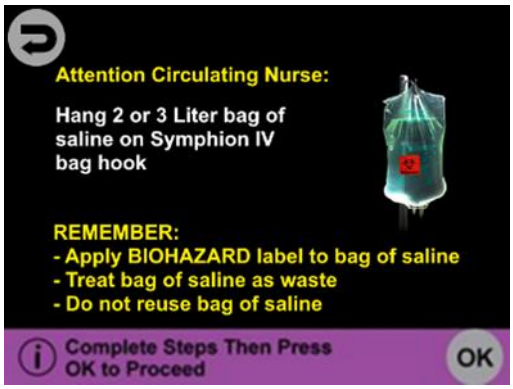


FIGURE 25: FDR HANG BAG SCREEN

13.4.3 **Circulating Nurse** – Hang the saline bag on the saline pole hook attached to the Controller.

13.4.4 **Scrub Nurse** – Place the sterilized Hysteroscope into the sterile field.

13.4.5 **Circulating Nurse –** Remove the sealed INFINITY FMA tray from the shelf box. Do not use if product or packaging is damaged.

13.4.6 **Circulating Nurse** – Following sterile practices, peel off the protecting cover sheet from the top of the tray, and hold the tray for the Scrub Nurse to remove the components within the sterile field.

13.4.7 **Scrub Nurse** – Tear the tubing tape to free the tubing. Remove the Introducer (**Figure 3, ID 12**), and the tubing from the tray by grabbing the distal ends of the Infusion and Aspiration tubing (connected by the Bypass Connector), and Pressure Sensor as shown in bottom of **Figure 26**. The remainder of the tubing will uncoil from the tray as the tubing is pulled.

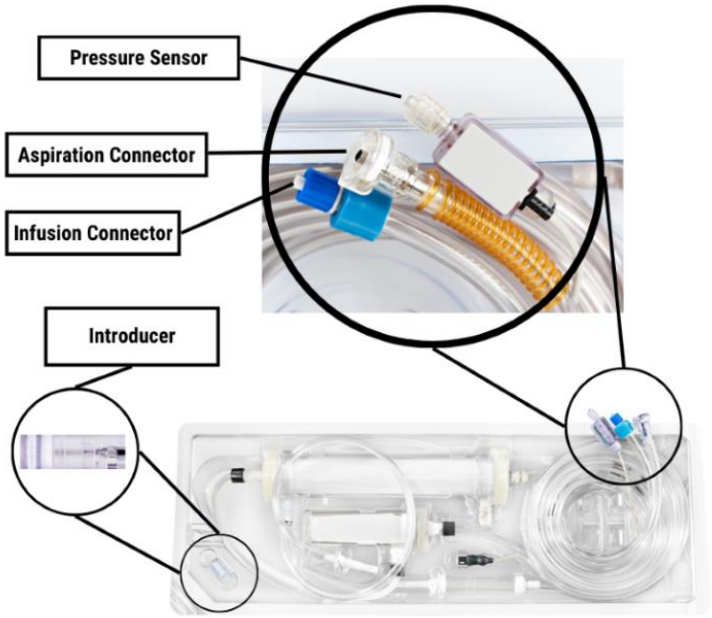


FIGURE 26: CONNECTIONS TO HYSTEROSCOPE LOCATED WITHIN TRAY (TOP), SAME CONNECTIONS REMOVED FROM TRAY (BOTTOM)

13.4.8 **Circulating Nurse** – Place the Fluid Management tray (with the system components inside) on top of or near the Controller (**Figure 27**).

FIGURE 27: TRAY PLACEMENT ON TOP OF OR NEAR CONTROLLER

13.4.9 **Circulating Nurse** – Continue the Fluid Management Accessory setup following the instructions on the Controller screen (**Figure 28**).

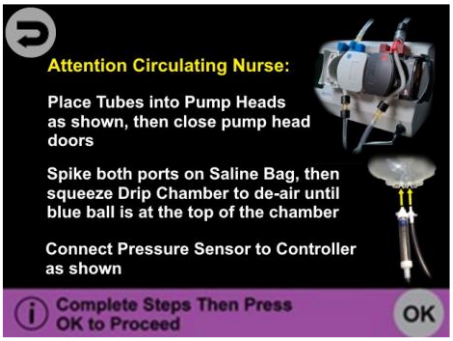


FIGURE 28:CONTROLLER SCREEN INSTRUCTIONS FOR TUBE PLACEMENT, BAG SPIKING, AND PRESSURE SENSOR CONNECTION

13.4.10 **Circulating Nurse** – Place Tubes into Pump Heads as shown in **Figure 29**. Open the pump head doors and place the sections of the Infusion Tubing (**Figure 3, ID 4**) and Aspiration Tubing (**Figure 3, ID 8**) between the indicators (approx. 12 cm) inside the Pump Heads (**Figure 1**, **ID 4** and **5**) by matching the red circle at the upper part of the pump head with the red indicator on the tube and the blue circle with the blue indicator (**Figure 29**).

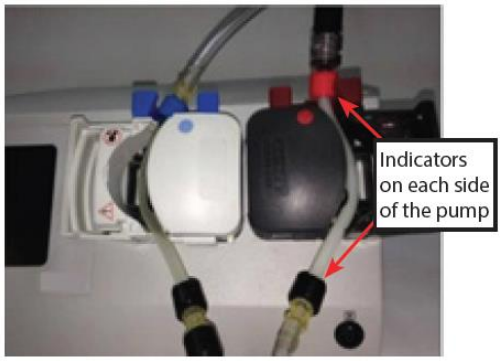


FIGURE 29: PERISTALTIC TUBE SECTIONS PLACED INTO PUMP HEADS

13.4.11 **Circulating Nurse** – Slowly close each pump head door until the latch is flush with the pump head (**Figure 30**).

FIGURE 30: PUMP HEAD DOORS FLUSH WITH PUMP HEAD

IMPORTANT: Do not kink the tubing or the tubing indicators in the pump head doors when closing the doors (Figure 31).

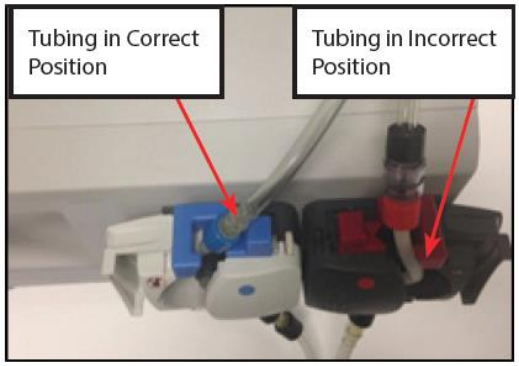


FIGURE 31: TUBING IN CORRECT POSITION (LEFT), TUBING IN INCORRECT POSITION (RIGHT)

13.4.12 **Circulating Nurse** – Following sterile practice, spike the Irrigation USP saline bag with the saline spikes on the end of the Infusion (**Figure 3, ID 5**) and Filter Tube (**Figure 3, ID 7**). Ensure that the saline spikes completely engage the saline orifice and no leakage occurs around the spikes (**Figure 32**). Inspect the saline bag for any damage.

FIGURE 32: SALINE SPIKE IN SALINE BAG WITH TWO SPIKE PORTS

NOTE: Either Port is acceptable for the saline spike (**Figure 32**).

IMPORTANT: When spiking saline bag, FDR may produce audible tones.

13.4.13 **Circulating Nurse** – De-air the drip chamber (**Figure 33**) at the end of the Infusion Tubing by squeezing the drip chamber (pushing the air out) and releasing it (allowing the saline to pass into the drip chamber). Repeat until the drip chamber is completely full of saline (free from air) and the blue ball is at the top of the chamber.

FIGURE 33: DRIP CHAMBER WITH BLUE BALL AT THE TOP OF THE CHAMBER AFTER DE-AIRING

13.4.14 **Circulating Nurse** – Connect the pressure sensor connector (**Figure 3, ID 10**) to the pressure sensor receptacle on the Controller (**Figure 34**) by aligning the white markings on the connector and receptacle.

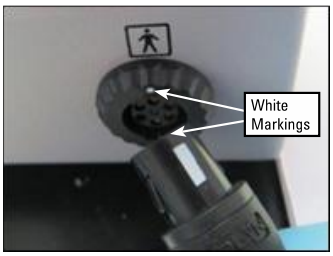


FIGURE 34: PRESSURE SENSOR RECEPTACLE DOT ALIGNED WITH PRESSURE CONNECTOR WHITE STRIP

IMPORTANT: Ensure that the connector is advanced into the Controller receptacle until flush.

13.4.15 **CIRCULATING NURSE** – When pressure sensor is connected, press OK on the Controller Screen. The Controller will run the Pressure Sensor Self-Test (approximately 5 seconds) **(Figure 35).** If pressure sensor test fails, the Controller will display the "Pressure Sensor Test FAILED" message and "Replace Pressure Sensor". If this were to occur, remove saline bag from IV hook, lay on flat surface, do not remove spike until new INFINTY FMA is ready to spike. Spike saline bag while on flat surface to minimize fluid leakage. Return to **Section 13.4.2** (if using FDR) or **Section 13.4.3** and resume INFINITY FMA setup.

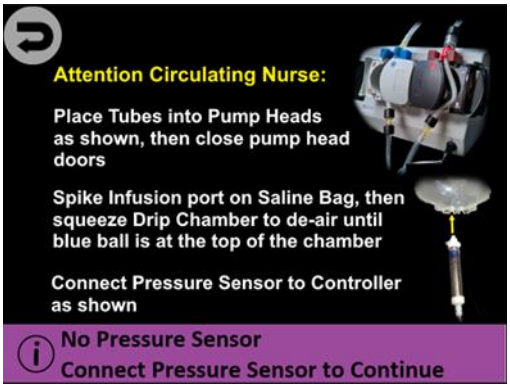


FIGURE 35: CONTROLLER SCREEN INSTRUCTIONS FOR PRESSURE SENSOR CONNECTION

IMPORTANT: If the Pressure Sensor is disconnected at any time during the procedure, the Controller will alert the user and the following message will appear on the touch screen: "No Pressure Sensor. Connect Pressure Sensor to Continue".

If the pressure sensor test passes the following instruction will appear on the Controller screen (**Figure 36**).

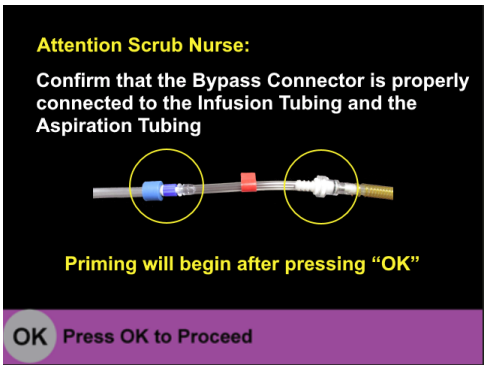


FIGURE 36: PRE-PRIMING INSTRUCTIONS SCREEN

13.4.16 **Scrub Nurse** – Verify that the Bypass Connector (**Figure 3, ID 13**) is properly in place connecting the infusion and aspiration ports together.

13.4.17 **Circulating Nurse** – Press "OK" and priming will begin (**Figure 36**). When priming is complete, the Controller will advance to the final Fluid Management Accessory setup screen (**Figure 37**).

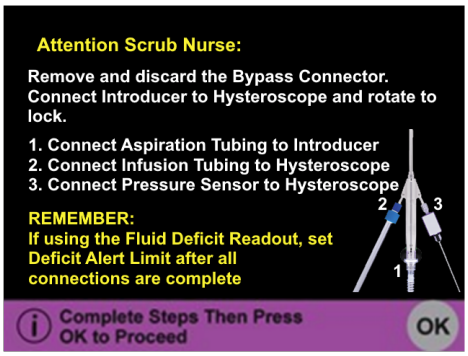


FIGURE 37: FINAL FMA SETUP SCREEN

Note: During the priming cycle, saline from the IV bag will be circulated through the Fluid Management circuit and back to the Saline bag. The total prime time is approximately 40 seconds.

IMPORTANT: FDR will generate audible tones during and after priming until the deficit alert limit is set.

13.4.18 **Scrub Nurse** – Remove and discard the Bypass Connector. Follow the Fluid Management Accessory set up instructions on the Controller screen to complete the set up (**Figure 37**).

IMPORTANT: If using FDR, Set deficit alert limit according to instructions below.

13.4.19 **Circulating Nurse** – Set the desired Fluid Deficit by pressing the up arrow . The maximum settable Deficit Limit based on the selected saline bag volume is shown in **Table 2**.

TABLE 2: MAXIMUM DEFICIT SET LIMIT

Saline Bag Volume	Maximum Deficit Limit
2 Liter	1450 mL
3 Liter	2450 mL

13.4.20 **Scrub Nurse** – Connect the Introducer (**Figure 3, ID 12**) to the proximal end of the Hysteroscope (**Figure 38**) by aligning the teeth on the Hysteroscope with the slots on the introducer. Once aligned, rotate clockwise until a click is felt (approximately 15°).

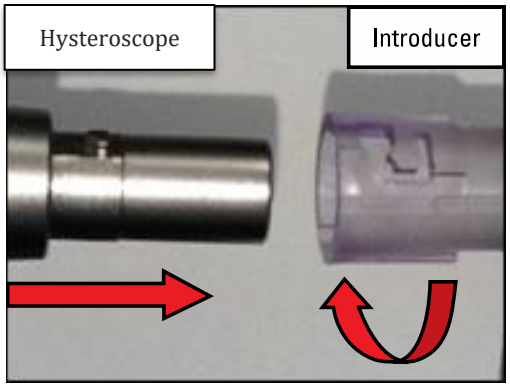


FIGURE 38: CONNECTION OF HYSTEROSCOPE TO INTRODUCER

13.4.21 **Scrub Nurse** – Connect the Aspiration Tubing (**Figure 3, ID 8**) to the proximal end of the Introducer (**Figure 39**).

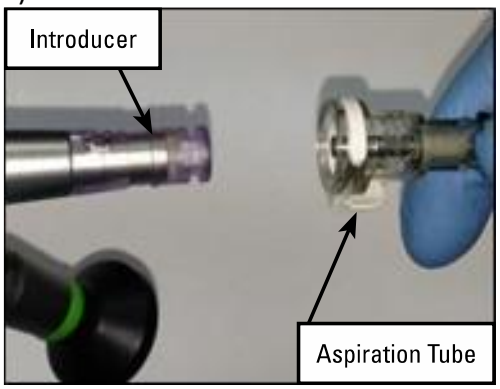


FIGURE 39: CONNECTION OF ASPIRATION TUBING TO INTRODUCER

IMPORTANT: For all quick-connect fittings (Figure 40) press connectors together until they click together securely. To disconnect, press tab on quick connect fitting and pull apart.

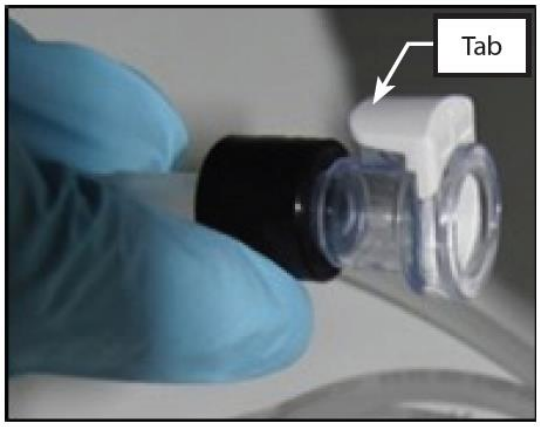


FIGURE 40: QUICK CONNECT FITTING

13.4.22 **Scrub Nurse** – Connect the luer on the Infusion Tubing (**Figure 3, ID 4**) to either of the two luer connections on the Hysteroscope (**Figure 41**).

FIGURE 41: INFUSION TUBING LUER CONNECTION ON HYSTEROSCOPE

13.4.23 **Scrub Nurse** – Connect the luer on the Pressure Sensor (**Figure 3, ID 10**) to the available luer connection on the Hysteroscope (**Figure 42**). A fully assembled Hysteroscope is depicted in **Figure 43**.

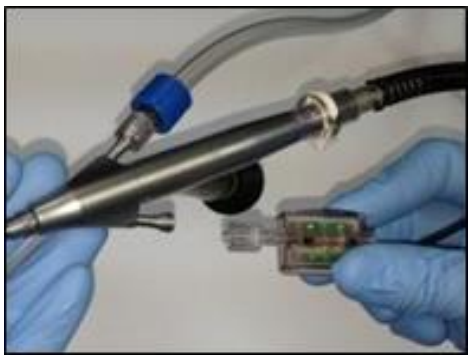


FIGURE 42: PRESSURE SENSOR LUER CONNECTION TO HYSTEROSCOPE

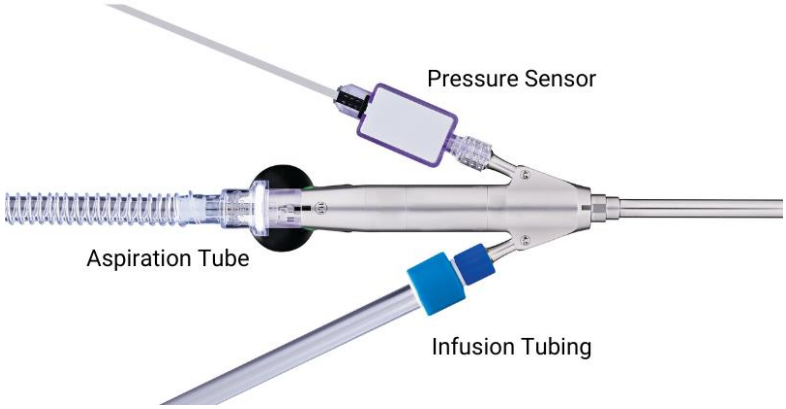


FIGURE 43: FULLY ASSEMBLED HYSTEROSCOPE

13.4.24 **Circulating Nurse** – Verify that the Scrub nurse has completed all required connections to the Hysteroscope. Press OK to enter diagnostic mode (**Figure 44**).

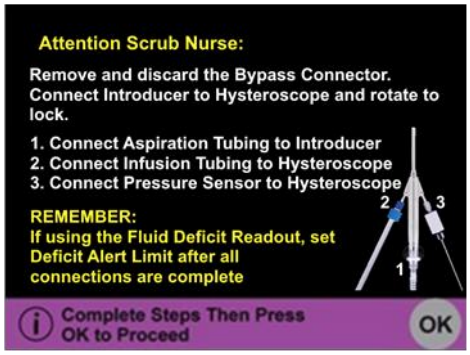


FIGURE 44: FINAL FMA SETUP SCREEN

NOTE: Ensure that the camera, the light source and the FMA tubing connections are properly connected to ensure adequate visualization.

14 SYSTEM OPERATION

CAUTION: IF THE SALINE BAG BECOMES EMPTY DURING THE PROCEDURE, STOP AND TERMINATE THE PROCEDURE IMMEDIATELY. DO NOT REPLACE THE SALINE BAG.

14.1 DIAGNOSTIC MODE

14.1.1 **Physician** – Set the desired cavity pressure on the touch screen of the Controller **(Figure 45)** by pressing the up arrow in the cavity pressure box. The cavity pressure can be adjusted at any time during the procedure. A cavity set pressure higher than 45 mmHg is REQUIRED to start infusion.

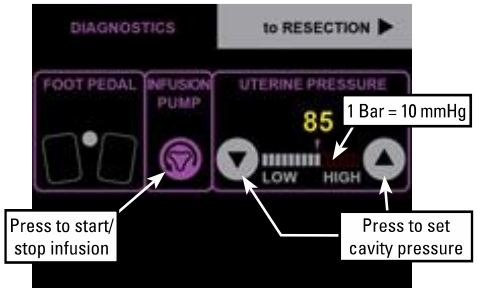


FIGURE 45: CONTROLLER CAVITY PRESSURE ADJUSTMENT

IMPORTANT: Use of pressure 100 mmHg or higher will require on-screen confirmation from the user (Figure 46). The maximum pressure that can be set by the user is 125 mmHg.

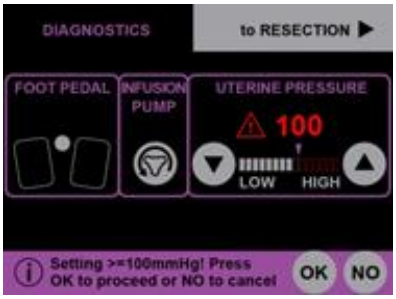


FIGURE 45: CONTROLLER HIGH PRESSURE ACKNOWLEDGEMENT SCREEN

14.1.2 **Physician** – Immediately before Hysteroscope insertion, start infusion by pressing the infusion pump button on the touch screen of the Controller (**Figure 45**) to start fluid flow.

14.1.3 **Physician** – Insert the Hysteroscope using standard hysteroscopic techniques.

IMPORTANT: Infusion must be on to maintain inflow and distension in the cavity. Pressing the aspiration button with infusion off will cause the cavity to collapse.

14.1.4 **Physician** – Aspiration (**Figure 47**) can be activated by pressing the center button on the footswitch (**Figure 4, ID 3**). This will circulate the fluid through the Infusion and Aspiration Tubing. RESECT (Yellow) and COAG (Blue) footswitch pedals will not work in diagnostic mode.

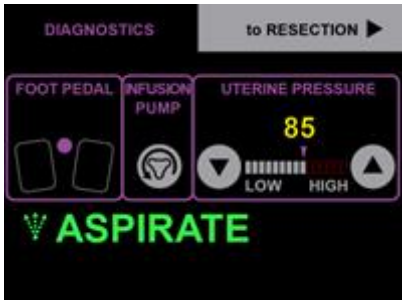


FIGURE 46: CONTROLLER ACTIVE ASPIRATION SCREEN

14.2 RESECTION MODE

14.2.1 **Circulating Nurse –** Remove the sealed Resecting Device from the shelf carton. Do not use if the product or packaging is damaged.

14.2.2 **Circulating Nurse –** Following sterile practices peel off the protecting cover sheet from the top of the tray and hold the tray for the Scrub Nurse to remove the Resecting Device.

14.2.3 **Scrub Nurse** – Remove the Resecting Device (**Figure 7**) from sterile package and place onto the sterile table.

14.2.4 **Scrub Nurse** – Following sterile practices pass the device cable out of the sterile field to the circulating nurse.

14.2.5 **Circulating Nurse –** Connect the device cable by pushing the device connector into the device receptacle (**Figure 1, ID 2**) on the Controller front panel (**Figure 48**).

FIGURE 47: CONTROLLER FOOTSWITCH RECEPTACLE

14.2.6 **Scrub Nurse or Physician** – Disconnect the Aspiration Tubing from the Introducer (**Figure 49**).

IMPORTANT: Ensure the infusion pump is turned off before disconnecting.

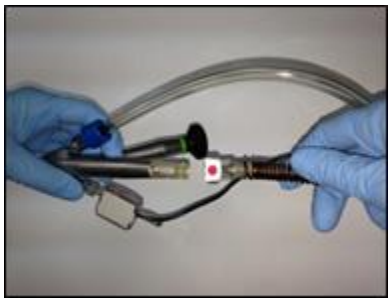


FIGURE 48: DISCONNECTED ASPIRATION TUBING

14.2.7 **Scrub Nurse** – Connect the Aspiration Tubing to the quick connect fitting on the proximal end of the Resecting Device (**Figure 50**).

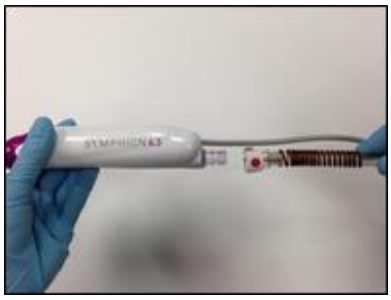


FIGURE 49: RESECTING DEVICE ASPIRATION QUICK CONNECT

14.2.8 **Scrub Nurse or Physician** – Introduce the Resecting Device into the working channel of the Hysteroscope through the Introducer (**Figure 51**).

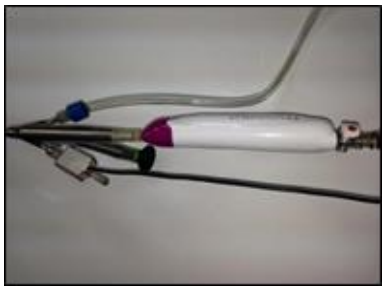


FIGURE 50: RESECTING DEVICE INSERTED INTO HYSTEROSCOPE

14.2.9 **Circulating Nurse –** To begin Resection Mode, press the "to RESECTION" tab on the top right corner of the screen on the Controller (**Figure 52**).

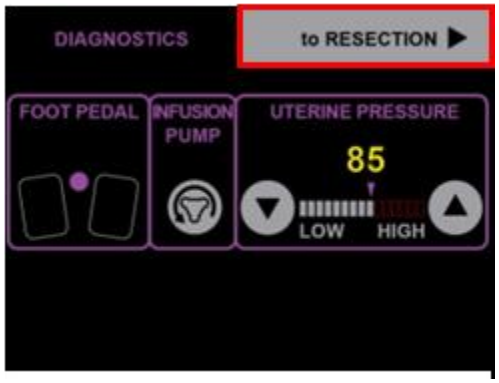


FIGURE 51: CONTROLLER RESECTION SELECTION SCREEN

Note: If the Resecting Device is disconnected from the Controller for more than 10 seconds, the Controller will return to DIAGNOSTIC mode.

14.2.10 **Physician** – Position the window of the Resecting device onto the surface of the tissue **(Figure 53)** and press the RESECT pedal to perform resection.

IMPORTANT: Ensure infusion pump is on before initiating resection.

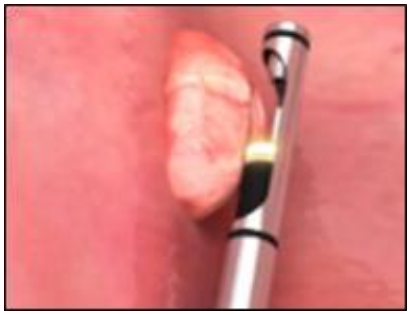


FIGURE 52: TISSUE PLACEMENT FOR RESECTION

14.2.11 **Physician** – The yellow RESECT foot pedal (**Figure 4, ID 1**) activates RF resection as indicated on the display **(Figure 54).** The Resecting Device operates at a fixed speed. The resected tissue is aspirated from the treatment area via the inner tube of the Resecting Device and then through the Aspiration Tubing to the Tissue Catch.

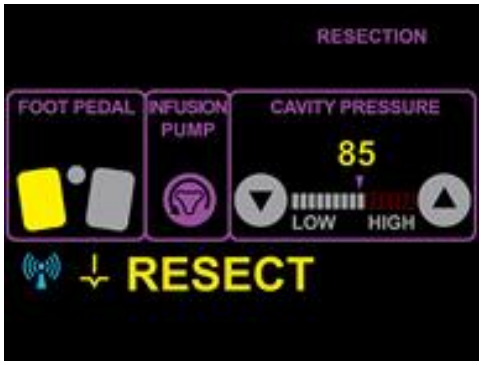


FIGURE 53: CONTROLLER ACTIVE RESECTION SCREEN

IMPORTANT: If the Resecting Device is not reciprocating during the procedure, ensure that all connections are properly made to the Controller.

14.2.12 **Physician** – If bleeding occurs during the procedure, advance the active electrode of the Resecting Device (**Figure 55**) to the source of the bleeding and depress the blue COAG foot pedal (**Figure 4, ID 2**).

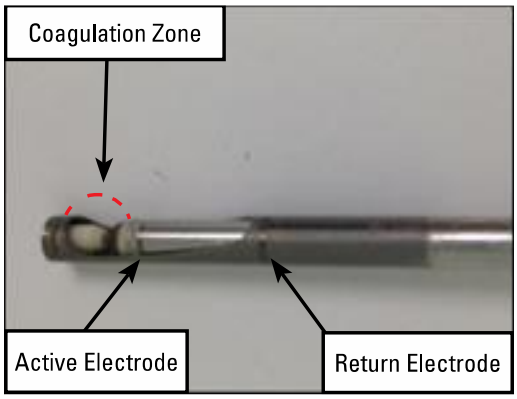


FIGURE 54: COAGULATION ZONE OF RESECTING DEVICE

14.2.13 **Physician** – The blue COAG foot pedal (**Figure 4, ID 2**) activates coagulation as indicated on the display (**Figure 56**).

FIGURE 55: CONTROLLER ACTIVE COAGULATION SCREEN

IMPORTANT: Clinical observation (e.g., vital signs and physical examination) is recommended to reduce the risk of blood loss and excessive bleeding. For INFINITY FMA, visualization of filtered/returned fluid is also recommended.

NOTE: To maintain visualization during coagulation, fluid will be circulated at 10 second intervals while coagulation is active.

15 FDR RECALL MODE

If the optional Fluid Deficit Readout is being used and is turned off or loses power, the FDR will store the last displayed deficit volume. To access the stored value using the "Recall" button, follow the instructions below.

15.1 Remove saline bag from hook

15.2 Power System on and wait for "HANG BAG" prompt, indicating completion of system initialization. DO NOT HANG SALINE BAG WHEN PROMPTED.

15.3 Press Recall Button (**Figure 57**) on the rear panel.

FIGURE 56: FDR REAR PANEL, RECALL BUTTON

15.4 The recall value will be displayed in the Initial Value/Deficit display (**Figure 58**).

FIGURE 57: FDR FRONT PANEL DEFICIT DISPLAY

15.5 To exit recall mode and resume typical functionality, power the system off and back on.

16 DISASSEMBLY

16.1 FLUID MANAGEMENT ACCESSORIES

16.1.1 Immediately before the removal of the Hysteroscope and Resecting Device from the uterine cavity, turn off saline infusion by pressing the “infusion pump” button on the touch screen of the Controller.

16.1.2 Remove the Resecting Device and Hysteroscope together from the uterine cavity.

16.1.3 Wait a minimum of 60 seconds for any fluid pressure to dissipate from the tubing set.

16.1.4 Remove the tissue catch and obtain the tissue specimen (**Figure 59**)

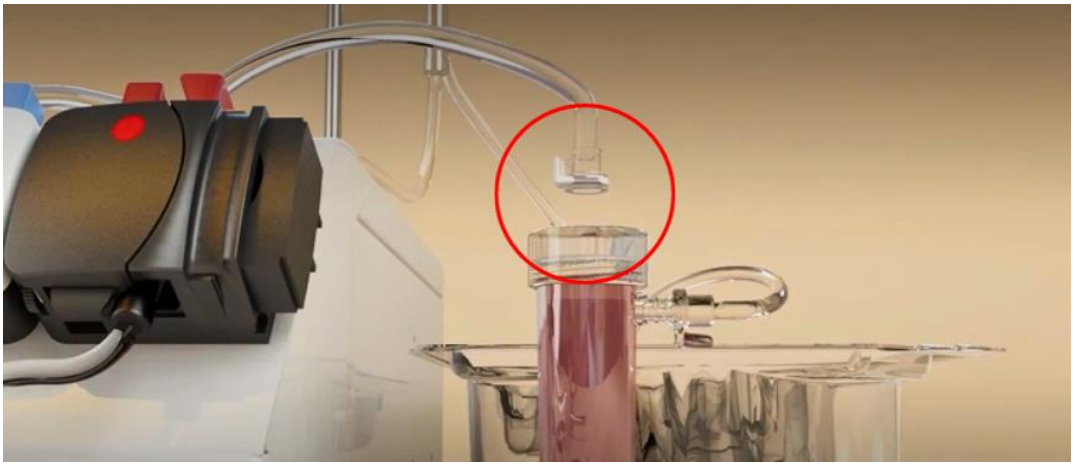


FIGURE 58: QUICK DISCONNECT REMOVAL

16.1.5 Disconnect the Pressure Sensor and Resecting Device from the Controller.

IMPORTANT: If un-plugging the foot switch connector, always un-plug the footswitch connector from the controller by pulling back on outer collar prior to pulling connector from controller. Failure to do this may result in damage to the footswitch connector.

16.1.6 Disconnect the Pressure Sensor and the Infusion Tubing from the Hysteroscope.
16.1.7 Disconnect the Introducer from the Hysteroscope and remove it with the Resecting Device. See (**Figure 60)** for fully disassembled Hysteroscope.

FIGURE 59: DISASSEMBLED HYSTEROSCOPE

NOTE: Follow reprocessing instructions for Hysteroscope (Refer to L0156 Symphion 6.3 Hysteroscope IFU at WWW.MINERVASURGICAL.COM/IFU_SYMBOLS-GLOSSARY).

16.1.8 Place the Resecting Device, tubing and cable on the Fluid Management Tray.
16.1.9 Unhook the saline bag and place it/them on the Fluid Management Tray.
16.1.10 Turn off Fluid Deficit Readout and unplug power cord from FDR. Remove the Fluid Deficit Readout from Controller pole. Clean and store according to instructions in **Section 17**.

NOTE: If procedure is not yet complete and a new FMA will be used, skip this step.

IMPORTANT: If the procedure is to be continued, ensure the same initial saline bag is used. Do not use a new saline bag.

IMPORTANT: Saline bag is a biohazardous material. Dispose of the remaining saline and the saline bag per hospital standards concerning biohazard materials.

16.1.11 Open the pump heads to remove the tubing.
16.1.12 Dispose of the remainder of the Resecting Device, FMA and saline bag per hospital standards concerning biohazardous materials.
16.1.13 Disconnect the footswitch and turn off the Controller.

16.2 SALINE POLE (OPTIONAL)

16.2.1 Push the button on the left side of the bracket.
16.2.2 Lift the pole straight up to remove.

16.3 TISSUE CATCH

16.3.1 Disconnect both quick connect fittings from the Tissue Catch.

16.3.2 Unthread the Tissue Catch cap and remove cap and tissue bag to access resected tissue. (**Figure 61**).

FIGURE 60: FMA TISSUE CATCH CAP REMOVAL

17 CLEANING

It is recommended that the Symphion controller is inspected and cleaned after each use. Listed below are recommendations for cleaning the Controller, Footswitch and optional Fluid Deficit Readout Accessory. These devices do not need to be sterilized before or after use.

NOTE: Follow standard hospital procedures for cleaning.

17.1 Disconnect the Controller or Fluid Deficit Readout accessory from the electrical source.

17.2 Wipe the Controller, footswitch, footswitch cable, the FDR and FDR cables (if used) with a clean damp cloth wetted with water, isopropyl alcohol, 1.5% hydrogen peroxide, or a mild bleach solution. Prolonged exposure to any corrosive solvents or disinfectants should be avoided.

18 STORAGE AND HANDLING

18.1 CONTROLLER

The Symphion Controller is intended to be transported and stored in an environment that is kept within the following conditions see **Table 3**:

TABLE 3: CONTROLLER STORAGE CONDITIONS

Temperature	0°F to 140°F (-18°C to 60°C)
Relative Humidity	15% to 85% non-condensing
Atmospheric Pressure	50 to 106 kPa

18.2 FLUID MANAGEMENT ACCESSORY

The unused FMA should be stored at room temperature, away from moisture and direct heat.

18.3 RESECTING DEVICE

The Resecting Device should be stored at room temperature, away from moisture and direct heat.

18.4 FLUID DEFICIT READOUT

The Symphion Fluid Deficit Readout is intended to be transported and stored in an environment that is kept within the conditions stated in **Table 4**.

TABLE 4: FDR STORAGE CONDITIONS

Temperature	-4°F to 140°F (-20°C to 60°C)
Relative Humidity	10% to 90% (non- condensing)
Atmospheric Pressure	50 kPa to 106 kPa

19 MAINTENANCE, TROUBLESHOOTING AND REPAIR

19.1 TROUBLESHOOTING

See **Appendix E** for further information on Troubleshooting.

19.2 ADJUSTING VOLUME

The Controller has an adjustable volume control (**Figure 2, ID 2**) on the back of the unit. Twisting the adjustor clockwise will increase the volume.

19.3 REPLACING A FUSE IN THE CONTROLLER

In the event of a blown fuse, only 5x20 mm 6.3A/250VAC Type “T” (slow blow) fuses should be used as replacements. Turn the power off and disconnect the power cord from the electrical outlet. Remove the fuses by opening the Power Entry Module’s Fuse Drawer (**Figure 2, ID 5**) on the back of the Controller. Replace both fuses with new ones; then close the fuse drawer. Other than the fuses, there are no user serviceable parts. For replacement, return cleaned unit to manufacturer.

19.4 SOFTWARE SECURITY

- The Symphion Controller 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 onsite by a Minerva Surgical representative only.
- Do not attempt to access, tamper with, or otherwise make any software modifications. Doing so will void the warranty and may cause the controller to become unresponsive.
- When the Symphion Controller is not in use, ensure that it is secured physically to prevent potential tampering.

19.5 FDR ANNUAL INSPECTION – BASIC FUNCTION SCALE TEST

Biomedical technicians or otherwise qualified personnel are required to check the accuracy of the Fluid Deficit Readout annually. The accuracy can be evaluated with the following equipment:

- Weight: Appropriate 3 Kg weight (e.g. Rice Lake 3Kg P/N 96403, Certified Scale P/N 12517-AC, or similar)

The procedural steps to evaluate the FDR accuracy are as follows:

1. Follow **Section 12** System Setup until the Fluid Deficit Readout set-up is finished.
2. Follow the "FDR Preparation for Bag Hanging" section in **Section 12.4.2** (INFINITY FMA) but instead of hanging a saline bag, hang the weight specified.
3. Wait for the readings and the weight to stabilize when measuring.
4. Once stabilized, verify the displayed volume with the applied weight according to **Table 5**.

TABLE 5: WEIGHT CONFIRMATION RANGE

Weight	Confirmation Range
3 Kg	2950 – 3270 mL

Record the results in the recommended test log in Appendix B. The accuracy is acceptable if the displayed value is within the confirmation range associated with the provided weight. If the accuracy is outside the confirmation range shown, contact a Minerva service representative to send FDR to the manufacturer for repair. **Do not continue to use FDR.**

20 LIMITED WARRANTY

20.1 SYMPHION CONTROLLER AND FLUID DEFICIT READOUT ACCESSORY

Minerva Surgical warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Minerva's control directly affect the instrument and the results obtained from its use. Minerva's obligation under this warranty is limited to the repair or replacement of this instrument that Minerva Surgical determines is caused by defects in material and workmanship if notice thereof is received within one year plus a 7-day grace period from the date of shipment. Minerva shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Minerva Surgical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Buyer may, at its sole cost and expense, purchase an extended warranty (CORECare Warranty Agreement) from Minerva Surgical to extend the term of this warranty.

20.2 SYMPHION RESECTING DEVICE AND SYMPHION FLUID MANAGEMENT ACCESSORY

Minerva Surgical warrants that reasonable care has been used in the design and manufacture of these devices. **This warranty is in lieu of and excludes all other warranties not expressly**

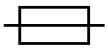
set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Minerva's control directly affect the instrument and the results obtained from its use. Minerva's obligation under this warranty is limited to the repair or replacement of this instrument that Minerva Surgical determines is caused by defects in material and workmanship if notice thereof is received within one year plus a 7-day grace period from the date of shipment. Minerva shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Minerva neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Minerva Surgical assumes no liability with respect to Symphion Resecting Devices and Symphion Fluid Management Accessory that are reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.** Buyer may, at its sole cost and expense, purchase an extended warranty (CORECare Warranty Agreement) from Minerva Surgical to extend the term of this warranty.

21 CUSTOMER SERVICE/TECHNICAL SUPPORT

Contact Minerva Surgical Customer Service for customer support.
Call +1 (855) 646-7874

22 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

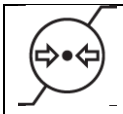
	Infusion Pump ON / Off		Message Screen Info
	OK button		No Button
	Do not push here while saline bag is mounted		RF On
	Back Button		Fuses
	Footswitch		

23 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_1N_2	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).	Manufacturer-determined degree of particle and water ingress protection, where... N1= degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8)
	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer	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

Legal Manufacturer

Minerva Surgical, Inc.
4255 Burton Drive,
Santa Clara, CA 95054 USA
Customer Service 855-646-7874

APPENDIX A - SPECIFICATIONS

TABLE 6: CONTROLLER PRODUCT SPECIFICATIONS

I. Specifications	
Mode of Operation	Intermittent. Duty Cycle: 30 seconds ON 10 seconds OFF
Input	100-240VAC, 50-60Hz, 700VA
Dimensions without Pump Heads and Saline Pole	6 ¾ ”(H) x 16 ⅛”(W) x 21 ⅛”(D) (17.1 x 41.0 x 53.7 cm)
Packaged Weight	39 lbs (17.7kg)
Output (Resect):	275W ±20%, 275VMAX, 148 kHz, 200 Ω load
Output (Coag):	110W ±20%,, 200VMAX, 148 kHz, 200 Ω load
Fuses	5x20mm Type “T” 6.3A/250V slow blow (Qty. 2; Littelfuse or equivalent)
Weight and dimensions indicated are approximate. Specifications are subject to change without notice.	
II. Protection	
Class 1, Type BF, intermittent operation; Enclosure IP 21	
III. Operating Conditions	
Temperature	60°F to 80°F (16°C to 27°C)
Relative Humidity	30% to 75% non-condensing
Atmospheric Pressure	86 to 106 kPa
IV. Transport and Storage Requirements	
Temperature	0°F to 140°F (-18°C to 60°C)
Relative Humidity	15% to 85% non-condensing
Atmospheric Pressure	50 to 106 kPa

TABLE 7: FLUID DEFICIT READOUT SPECIFICATIONS

I. **Specifications**	
Mode of Operation	Continuous Operation
Power Supply Manufacturer	SL Power Electronics
Power Supply Input	100 – 240 VAC, 50-60 Hz
Power Supply Output	5V DC, 2.0A, 10 Watts
Power Cord Length	12 ft minimum
Dimensions	14.5 inches x 12.5 inches x 5.75 inches (LxWxH)

Packaged Weight	5.3 lbs (2413 g)
Weight and dimensions indicated are approximate. Specifications are subject to change without notice.	
II. Protection	
Class 1; Continuous Operation; Enclosure IP21	
III. Operating Conditions	
Temperature	50°F to 95°F (10°C to 35°C)
Relative Humidity	30% to 75% (non-condensing)
Atmospheric Pressure	70 kPa to 106 kPa
IV. Transport and Storage Conditions	
Temperature	-4°F to 140°F (-20°C to 60°C)
Relative Humidity	10% to 90% (non-condensing)
Atmospheric Pressure	50 kPa to 106 kPa

APPENDIX B - FLUID DEFICIT READOUT ACCURACY CHECK LOG

Recommendation: Fill out accuracy check log when FDR is being evaluated for accuracy. Keep log with the FDR unit for reference of preventative maintenance performed and for ongoing documentation of subsequent accuracy checks. See **Section 19.5** for instructions on performing annual accuracy inspection.

Fluid Deficit Readout Accuracy Check					
Date	**FDR Serial#**	**Weight Reading**	**Signature**	**Results**	**Comments**

APPENDIX C – ABBREVIATIONS

Controller	Symphion® Controller
LED	Light Emitting Diode
RF	Radio Frequency
LCD	Liquid Crystal Display

APPENDIX D – TONES

TABLE 8: CONTROLLER TONES

Controller	
Tone Name	**Description**
Tone 1	Self Test Tone – at Power up
Tone 2	Treatment Tone RESECT
Tone 3	Treatment Tone COAG
Tone 4	High Pressure Tone
Tone 5	Tube Blocked Tone
Tone 6	Connect Tone
Tone 7	Disconnect Tone
Tone 8	Error Tone – continuous until unit powered off
Tone 9	Notification Tone
Tone 10	Leak Tone
Tone 11	Click Tone

TABLE 9: FLUID DEFICIT READOUT TONES

Fluid Deficit Readout	
Tone Name	**Description**
Unset Notification	1 beep / 3 seconds: The Deficit Limit has not been set
Fluid Deficit Notification	2 beeps / 3 seconds: The Fluid Deficit has reached the Deficit Limit

APPENDIX E - TROUBLESHOOTING

IMPORTANT: If you cannot eliminate the issue with the help of this table, please contact the service department or return the device for repair. There are no user serviceable parts inside of the Controller or Fluid Deficit Readout! Opening the unit may cause electrical shock to the user and voids warranty.

TABLE 10: CONTROLLER TROUBLESHOOTING

Controller			
DISPLAYED ERROR CODE	**ERROR CODE DESCRIPTION**	**POSSIBLE CAUSES**	**REMEDY**
Black screen, no LEDs on	The Controller does not power on	• The AC Power switch is not switched on • Power cable not connected • No line voltage • Fuses defective • Controller defective	• Switch on the power switch on the back of the controller • Ensure power cable is connected to Controller and wall. • Ensure power is being supplied to the Controller • Replace Fuses • Send in for repair
N/A	The Controller lost Power	• Power Cord was not installed properly	• Fully plug Cord into Power Entry Module as described Controller Set Up Instructions (Section 13 System Setup)
Check Aspiration Tubing for Kink Press OK to CONTINUE	Insufficient Aspiration	• Aspiration Tubing not connected correctly • Aspiration tubing kinked or occluded • Resecting Device defective	• Check that Aspiration Tubing is properly inserted in pump, check that connections are secure, replace if necessary • Check Aspiration tubing for occlusion • Replace Resecting Device
Check Infusion Tubing for Kink Press OK to CONTINUE	Kinked Tubing	• Infusion Tubing is kinked or occluded • Position indicators on tubing are inside of infusion pump	• Check Infusion Tubing for kinks and constrictions • Check that Infusion Tubing is properly inserted into pump
Unkink Aspiration Tube or, Replace FMA	Return Fluid Path Obstructed	• Filter is at capacity (INFINITY only) • Tissue Catch/Tissue Catch Tubing/ Filter Tubing or recovery bag tubing is kinked	• Replace FMA. See section 13.4 (INFINTY FMA) above for instructions. If using optional FDR, record deficit value prior to

Controller			
DISPLAYED ERROR CODE	**ERROR CODE DESCRIPTION**	**POSSIBLE CAUSES**	**REMEDY**
		or occluded	restart. **CAUTION: DO NOT HANG A NEW SALINE BAG. HANG THE SAME SALINE BAG USED IN THE BEGINNING OF THE PROCEDURE TO CONTINUE.** Note: Priming the FMA results in a loss of 500-600mL of saline from the hanging saline bag. Plan the procedure accordingly based on the remaining fluid within the saline bag. • Check that Aspiration Tubing is properly inserted into pump • Check Tissue Catch/Tissue Catch Tubing/ Filter Tubing or recovery bag tubing for kink or occlusion
No Device Detected Connect Device to CONTINUE	No Device Detected	• Resecting Device not connected, connected improperly, or defective	• Check Resecting Device connection, replace if necessary • Ensure the Resecting Device is securely plugged into the blue connector
Device Failure Replace DEVICE to CONTINUE	Device Failure	• Resecting Device malfunction	• Replace Resecting Device
Infusion Tubing not present Insert Tubing Pressure Too High Make Sure Scope Not In Cavity	Prime Stopped	• Infusion Tubing not connected correctly • Excessive Pressure Detected	• Check that Infusion Tubing is properly inserted in pump, check that connections are secure, replace if necessary • Check that Hysteroscope end is not inserted into cavity
Check System for Leak	Fluid Leak	• Device connections leaking saline • Leaking fluid around the cervix • Perforation	• Check device/tubing connections Reconnect/replace as needed • Check cervix for leaking,

Controller			
DISPLAYED ERROR CODE	**ERROR CODE DESCRIPTION**	**POSSIBLE CAUSES**	**REMEDY**
			add/adjust tenaculum at the cervix • Check for perforation
No Pressure Sensor Connect Pressure Sensor to Continue Unscrew Pressure Sensor from Scope then Press OK Testing Pressure Sensor Please Wait Re-Attach Pressure Sensor Press OK	Pressure Sensor Not Connected	• Pressure Sensor incorrectly connected or defective	• Check that Sensor is fully attached to Hysteroscope and inserted correctly to Controller; replace if necessary
Excessive Cavity Pressure Relieving Pressure	Excessive Cavity Pressure	• Pressure in the cavity is beyond set limit	• Wait and allow system to clear (<5 secs), check return tubing for occlusion
Pressure Sensor Test FAILED Replace Pressure Sensor	Pressure Sensor Failure	• Pressure Sensor incorrectly connected or defective • Pressure reading outside range	• Check that sensor plug is fully inserted into the Controller; replace if necessary
No Device Detected Connect Device to CONTINUE	Cannot RESECT or COAG	• Resecting Device does not RESECT or COAG	• Make sure that the Controller is in Resection mode • Ensure that normal saline [sodium chloride (0.9% w/v; 150mmol/L) is being used as irrigation solution • Ensure that the footswitch is plugged into the gray port on the Controller • Check Resecting Device connection, replace if necessary • Ensure the Resecting Device is securely plugged into the blue connector

Controller			
DISPLAYED ERROR CODE	**ERROR CODE DESCRIPTION**	**POSSIBLE CAUSES**	**REMEDY**
"Check System for Leak" "Low Pressure Detected"	Pressure below 15 mmHg	• Device connections leaking saline • Leaking fluid around the cervix • Pressure sensor is reading atmospheric pressure (Hysteroscope is outside patient) • Perforation	• Check device/tubing connections. Reconnect/replace as needed • Check cervix for leaking, add/adjust tenaculum at the cervix. • Message will be removed when Hysteroscope is within patient and cavity pressure is brought above 15 mmHg • Check for perforation
FAULT CODE: 17 RF Board Temperature Out Of Range	FAULT CODE: 17 Temperature is out of Controller's operating range	• Temperature is out of Controller's operating range	• Power off, then allow Controller to return to room temperature before powering on • Ensure Controller vent holes are not occluded
FAULT CODE: 19 CPU Board Temperature Out Of Range	FAULT CODE: 19 Temperature is out of Controller's operating range	• Temperature is out of Controller's operating range	• Power off, then allow Controller to return to room temperature before powering on • Ensure Controller vent holes are not occluded
FAULT CODE: 22 Footswitch Stuck: Restart and Check	FAULT CODE: 22 Footswitch Stuck	• Footswitch was depressed on startup • Liquid causing short in footswitch • Footswitch defective	• Power off, then make sure footswitch pedals are not pressed and then power on the Controller • Clear any residual liquid, allow switch to air dry • Replace footswitch
N/A	Unsuccessful Self-Test (Tone 8)	• Various internal self-diagnostics	• Power off, then power back on the Controller. If the problem persists contact customer service

TABLE 11: FLUID DEFICIT READOUT TROUBLESHOOTING

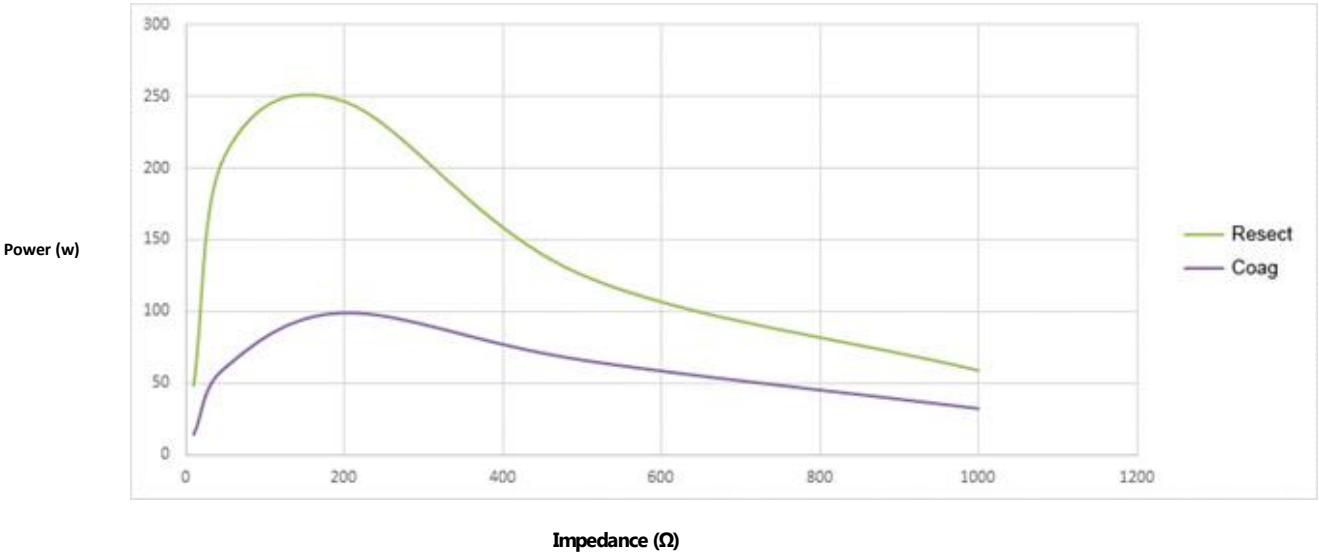
Fluid Deficit Readout			
DISPLAYED ERROR CODE	**ERROR CODE DESCRIPTION**	**POSSIBLE CAUSES**	**REMEDY**
1	Error captured when a weight is detected at power on	Saline bag hung prior to system completing initialization.	Remove all weight hanging from system and power cycle device.
2	Error captured when the 5V internal voltage rail is outside defined ranges	Incorrect power supply in use.	Confirm that power supply connected to Fluid Deficit Readout Accessory is the Minerva Surgical issued power supply.
3	Error captured when the system has not been calibrated	System has an incomplete calibration from manufacturer.	Power cycle device, if error continues contact Customer Service.
4	Software Error (Calibration constants do not match values in EEPROM)	Software corruption.	Power cycle device, if error continues contact Customer Service.
5	Error capturing when buttons are stuck on	System detects buttons stuck in on position during system initialization.	Power cycle device, if error continues contact Customer Service.
6 - 46	Software Error (Multiple)	Unexpected system/software outcome.	Power cycle device, if error continues contact Customer Service.

APPENDIX F - ESSENTIAL PERFORMANCE, POWER CURVE

ESSENTIAL PERFORMANCE

The essential performance of the Symphion® System consists of output RF power tolerance of +/-20% while actively delivering RF; no unintentional activation of RF output, no unintentional activation of pump motors and correct pressure sensor indication within +/- one indicator bar.

POWER CURVE



APPENDIX G - EMC

EMC TABLES

The following tables provide information on the electromagnetic environment in which the Symphion System is capable of operating 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, a Hospital Grade Power Cord must be used with a receptacle marked “Hospital Grade”.

The Symphion Controller was tested to IEC 60601-1-2:2007
The Fluid Deficit Readout was tested to IEC 60601-1-2:2014 +A1:2020

LIST OF SYMPHION ACCESSORIES:

- Symphion Fluid Deficit Readout
- Symphion Fluid Management Accessories
  - INFINITY FMA
  - EXPRESS FMA (Currently not available for sale in the US)
- Symphion Footswitch
- Symphion Resecting Device
- Symphion 6.3 Hysteroscope
- 10 ft. Hospital Grade Power Cord
- Saline Pole

TABLE 12: ELECTROMAGNETIC EMISSIONS STATEMENT – SYMPHION CONTROLLER (IEC 60601-1-2:2007)

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
The Symphion Fluid Deficit Readout is intended for use in the electromagnetic environment specified below. The customer or the user of the Symphion Fluid Deficit Readout should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Class A, Group 2	The Symphion Fluid Deficit Readout is suitable for use in all establishments other than domestic 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

TABLE 13: ELECTROMAGNETIC EMISSIONS STATEMENT – SYMPHION FLUID DEFICIT READOUT (IEC 60601-1-2:2014 +A1:2020)

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions
The Symphion System is intended for use in the electromagnetic environment specified below. The customer or the user of the Symphion System should be sure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Class A, Group 1	The Symphion System is suitable for use in all establishments other than domestic 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

TABLE 14: ELECTROMAGNETIC IMMUNITY STATEMENT – SYMPHION CONTROLLER(IEC 60601-1-2:2007)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Symphion System is intended for use in the electromagnetic environment specified below. The customer or the user of the Symphion System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
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 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Symphion System requires continued operation during power mains interruptions, it is recommended that the Symphion System be powered from an uninterruptible power supply or a battery.

	<5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 5 s	
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) 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. Portable and mobile RF communications equipment should be used no closer to any part of the Symphion System, including cables, than the recommended separation distance. The separation distance is calculated from the equation applicable to the frequency of the transmitter.

TABLE 15: ELECTROMAGNETIC IMMUNITY STATEMENT – SYMPHION FLUID DEFICIT READOUT (IEC 60601-1-2:2014 +A1:2020)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Symphion Fluid Deficit Readout is intended for use in the electromagnetic environment specified below. The customer or the user of the Symphion Fluid Deficit Readout should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

<table>
<tr><td>Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>Voltage Dips:
- 0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
- 0% U_T; 1 cycle and 70 % U_T; 25/30 cycles
- Single phase: at 0°

Voltage Interruptions:
- 0% U_T 250/300 cycles</td><td>Voltage Dips:
- 0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
- 0% U_T; 1 cycle and 70 % U_T; 25/30 cycles
- Single phase: at 0°

Voltage Interruptions:
- 0% U_T 250/300 cycles</td><td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Symphion Fluid Deficit Readout requires continued operation during power mains interruptions, it is recommended that the Symphion Fluid Deficit Readout be powered from an uninterruptible power supply or a battery.</td></tr>
<tr><td colspan="4">NOTE UT is the a.c. mains voltage prior to application of the test level.</td></tr>
<tr><td>Power frequency (50/60 Hz) magnetic field
IEC 61000-4-8</td><td>30 A/m</td><td>30 A/m</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the Symphion Fluid Deficit Readout, including cables, than the recommended separation distance. The separation distance is calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>60601-1-2:2020 Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields</td><td colspan="3">
<table>
<tr><th>Test Frequency</th><th>Modulation</th><th>IMMUNITY TEST LEVEL (A/m)</th></tr>
<tr><td>30 kHz [a)]</td><td>CW</td><td>8</td></tr>
<tr><td>134.2 kHz</td><td>Pulse modulation [b)]
2.1 kHz</td><td>65 [c)]</td></tr>
<tr><td>13.56 MHz</td><td>Pulse modulation [b)]
50 kHz</td><td>7.5 [c)]</td></tr>
<tr><td colspan="3">[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE
ENVIRONMENT.
[b)] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c)] r.m.s., before modulation is applied.</td></tr>
</table>
</td></tr>
</table>

TABLE 16: RECOMMENDED SEPARATION DISTANCES – SYMPHION CONTROLLER(IEC 60601-1-2:2007)

Recommended separation distances between portable and mobile RF communications equipment and the Symphion System			
The Symphion System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Symphion System can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Symphion System as recommended below, according to the maximum output power of the communications equipment.			
Conducted RF IEC 61000-4-6	**3 Vrms 150 kHz to 80 MHz**	**3 V**	**d = 1.2 √P**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	d = 1.2 √P
	3 V/m 800 MHz to 2.5 GHz	3 V/m	d = 2.3 √P
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. Interference may occur in the vicinity of equipment marked with the following symbol: 			

Recommended separation distances between portable and mobile RF communications equipment and the Symphion System			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d = 1.2 √P	**80 MHz to 800 MHz** d = 1.2 √P	**800 MHz to 2.5 GHz** 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

Recommended separation distances between portable and mobile RF communications equipment and the Symphion System
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.
[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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Symphion System is used exceeds the applicable RF compliance level above, the Symphion System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Symphion System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 17: RECOMMENDED SEPARATION DISTANCES – SYMPHION FLUID DEFICIT READOUT (IEC 60601-1-2:2014 +A1:2020)

Recommended separation distances between portable and mobile RF communications equipment and the Symphion Fluid Deficit Readout, except as indicated in [Immunity to RF Wireless Communications Equipment Table (Table 9 of 60601-1-2)] on page 80.			
The Symphion Fluid Deficit Readout is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Symphion Fluid Deficit Readout can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications equipment (transmitters) and the Symphion Fluid Deficit Readout as recommended below, according to the maximum output power of the communications equipment.			
Conducted RF IEC 61000-4-6	**3 Vrms 150 kHz to 80 MHz 6VRms for ISM bands**	**3 V**	**d = 1.2 √P**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	d = 1.2 √P
	3 V/m 800 MHz to 2.7 GHz	3 V/m	d = 2.3 √P
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. Interference may occur in the vicinity of equipment marked with the following symbol:			

Recommended separation distances between portable and mobile RF communications equipment and the Symphion Fluid Deficit Readout, except as indicated in [Immunity to RF Wireless Communications Equipment Table (Table 9 of 60601-1-2)] on page 80.

60601-1-2:2020 Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the Symphion Fluid Deficit Readout

Recommended separation distances between portable and mobile RF communications equipment and the Symphion Fluid Deficit Readout, except as indicated in [Immunity to RF Wireless Communications Equipment Table (Table 9 of 60601-1-2)] on page 80.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d = 1.2 √P	**80 MHz to 800 MHz** d = 1.2 √P	**800 MHz to 2.7 GHz** 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.			
[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 electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Symphion Fluid Deficit Readout is used exceeds the applicable RF compliance level above, the Symphion Fluid Deficit Readout should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Symphion Fluid Deficit Readout. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

APPENDIX H - FCC COMPLIANCE INFORMATION

The Symphion Operative Hysteroscopy System complies with part 18 of the FCC Rules.