Boston Scientific

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(EN)

Symphion™

Tissue Removal System

APPLICABLE TO SOFTWARE VERSION 2.0.19

ABOUT THIS MANUAL

This manual provides information on how to operate, and maintain the Symphion System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

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℞ ONLY

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

1. REUSE WARNING

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 Boston Scientific representative.

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.

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

2. DEVICE DESCRIPTION

The Symphion System consists of the following procedural components:

- Symphion Controller with Integrated Fluid Management
  - Symphion Fluid Management Accessories
  - Footswitch
  - Saline Pole
- Symphion Resecting Device
- Symphion 6.3 Endoscope

The Controller provides bipolar radiofrequency outputs (resection and coagulation) and fluid management through the use of two integrated peristaltic pumps. The Resecting Device is a disposable, hand held bipolar radiofrequency device configured for the resection and aspiration of uterine pathology. Fluid infusion and aspiration of the uterine cavity are controlled by the Controller's peristaltic pumps, in conjunction with the disposable Fluid Management Accessories; these components form a closed-loop re-circulating system. The Controller with Integrated Fluid Management System has two distinct modes; diagnostic mode and resection mode.

The Symphion 6.3 Endoscope is a reusable instrument that provides access to and visualization of the uterine cavity. The Endoscope connects with the Fluid Management Accessories to enable the fluid to be delivered to and returned from the uterine cavity as part of the closed-loop re-circulating system. The Endoscope contains a working channel that is compatible for use with the Resecting Device.

Diagnostic Mode

The Controller with the integrated closed loop recirculating Fluid Management System provides distension of the uterus during diagnostic hysteroscopy. Bipolar radiofrequency energy is NOT active in this mode (no resection and coagulation). A footswitch allows the surgeon to aspirate and re-circulate the saline.

Resection Mode

In Resection mode, bipolar radiofrequency energy is active (bipolar resection and coagulation). Aspiration is also active in Resection Mode.

The Symphion System is for use with the Symphion Endoscope. Refer to Endoscope Instructions.

3. INTENDED USE/INDICATIONS FOR USE

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

REFER TO ENDOSCOPE INSTRUCTIONS FOR USE FOR SPECIFIC INDICATIONS FOR USE.

4. CONTRAINDICATIONS

Pregnancy, genital tract infections, and known uterine cancer are contraindications to hysteroscopy.

Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

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.

5. WARNINGS

Symphion System General Warning

- The Symphion System is only intended for use as outlined in Section 3, Intended Use/Indications For Use.
- Before using the Symphion System, please review all available product information carefully!
- 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.
- **Do not** use the Symphion System with another fluid management system, endoscope, or controller. Use with another fluid management system, endoscope or controller may result in failure of the device to operate or lead to patient or physician injury.
- **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.

Controller with Integrated Fluid Management Warnings

- **Known Risks Associated with use of Electrosurgical Devices:**
  - EMC issues – interference causes device failure, interference causes other devices to fail, RF interferes with pacemaker, defibrillator
  - Electrical safety issues – shock, burn – device/ controller overheats, incorrect power source used, water enters the controller, use of incorrect power source, arcing
  - Explosion/fire if operated near volatile solvents
  - Tissue damaged during coagulation/resection
- Fluid Overload: There is a risk of distension fluid reaching the circulatory system of the patient by passing into the capillaries of the body cavity. This can be caused by distension pressure, flow rate, perforation of the body 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.
- Fluid Deficit: The fluid absorbed by the patient must be monitored. The following equation should be used to calculate the fluid deficit using a single 3-liter saline bag:
  - 3000 mL – (Remaining Volume in bag + 550 mL) = total fluid loss
  - 3000 mL: Total amount of fluid in the saline bag at the start of the procedure*
  - 550 mL: Dead volume (undeliverable volume in the tubing, filter, and tissue catch)

  The following equation should be used to calculate the fluid deficit using a single 2-liter saline bag:
  - 2000 mL – (Remaining Volume in bag + 550 mL) = total fluid loss
  - 2000 mL: Total amount of fluid in the saline bag at the start of the procedure*
  - 550 mL: Dead volume (undeliverable volume in the tubing, filter, and tissue catch)

  **Take notice of the measurement tolerance of the saline bag (+/- 10%).*
- 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.
- 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.
- 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.

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Black (K) ΔE ≤5.0

- 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 purged 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 purge 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 purge or is noted in the infusion tubing at any point during the procedure after the scope has been inserted into the patient, remove the Endoscope from the uterine cavity and discontinue the procedure.
- To prevent hypo/hypernatremia assess electrolytes before and after procedure, and observe for signs of significant electrolyte imbalance (e.g., electrocardiogram and physician examination).
- 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.
- While fluids must always be monitored during use, exercise extreme caution and very close fluid monitoring in patients with severe cardiopulmonary disease.
- The Symphion™ closed-loop system permits the operator to elect intrauterine pressure up to 125 mmHg. Clinicians using the Symphion System should be aware of the 2013 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.
- 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.
- 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.

Resecting Device Warnings

- **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.

Warnings Applicable to Air/Gas Emboli Hazards:

- 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.
- Surgeons should consider the anticipated length of surgery and size of leiomyomata when selecting patients for procedures.
- Operating room personnel must be trained to purge air from fluid lines 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.
- 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.
- Surgical team must have access to appropriate resuscitative capabilities.
- Patients should be kept in flat or in reverse Trendelenburg position.
- 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.
- Surgeon should avoid entry of air into uterus by:
  - Carefully purging air from 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

Considerations for anesthesia

- Nitrous oxide anesthesia may enlarge the size of air bubbles and thus should be avoided when possible in operative hysteroscopy.
- Patients at high risk for room air and gas embolism should be managed using controlled ventilation.
- For high-risk patients undergoing operative hysteroscopy, one should consider intra-operative monitoring, such as end-tidal CO2 monitoring if under general anesthesia and pre-cordial Doppler monitoring to detect room air and gas emboli early.

6. PRECAUTIONS

Symphion System General Precautions

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).

Use Resection and COAG 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.

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.

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.

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.

Do not use the Resecting Device or the Fluid Management Accessories 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.

Do not lubricate the Resecting Device or the Fluid Management Accessories.

Do not use the Resecting Device or the Fluid Management Accessories after the expiration date.

The Resecting Device and Fluid Management Accessories are intended for single use only. Discard the Resecting Device and Fluid Management Accessories after use.

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

Controller with Integrated Fluid Management Precautions

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

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

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

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

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

In case of Controller failure, remove the Endoscope and Resecting Device from the body cavity immediately. Remove the tubing from the pump heads; switch off/ unplug the power cord to stop Controller operation.

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

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

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

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

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

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 that portable and mobile RF communication equipment can affect the performance of the Controller (See Appendix G).

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.

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.

Needle monitoring electrodes are not recommended.

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

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

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.

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 use of any other solution.

The Fluid Management Accessories is designed for use with a SINGLE 2-liter or 3-liter Irrigation USP saline bag:

- 2-liter saline bag such as Hospira part# 0409-7972-07
- 3-liter saline bag such as Baxter part# 2B7477 or Hospira part# 0409-7972-08.

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.

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

Do not close the latch of the pump on the indicators installed on tubing. This may result in a failure of the pump.

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.

Resecting Device Precautions

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

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.

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.

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

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

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.

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

7. ADVERSE EVENTS

Potential complications of continuous flow endoscopic 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

8. ENVIRONMENTAL PROTECTION

Follow local governing ordinances and hospital practice regarding the disposal of the Resecting Device and Fluid Management Accessories – 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.

9. HOW SUPPLIED

9.1. Controller with Integrated Fluid Management

The Controller is supplied in a semi-ready-to-use state.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

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

9.2. Fluid Management Accessories

The Fluid Management Accessories are supplied sterile and are intended for single use.

The shelf box contains:

- One (1) Fluid Management System
  (See Figure 2 for package contents)
- One (1) Biohazard Sticker
- One (1) Symphion System Package Insert

9.3. 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. COMPATIBILITY

The Symphion System is used in conjunction with:

- Symphion Endoscope
- A single 2-liter or 3-liter Irrigation USP Saline Bag (sodium chloride (0.9% w/v; 150 mmol/L)) Irrigation Solution:
  - 2-liter saline bag such as Hospira part# 0409-7972-07
  - 3-liter saline bag such as Baxter part# 2B7477 or Hospira part# 0409-7972-08.
- Light Sources and Flexible Light Cables
- Endoscopic Accessories (light cable adapters, brushes)

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

11. SYSTEM COMPONENTS

11.1 Controller with Integrated Fluid Management

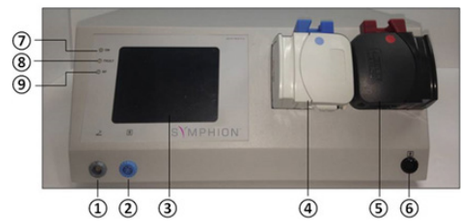


Figure 1A: Controller Front

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

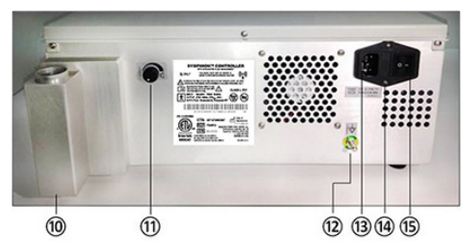


Figure 1B: Controller Back

10. Saline Pole Bracket
11. Volume Control Knob
12. Equipotential Lug
13. Power Entry Module
14. Fuse Drawer
15. Power ON / OFF Switch

11.2. Controller Accessories

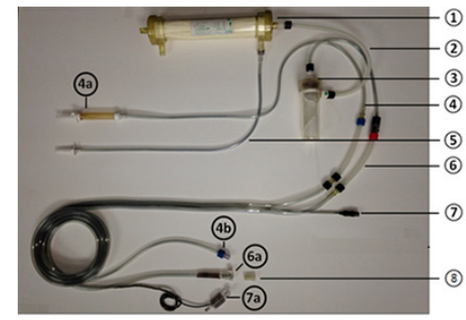


Figure 2: Fluid Management Accessories

1. Filter
2. Tissue Catch Tube
3. Tissue Catch
4. Infusion Tube

4a. Saline Spike – Infusion Tube

4b. Luer – Infusion Tube

5. Filter Tube
6. Aspiration Tube

6a. Quick Connect – Aspiration Tube

7. Pressure Sensor

7a. Luer – Pressure Sensor

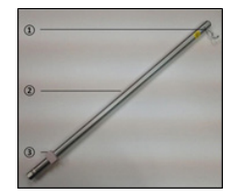
8. Introducer

1. RESECT (Yellow) Pedal
2. COAG (Blue) Pedal
3. Aspiration Button

Figure 3: Footswitch

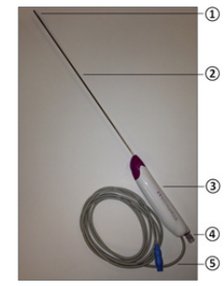
1. Hospital Grade Power Cord (10 ft)

Figure 4: Power Cord



1. Saline Hook
2. Saline Pole
3. Silicone Cap

Figure 5: Saline Pole



1. Resecting Window
2. Shaft
3. Device Handle
4. Aspiration Quick Connect Fitting
5. Resecting Device Cable

Figure 6: Resecting Device

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12. SYSTEM SETUP

12.1. Assemble the Saline Pole

1. Remove Controller and saline pole from packaging.
2. Remove plastic cap from saline pole bracket (Fig 7) on the back of the Controller (Fig. 1B Item 10).

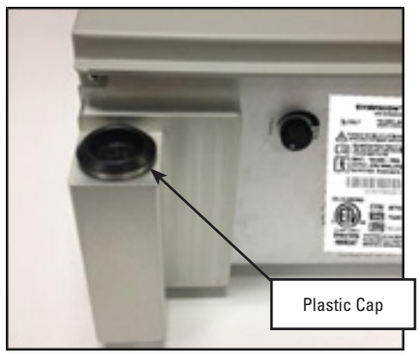

Figure 7

3. To attach the saline pole to the Controller slide the pole into the bracket on the back of the Controller.
4. Push the button on the left side of the pole bracket and rotate the pole until it settles to the bottom of the mount (Fig. 8); the saline hook on the pole will be facing away from the Controller when the pole is oriented in the final position.

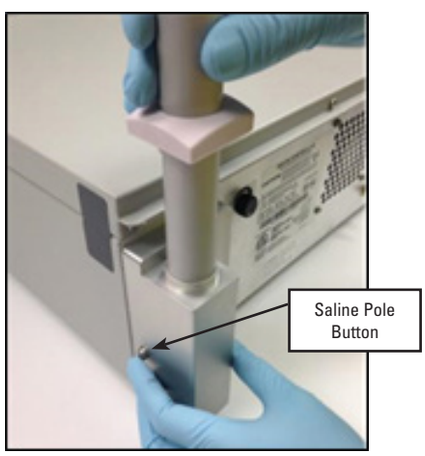

Figure 8

5. Pole should be in a locked position, verify by gently lifting up on the pole.
6. Slide the silicone cap down the pole and place over the pole mount bracket to prevent ingress of liquid into the pole mount cavity (Fig. 9).

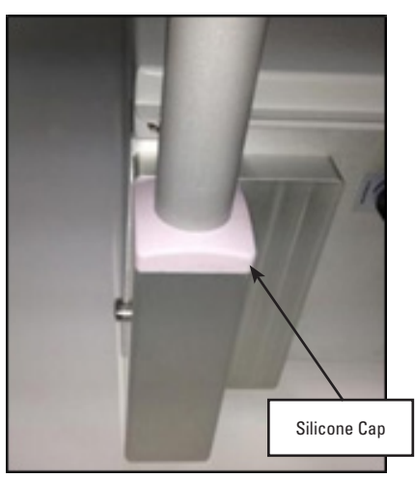

Figure 9

12.2. Controller Set up Instructions

1. Place the Controller on a stable flat work surface.

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

2. Connect the Controller Power Cord (Fig.10a) to the power entry module (Fig. 1B, Item 13).

Figure 10a
Fully Seated

Figure 10b
Not Fully Seated

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

3. Connect the footswitch cable to the footswitch receptacle (Fig. 1A, Item 1) on the left-hand side of the front panel of the Controller (Fig. 11).

Figure 11

4. Turn on the Controller using the power switch (Fig. 1B, Item 15) on the back of the Controller.
5. The Software revision will appear on the screen. Press OK to proceed (Fig. 12)

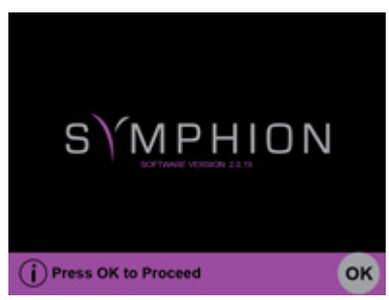

Figure 12

6. Set up instructions will appear on the Controller Screen (Fig. 13).

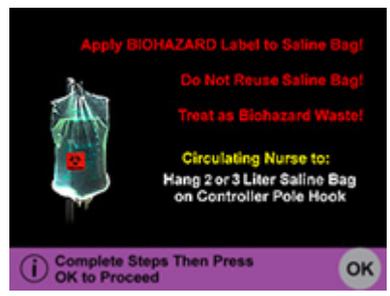

Figure 13

CIRCULATING NURSE – 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 Fluid Management shelf box) to the saline bag as instructed on the screen as a visual reminder not to reuse the saline bag (Fig.13)

CIRCULATING NURSE – Hang the saline bag on saline pole hook.

CIRCULATING NURSE – Confirm that a SINGLE 2-liter or 3-liter saline bag is being used, if yes, press OK (Fig. 13).

Fluid Management Accessories set up instructions will appear on the Controller screen (Fig. 16).

12.3. FLUID MANAGEMENT SET UP INSTRUCTIONS

SCRUB NURSE – Place the sterilized Endoscope into the sterile field.

CIRCULATING NURSE – Remove the Fluid Management Accessories from the shelf box. **Do not** use if product or packaging is damaged.

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.

SCRUB NURSE – Tear the tubing tape to disconnect the tubing. Remove the Introducer (Fig. 2 Item 8), and the tubing from the tray by grabbing the distal ends of the Infusion, Aspiration tube, and Pressure Sensor as shown in figure 14. The remainder of the tubing will uncoil from the tray as the tubing is pulled.

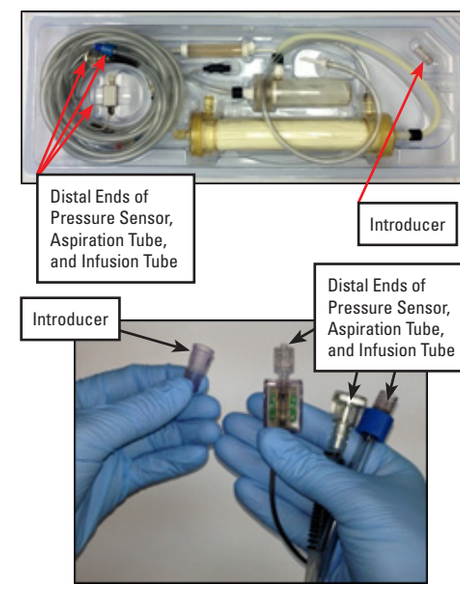

Figure 14

CIRCULATING NURSE – Place the Fluid Management tray (with the system components inside) adjacent to the Controller (Fig. 15).

Figure 15

SCRUB NURSE – Follow the Fluid Management Accessories set up instructions on the Controller screen (Fig. 16).

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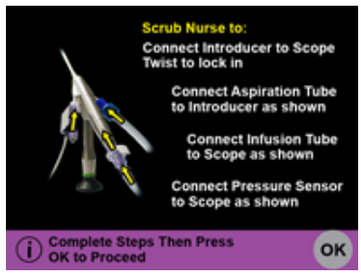

Figure 16

SCRUB NURSE – Connect the Introducer to Scope twist to lock in.

- Connect the Introducer (Fig. 2, Item 8) to the proximal end of the Endoscope (Fig. 17) by aligning the grooves on the Endoscope with the slots on the introducer. Once aligned rotate counter clockwise until a click is felt (approximately 15 °).

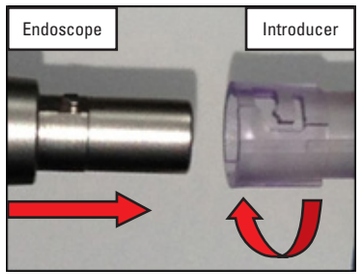

Figure 17

SCRUB NURSE – Connect the Aspiration Tube to Introducer as shown.

☞ *IMPORTANT: For all quick-connect fittings (Fig. 18) press connectors together until they click together securely. To disconnect, press tab on quick connect fitting and pull apart.*

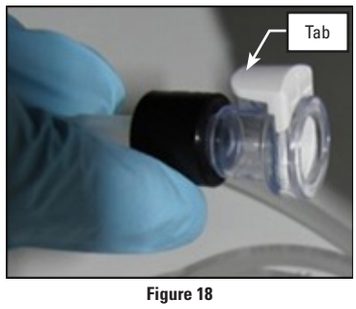

Figure 18

- Connect the Aspiration Tube (Fig. 2, Item 6a) to the proximal end of the Introducer (Fig. 19).

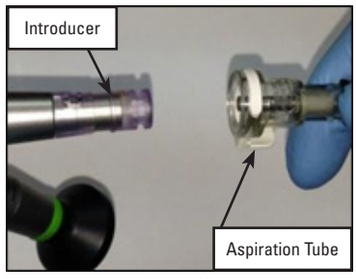

Figure 19

SCRUB NURSE – Connect the Infusion Tube to Scope as shown.

- Connect the luer on the Infusion Tube (Fig. 2 Item 4b) to either of the two luer connections on the Endoscope (Fig. 20.).

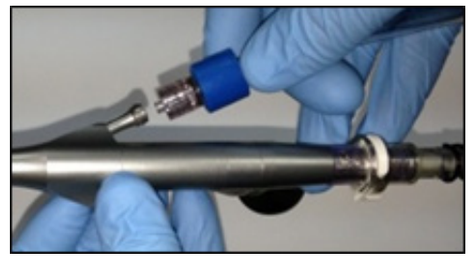

Figure 20

SCRUB NURSE – Connect the Pressure Sensor to Scope as shown.

- Connect the luer on the Pressure Sensor (Fig. 2 Item 7a) to the available luer connection on the Endoscope (Fig. 21).

Figure 21

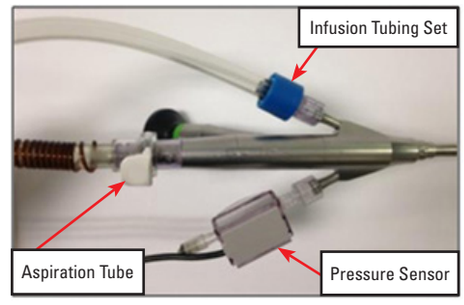

Figure 22 Fully Assembled Endoscope

CIRCULATING NURSE – When step 4 is completed, press OK on the Controller Screen (Fig. 16).

Continue the Fluid Management Accessories setup following the instructions on the Controller screen (Fig. 23).

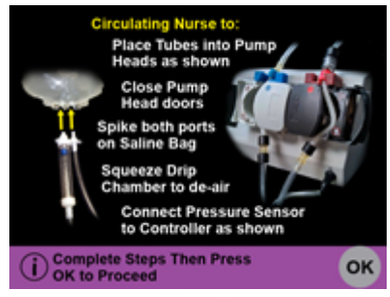

Figure 23

CIRCULATING NURSE – Place Tubes into Pump Heads as shown.

- Place the sections of the Infusion Tube (Fig. 2 Item 4) and Aspiration Tube (Fig. 2 Item 6) between the indicators (approx. 12 cm) inside the Pump Heads (Fig. 1A Item 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. (Fig. 24).

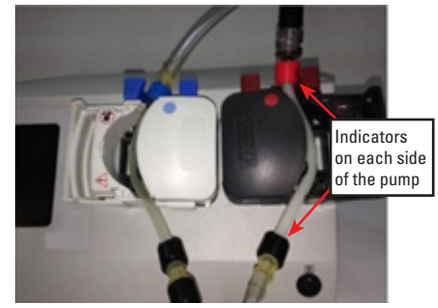

Figure 24

CIRCULATING NURSE – Close Pump Head Doors.

- Slowly close each pump head door until the latch is flush with the pump head (Fig. 25).

Figure 25

☞ *IMPORTANT:* **Do not** *close the latch of the pump head door on the tubing indicators or on the tubing (Fig. 26).*

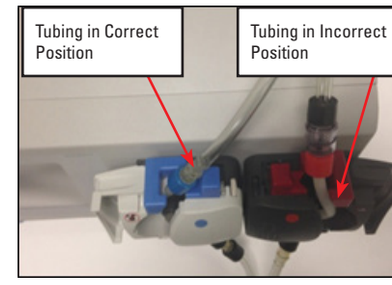

Figure 26

CIRCULATING NURSE – Spike both ports of the Saline Bag.

- Following sterile practices spike the Irrigation USP saline bag with the saline spikes on the end of the Infusion (Fig. 2 Item 4a) and Filter Tubes (Fig. 2 Item 5). Ensure that the saline spikes completely engage the saline orifice and no leakage occurs around the spikes (Fig. 27). Inspect the saline bag for any damage.

Note: Either port is acceptable for the saline spikes.

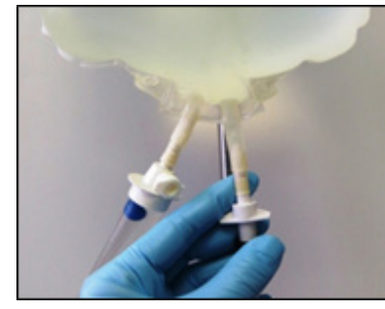

Figure 27

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

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CIRCULATING NURSE – Squeeze Drip Chamber to de-air.

- De-air the drip chamber (Fig. 28) at the end of the Infusion Tube 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.

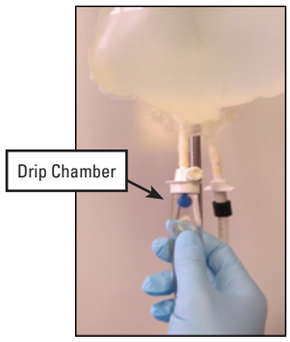

Figure 28

CIRCULATING NURSE – Connect the Pressure Sensor to Controller as shown.

- Connect the pressure sensor connector to the pressure sensor receptacle on the Controller (Fig. 29) by aligning the white markings on the connector and receptacle.

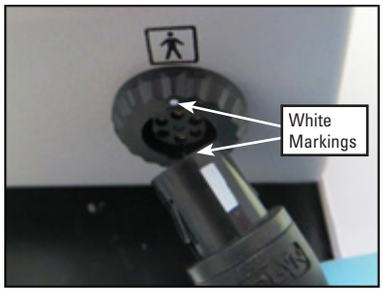

Figure 29

☞ *IMPORTANT: Ensure that the connector is advanced into the Controller receptacle in flush.*

CIRCULATING NURSE – When pressure sensor is connected press OK on the Controller Screen (Fig. 23).

The Controller will run the Pressure Sensor Self-Test (approximately 5 seconds).

- If pressure sensor test fails, the Controller will display the "Pressure Sensor Test FAILED" message and "Replace Pressure Sensor". If this occurs, replace the Fluid Management Accessories (see section 12 Fluid Management set up instructions)

☞ *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 (Fig. 30).

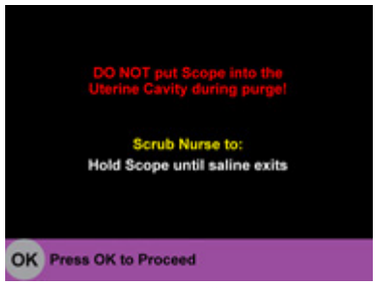

Figure 30

CIRCULATING NURSE – Press OK to purge System

SCRUB NURSE – Hold Scope until saline exits.

During the purge cycle, air from the infusion tube will be expelled from the end of the endoscope to de-air the infusion tube prior to insertion into the uterine cavity. At the end of the purge approximately 20 mL of fluid will be expelled. The total purge time is within 10 seconds.

When purging is complete the Controller will enter diagnostic mode.

13. SYSTEM OPERATION

13.1. Diagnostic Mode

1. Set the desired cavity pressure on the touch screen of the Controller (Fig. 31) 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.

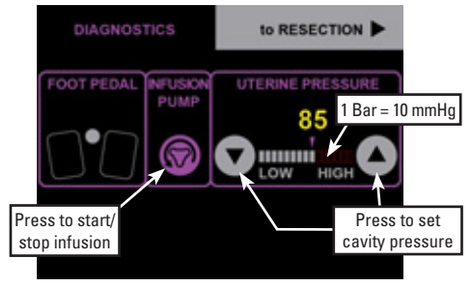

Figure 31

☞ *IMPORTANT: Use of pressure 100 mmHg or higher will require confirmation from the user (Fig. 32). The maximum pressure that can be set by the user is 125 mmHg.*

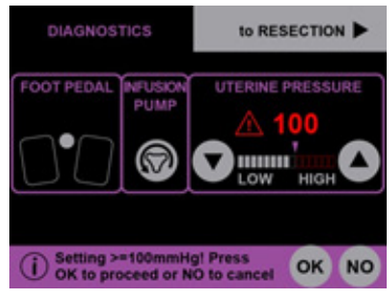

Figure 32

2. Immediately before Endoscope insertion, start infusion by pressing the infusion pump button on the touch screen of the Controller to start fluid flow.
3. Insert the Endoscope 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.*

4. Aspiration (Fig. 33) can be activated by pressing the center button on the footswitch (Fig. 3, Item 3). This will circulate the fluid through the Infusion and Aspiration Tubes. RESECT (Yellow) and COAG (Blue) footswitch pedals will not work in diagnostic mode.

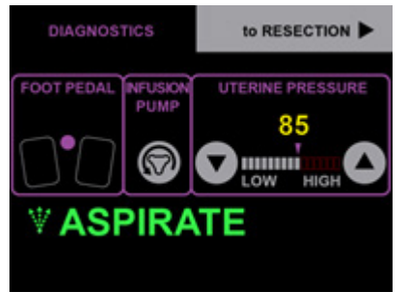

Figure 33

13.2. Resection Mode

CIRCULATING NURSE – Remove the Resecting Device from the shelf box. **Do not** use if product or packaging is damaged.

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.

SCRUB NURSE – Remove the Resecting Device (Fig. 6) from sterile package and place onto the sterile table.

SCRUB NURSE – Following sterile practices pass the device cable out of the sterile field to the circulating nurse.

CIRCULATING NURSE – Connect the device cable by pushing the device connector into the device receptacle (Fig. 1A. Item 2) on the Controller front panel (Fig. 34).

Figure 34

CIRCULATING NURSE or PHYSICIAN – Disconnect the Aspiration Tube from the Introducer (Fig. 35).

Figure 35

CIRCULATING NURSE – Connect the Aspiration Tube to the quick connect fitting on the proximal end of the Resecting Device (Fig.36).

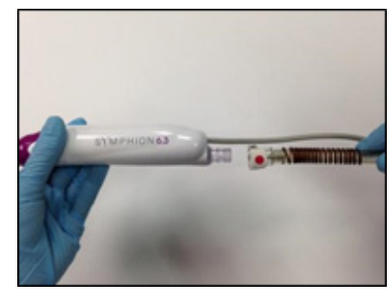

Figure 36

CIRCULATING NURSE or PHYSICIAN – Introduce the Resecting Device into the working channel of the Endoscope through the Introducer (Fig. 37).

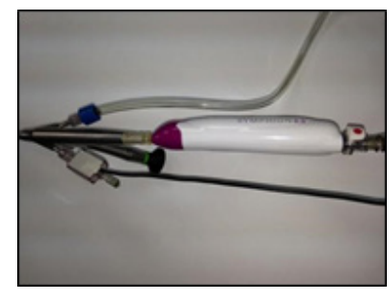

Figure 37

To begin Resection Mode, press the "to RESECTION" tab on the top right corner of the screen on the Controller (Fig. 33).

Position the window of the Resecting device onto the surface of the tissue and press the resect pedal to perform resection (Fig. 38).

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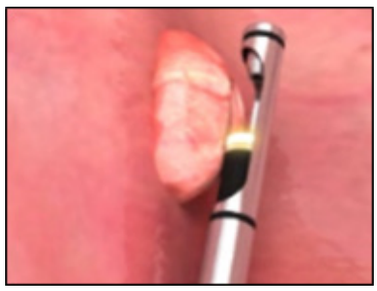

Figure 38

The yellow RESECT foot pedal (Fig. 39) activates RF resection as indicated on the display (Fig. 40). 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 Tube to the Tissue Catch.

1. RESECT (Yellow) Pedal
2. COAG (Blue) Pedal
3. Aspiration Button

Figure 39

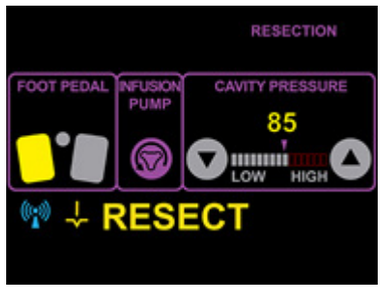

Figure 40

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

If bleeding occurs during the procedure, advance the active electrode of the Resecting Device (Fig 41) to the source of the bleeding and depress the blue COAG foot pedal (Fig. 39).

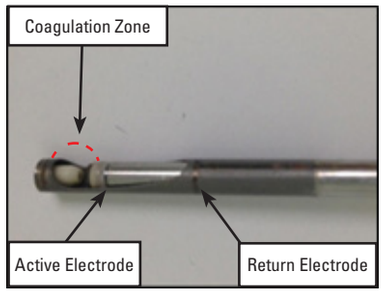

Figure 41

The blue COAG foot pedal (Fig. 39) activates coagulation as indicated on the display (Fig. 42).

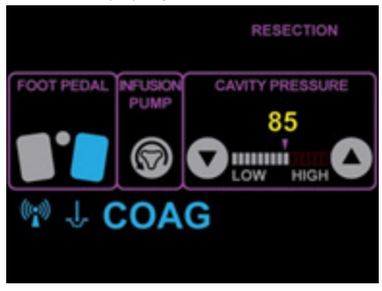

Figure 42

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

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

14. REPLACING THE FILTER

1. If an error message appears on the Controller indicating "Check filter tubing for kink, or replace filter to continue" check the Filter Tube (Fig. 2 Item. 5) for kink.
2. If there is no kink on the Filter Tube turn off infusion by deactivating the infusion pump button on the touch screen of the Controller (Fig. 31).
3. Remove Resecting Device and Endoscope from the body cavity.
4. Remove saline bag from saline pole and place level with filter tubing to prevent saline leakage during filter replacement.
5. Disassemble the Fluid Management Accessories and re-setup a new one per section 12 Fluid Management Accessories Set Up Instructions.
6. Re-hang the saline bag on saline pole hook.

15. DISASSEMBLY

1. Immediately before the removal of the Endoscope and Resecting Device from the uterine cavity, turn off saline infusion by pressing the "infusion pump" button on the touch screen of the Controller (Fig. 31).
2. Remove the Resecting Device and Endoscope together from the uterine cavity.
3. Wait a minimum of 60 seconds for any fluid pressure to dissipate from the tubing set.
4. Remove the tissue catch and obtain the tissue specimen (Fig. 43)

Figure 43

5. Disconnect the Pressure Sensor and Resecting Device from the Controller.
6. Disconnect the Pressure Sensor and the Infusion Tubing from the Endoscope.
7. Disconnect the Introducer from the Endoscope and remove it with the Resecting Device. See Figure 44 for fully disassembled Endoscope.

Figure 44

☞ *Follow reprocessing instructions for Endoscope (See Symphion™ 6.3 Endoscope IFU).*

8. Place the Resecting Device, tubing and cable on the Fluid Management Tray.
9. Unhook the saline bag and place it on the Fluid Management Tray.

☞ *IMPORTANT: SALINE BAG IS A BIOHAZARD. DISPOSE OF THE LEFT-OVER SALINE AND THE SALINE BAG per hospital standards concerning biohazard materials.*

10. Open the pump heads to remove the tubing.
11. Dispose of the remainder of the Resecting Device, Fluid Management Accessories and saline bag per hospital standards concerning biohazardous materials.
12. Disconnect the footswitch and turn off the Controller.

15.1. Saline pole disassembly (optional)

a. Push the button on the left side of the bracket
b. Lift the pole straight up to remove

15.2. Tissue Catch disassembly

a. Disconnect both quick connect fittings from the Tissue Catch
b. Unthread the Tissue Catch cap and remove cap and tissue bag to access resected tissue. (Fig 45)

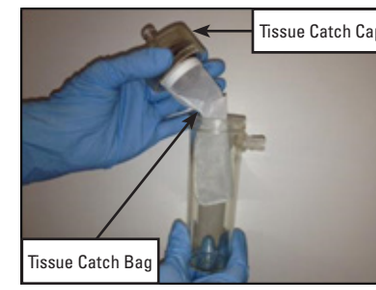

Figure 45

16. FOLLOW STANDARD HOSPITAL PROCEDURES FOR CLEANING

Follow this procedure after each operation to clean the Controller and footswitch:

1. Disconnect the Controller from the electrical source.
2. Wipe the Controller and the footswitch and footswitch cable 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.

17. STORAGE

17.1. Controller (See Appendix A)

17.1.1. Fluid Management Accessories

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

17.2. Resecting Device

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

18. CONTROLLER MAINTENANCE, TROUBLESHOOTING AND REPAIR

18.1. Adjusting Volume

The Controller has an adjustable volume control (Fig. 1b, Item 11) on the back of the unit. Twisting the adjustor clockwise will increase the volume.

18.2. 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 power off and disconnect the power cord from the electrical outlet. Remove the fuses by opening the Power Entry Module's Fuse Drawer (Fig. 1b, Item 14) 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.

18.3. Troubleshooting

See Appendix E for further information on Troubleshooting

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19. LIMITED WARRANTY

Symphion™ Controller

Boston Scientific Corporation (BSC) 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 BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Symphion Resecting Device and Symphion Fluid Management Accessory

Boston Scientific Corporation (BSC) 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 BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to Symphion Resecting Devices and Symphion Fluid Management Accessories 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.

CUSTOMER SERVICE/TECHNICAL SUPPORT

Contact Boston Scientific Customer Service for customer or technical support.

Call +1 (888) 272-1001

20. SYMBOLS USED ON THE SYMPHION™ SYSTEM LABELING

REF	Catalog Number		Consult Instructions for use on this website: www.bostonscientific-elabeling.com
LOT	Batch Code Lot Number	SN	Serial Number
	For Single Use Only Do not reuse		Legal Manufacturer
℞ ONLY	Federal (US) law restricts this device to sale by or on the order of a physician.	STERILE R	Sterilized Using Irradiation
	Use by date		Date of Manufacture
	Do not use if package is damaged.		Do not use in the presence of flammable anesthetics
	Type BF Applied Part		Radio Frequency (RF) Energy (non-ionizing radiation)
ETL CLASSIFIED c ETL us Intertek 4008347	ETL Certification Mark		Handle with Care!
10°C 40°C	Temperature Limits		Risk of Electrical Shock
NON STERILE	Non Sterile		Fuses
	On		Off
	Equipotentiality		Aspirate
	Coagulation		Resection
	Decrease Cavity Set Pressure		Increase Cavity Set Pressure
to RESECTION ▶	Mode Change to RESECTION		Pressure Warning
	Volume Control		Set Pressure Arrow
	Infusion Pump ON / Off		Message Screen Info
OK	OK button	NO	No Button
	Footswitch		Contents
MR	MR Unsafe		Do not push here while saline bag is mounted
Maximum Saline Load 3.3 kg (7.2 lbs)			

Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

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APPENDIX A

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	878 to 1082 cmH2O (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	510 to 1082 cmH2O (50 to 106 kPa)

APPENDIX B

OPTIONAL DATA OUTPUT

Not Used

APPENDIX C

ABBREVIATIONS

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

APPENDIX D

TONES

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

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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! Opening the unit may cause electrical shock to user and voids warranty!**

Problem	Display Message	Possible Causes	Remedy
The Controller does not power on	Black screen, no LEDs 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
The Controller lost Power	N/A	• Power Cord was not installed properly	• Fully plug Cord into Power Entry Module as described Controller Set Up Instructions (Section 12 System Setup)
Insufficient Aspiration	Check Aspiration Tubing for Kink Press OK to CONTINUE	• 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
Kinked Tubing	Check Infusion Tubing for Kink Press OK to CONTINUE	• 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
Return Fluid Path Obstructed	Check Filter Tubing for Kink OR, Replace FILTER to CONTINUE	• Filter is at capacity • Tissue Catch/Tissue Catch Tubing/ Filter Tubing kinked or occluded	• Replace Filter • Check that Aspiration Tubing is properly inserted into pump • Tissue Catch/Tissue Catch Tubing/ Filter Tubing for kink or occlusion
No Device Detected	No Device Detected Connect Device to CONTINUE	• 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	Device Failure Replace DEVICE to CONTINUE	• Resecting Device malfunction	• Replace Resecting Device
Purge Stopped	Infusion Tubing not present Insert Tubing Pressure Too High Make Sure Scope Not In Cavity	• 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 endoscope end is not inserted into cavity
Fluid Leak	Check System for Leak	• Device connections leaking saline • Leaking fluid around the cervix • Perforation	• Check device/tubing connections Reconnect/replace as needed • Check cervix for leaking, add/adjust tenaculum at the cervix • Check for perforation
Pressure Sensor Not Connected	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 incorrectly connected or defective	• Check that Sensor is fully attached to Endoscope and inserted correctly to Controller; replace if necessary
Excessive Cavity Pressure	Excessive Cavity Pressure Relieving Pressure	• Pressure in the cavity is beyond set limit	• Wait and allow system to clear (<5 secs), check return tubing for occlusion
Pressure Sensor Failure	Pressure Sensor Test FAILED Replace Pressure Sensor	• Pressure Sensor incorrectly connected or defective • Pressure reading outside range	• Check that sensor plug is fully inserted into the Controller; replace if necessary
Cannot RESECT or COAG	N/A N/A N/A No Device Detected Connect Device to CONTINUE	• 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

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Problem	Display Message	Possible Causes	Remedy
FAULT CODE: 17 Temperature is out of Controller's operating range	FAULT CODE: 17 RF Board Temperature Out Of 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 Temperature is out of Controller's operating range	FAULT CODE: 19 CPU Board Temperature Out Of 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	FAULT CODE: 22 Footswitch Stuck: Restart and Check	• 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
Unsuccessful Self-Test (Tone 8)	N/A	• Various internal self-diagnostics	• Power off, then power back on the Controller. If the problem persists contact customer service

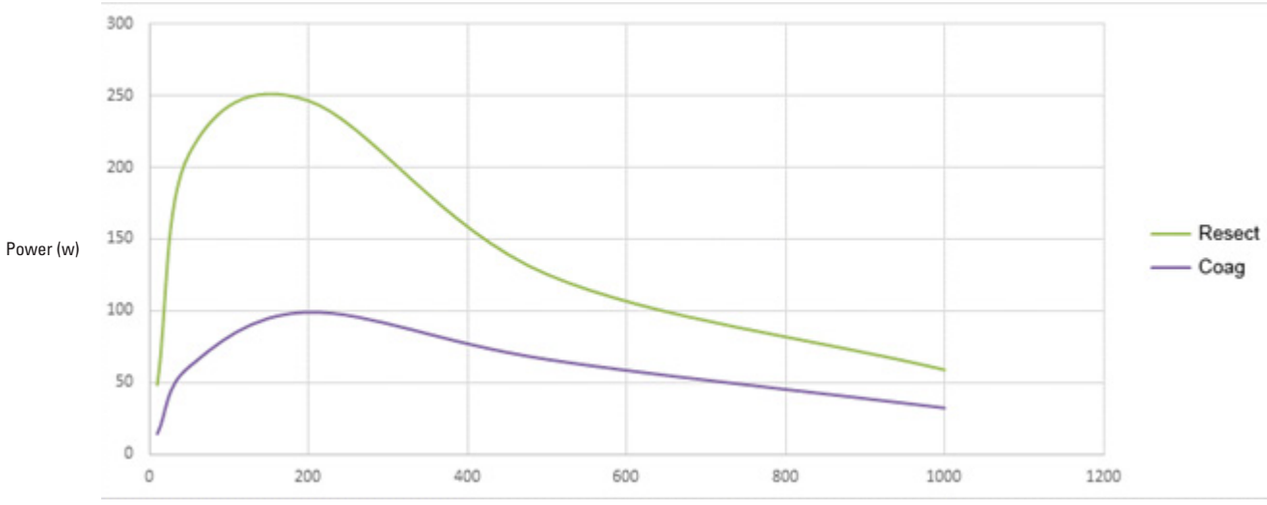
APPENDIX F

APPENDIX F ESSENTIAL PERFORMANCE, POWER CURVE

I. 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.

II. Power Curve



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APPENDIX G

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".

List of SYMPHION Accessories:

- Symphion Fluid Management Accessories
- Symphion Footswitch
- 10 ft. Hospital Grade Power Cord
- Saline Pole

Table 1: Electromagnetic Emissions Statement

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 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 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 2: Electromagnetic Immunity Statement

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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±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 5 s	<5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles <5% *UT* (>95% dip in *UT*) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 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.
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.

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Table 3: Recommended Separation Distances

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.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.3
10	3.79	3.79	7.27
100	12.0	12.0	23.0
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.			

APPENDIX H

FCC Compliance Information for Symphion Tissue Removal System

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

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