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 with available means to avoid such injury.
- Do not use the Symphion System with another fluid management system, endoscope, or controller. Use with another means to avoid such injury.
- DANGER: Do not operate the Symphion System in presence of 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 are 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 estimate the fluid deficit using a single 3-liter saline bag:
    - 2500 mL - Remaining volume in bag = total fluid deficit
  - Follow the same equation for a single 2-liter saline bag:
    - 1500 mL - Remaining volume in bag = total fluid deficit

Note: The Symphion System does not allow for more than 2500 mL to be absorbed by the patient when used in accordance with this manual.

- Fluid Intake: Strict monitoring of fluid intake should be maintained. Intravenous 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 concentration and subsequent electrolyte disturbances may occur. It is important that the physician monitor the patient's electrolytes if significant insufflation 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.

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 cause patient injury or risk of failure which, if not limited, 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 diseases 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.
• 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 Endoscope from the uterine cavity and discontinue the procedure.

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

• Of pressures higher than 100 mmHg is strongly discouraged. Intravascular 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 adjust intravascular 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 uterine fibroplasias (e.g., Sickle Cell Disease, Beta Thalassemia) and therefore, the possible effects are unknown.

• Hemolysis may occur during recirculation. If significant hemolysis is noted, the resin level in the reservoir tank (e.g., increased serum potassium) changes or decrease in hemoglobin. Hemolysis may reveal red-tinted 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.

• Use only normal saline (sodium chloride (0.9% w/v; 150 mmol/L)) constitute a risk of electric shock to persons.

• Gas bubbles are a normal by-product of electrosurgical procedures performed in liquids. When bubbles occur in the uterus, they should be managed to prevent the removal of air/gas bubbles to minimize the inherent risk of emboli. Bubbles produced during tissue vaporization may interrupt surgery by temporarily impairing 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 use of the Symphion System.

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

• If air or gas embolism is suspected, surgeon should consider interrupting surgery, deflating the uterus, and removing source 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 anesthetic line immediately. Do not use the Symphion System to aspirate fluid from the body cavity.
  • 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 suction to effectively flush the uterus of bubbles and debris
  • Minimizing the frequency of removal and reinserter 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.

• At high risk for room air or gas embolism should be managed using ventilated technique

• 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 embolism 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 entire uterine cavity or 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. Use only normal saline (sodium chloride (0.9% w/v; 150 mmol/L)) constitutes a risk of electric shock to persons.

Disease, Beta Thalassemia) and therefore, the possible effects are unknown.

• Do not use in patients with severe cardiopulmonary disease.

• 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. Use only normal saline (sodium chloride (0.9% w/v; 150 mmol/L)).

Do not use in patients with severe cardiopulmonary disease.

• Do not use in patients with severe cardiopulmonary disease.

• 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# 0409-7927-07
  • 3-liter saline bag such as Baxter part# 237477 or Hospira part# 0409-7927-08.

• 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 communication may cause multiple activations of ICDs.

• If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing myometry or tissue coagulation. Electrocautery 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 electrostimulation. Per standard of care, ensure that the patient’s legs are supported and secured appropriately.

• Prior to use, ensure 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 sterile contamination 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 set to the correct settings prior to starting the clinical procedure. Failure of the Controller could result in an unintended increase of output power.

Interference produced by the high-frequency equipment may advetently 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 invalid 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, reorient 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.

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# 0409-7927-07
• 3-liter saline bag such as Baxter part# 237477 or Hospira part# 0409-7927-08.
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
- Dyspareunia
- Hypovolemia
- 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# 287477 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. Aspiration Tube
5. Saline Spike – Infusion Tube
6. Filter Tube
7. Aspiration Pump
8. RF ON LED
9. Fault LED
10. Power ON / OFF Switch
11. Volume Control Knob
12. Equipotential Lug
13. Power Entry Module
14. Fuse Drawer
15. Power ON / OFF Switch

**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

**Figure 3: Footswitch**

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

**Figure 4: Power Cord**

1. Hospital Grade Power Cord (10 ft)
2. COAG (Blue) Pedal
3. Hospital Grade Power Cord (10 ft)
4. Resecting Window
5. Shaft
6. Device Handle
7. Aspiration Quick Connect Fitting
8. Resecting Device Cable
9. Resecting Window
10. Shaft
11. Device Handle
12. Aspiration Quick Connect Fitting
13. Resecting Device Cable

**Figure 5: Saline Pole**

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

**Figure 6: Resecting Device**
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).
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.
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).

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).

   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).

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)

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

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

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

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

**Figure 17**

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

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

![Figure 19](image)

**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](image)

**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](image)

**Figure 21**

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](image)

**Figure 24**

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](image)

**Figure 27**

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

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.

**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).

**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.

**13. SYSTEM OPERATION**

13.1. Diagnostic Mode
- 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.

**Note:** 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.

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.

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.

5. 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.

**6. FLUID REQUIREMENTS**

- The volume of saline to be infused varies depending on the desired cavity pressure and pressure setting.
- Infusion off will cause the cavity to collapse.

- The total purge time is approximately 22 seconds.

**7. DIAGNOSTIC MODE**

**8. MANUAL DRAINAGE AND ASPIRATION**

- To begin Resection Mode, press the “to RESSECTION” tab on the top right corner of the controller (Fig. 33).

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

**9. RESECTING MODE**

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

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

**12. 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).

**13. CIRCULATING NURSE** or PHYSICIAN – Disconnect the Aspiration Tube from the introducer (Fig. 35).

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

**15. SCRUB NURSE** or PHYSICIAN – Introduce the Resecting Device into the working channel of the Endoscope through the introducer (Fig. 37).

**16. SCRUB NURSE** – Hold Scope until saline exits.
- If saline exits through the endoscope, do not start the infusion.

**17. 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 187 mL of fluid will be expelled. The total purge time is approximately 22 seconds.

When purging is complete the Controller will enter diagnostic mode.
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-set up 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).
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 Intrudcer from the Endoscope and remove it with the Resecting Device. See Figure 44 for fully disassembled Endoscope.

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)

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.
## 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

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch Code Lot Number</td>
</tr>
<tr>
<td>X</td>
<td>For Single Use Only</td>
</tr>
<tr>
<td>X</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>R</td>
<td>Sterile Using Irradiation</td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>Legal Manufacturer</td>
<td></td>
</tr>
</tbody>
</table>

### Temperature Limits

- Risk of Electrical Shock

### Non Sterile

- Fuses

### 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

### Footswitch

- Contents

### MR Unsafe

- Do not push here while saline bag is mounted

Maximum Saline Load 3.3 kg (7.2 lbs)

© 2019 Boston Scientific Corporation or its affiliates. All rights reserved.
APPENDIX A
CONTROLLER PRODUCT SPECIFICATIONS

I. Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of Operation</td>
<td>Intermittent. Duty Cycle: 30 seconds ON 10 seconds OFF</td>
</tr>
<tr>
<td>Input</td>
<td>100-240VAC, 50-60Hz, 700VA</td>
</tr>
<tr>
<td>Dimensions without Pump Heads and Saline Pole</td>
<td>6 ¾&quot; (H) x 16 ¼&quot;(W) x 21 ¼&quot;(D) (17.1 x 41.0 x 53.7 cm)</td>
</tr>
<tr>
<td>Packaged Weight</td>
<td>39 lbs (17.7kg)</td>
</tr>
<tr>
<td>Output (Resect):</td>
<td>275W ±20%, 275VMAX, 148 kHz, 200Ω load</td>
</tr>
<tr>
<td>Output (Coag):</td>
<td>110W ±20%, 200VMAX, 148 kHz, 200Ω load</td>
</tr>
<tr>
<td>Fuses</td>
<td>5x20mm Type “T” 6.3A/250V slow blow (Qty. 2; Littelfuse or equivalent)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>60°F to 80°F (16°C to 27°C)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>30% to 75% non-condensing</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>878 to 1082 cmH2O (86 to 106 kPa)</td>
</tr>
</tbody>
</table>

IV. Transport and Storage Requirements

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>0°F to 140°F (-18°C to 60°C)</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>15% to 85% non-condensing</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>510 to 1082 cmH2O (50 to 106 kPa)</td>
</tr>
</tbody>
</table>

APPENDIX B
OPTIONAL DATA OUTPUT

Not Used

APPENDIX C
ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller</td>
<td>Symphion™ Controller</td>
</tr>
<tr>
<td>LED</td>
<td>Light Emitting Diode</td>
</tr>
<tr>
<td>RF</td>
<td>Radio Frequency</td>
</tr>
<tr>
<td>LCD</td>
<td>Liquid Crystal Display</td>
</tr>
</tbody>
</table>

APPENDIX D
TONES

<table>
<thead>
<tr>
<th>Tone</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Self Test Tone – at Power up</td>
</tr>
<tr>
<td>2</td>
<td>Treatment Tone RESECT</td>
</tr>
<tr>
<td>3</td>
<td>Treatment Tone COAG</td>
</tr>
<tr>
<td>4</td>
<td>High Pressure Tone</td>
</tr>
<tr>
<td>5</td>
<td>Tube Blocked Tone</td>
</tr>
<tr>
<td>6</td>
<td>Connect Tone</td>
</tr>
<tr>
<td>7</td>
<td>Disconnect Tone</td>
</tr>
<tr>
<td>8</td>
<td>Error Tone – continuous until unit powered off</td>
</tr>
<tr>
<td>9</td>
<td>Notification Tone</td>
</tr>
<tr>
<td>10</td>
<td>Leak Tone</td>
</tr>
<tr>
<td>11</td>
<td>Click Tone</td>
</tr>
</tbody>
</table>
## 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.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Display Message</th>
<th>Possible Causes</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| 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 in 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 |
<table>
<thead>
<tr>
<th>Problem</th>
<th>Display Message</th>
<th>Possible Causes</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot RESECT or COAG</td>
<td>N/A</td>
<td>- Resecting Device does not RESECT or COAG</td>
<td>- Make sure that the Controller is in Resection mode&lt;br&gt; - Ensure that normal saline (0.9% w/v; 150mmol/L) is being used as irrigation solution&lt;br&gt; - Ensure that the footswitch is plugged into the gray port on the Controller&lt;br&gt; - Check Resecting Device connection, replace if necessary&lt;br&gt; - Ensure the Resecting Device is securely plugged into the blue connector</td>
</tr>
<tr>
<td>Pressure below 15 mmHg</td>
<td>“Check System for Leak” “Low Pressure Detected”</td>
<td>- Device connections leaking saline&lt;br&gt; - Leaking fluid around the cervix&lt;br&gt; - Pressure sensor is reading atmospheric pressure (endoscope is outside patient)&lt;br&gt; - Perforation</td>
<td>- Check device/tubing connections. Reconnect/replace as needed&lt;br&gt; - Check cervix for leaking, add/adjust tenaculum at the cervix. &lt;br&gt; - Message will be removed when endoscope is within patient and cavity pressure is brought above 15 mmHg&lt;br&gt; - Check for perforation</td>
</tr>
<tr>
<td>FAULT CODE: 17 Temperature is out of Controller’s operating range</td>
<td>FAULT CODE: 17 RF Board Temperature Out Of Range</td>
<td>- Temperature is out of Controller’s operating range</td>
<td>- Power off, then allow Controller to return to room temperature before powering on&lt;br&gt; - Ensure Controller vent holes are not occluded</td>
</tr>
<tr>
<td>FAULT CODE: 19 Temperature is out of Controller’s operating range</td>
<td>FAULT CODE: 19 CPU Board Temperature Out Of Range</td>
<td>- Temperature is out of Controller’s operating range</td>
<td>- Power off, then allow Controller to return to room temperature before powering on&lt;br&gt; - Ensure Controller vent holes are not occluded</td>
</tr>
<tr>
<td>FAULT CODE: 22 Footswitch Stuck</td>
<td>FAULT CODE: 22 Footswitch Stuck: Restart and Check</td>
<td>- Footswitch was depressed on startup&lt;br&gt; - Liquid causing short in footswitch&lt;br&gt; - Footswitch defective</td>
<td>- Power off, then make sure footswitch pedals are not pressed and then power on the Controller&lt;br&gt; - Clear any residual liquid, allow switch to air dry&lt;br&gt; - Replace footswitch</td>
</tr>
<tr>
<td>Unsuccessful Self-Test (Tone 8)</td>
<td>N/A</td>
<td>- Various internal self-diagnostics</td>
<td>- Power off, then power back on the Controller. If the problem persists contact customer service</td>
</tr>
</tbody>
</table>

**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

![Power Curve Graph](image-url)
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

<table>
<thead>
<tr>
<th>Guidance and Manufacturer’s Declaration – Electromagnetic Emissions</th>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11 Class A, Group 2</td>
<td>±6 kV contact</td>
<td>±6 kV air</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2 Class A</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions IEC 61000-3-3 Complies</td>
<td>±1 kV line(s) to line(s)</td>
<td>±1 kV line(s) to line(s)</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
</tbody>
</table>

Table 2: Electromagnetic Immunity Statement

<table>
<thead>
<tr>
<th>Guidance and Manufacturer’s Declaration – Electromagnetic Immunity</th>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2 ±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4 ±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5 ±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 &lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>&lt;5% UT (&gt;95% dip in UT) for 0.5 cycle</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE UT is the a.c. mains voltage prior to application of the test level.
Table 3: Recommended Separation Distances

<table>
<thead>
<tr>
<th>Conducted RF</th>
<th>3 Vrms 150 kHz to 80 MHz</th>
<th>3 V</th>
<th>( d = 1.2 \sqrt{P} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 800 MHz</td>
<td>3 V/m</td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td></td>
<td>3 V/m 800 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>( d = 2.3 \sqrt{P} )</td>
</tr>
</tbody>
</table>

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:

![Electromagnetic Compatibility Symbol]

### Conducted RF

- **IEC 61000-4-6**
  - Field strength: 3 Vrms
  - Frequency range: 150 kHz to 80 MHz
  - Separation distance: \( d = 1.2 \sqrt{P} \) meters

### Radiated RF

- **IEC 61000-4-3**
  - Field strength: 3 V/m
  - Frequency range: 80 MHz to 800 MHz
  - Separation distance: \( d = 1.2 \sqrt{P} \) meters

- **800 MHz to 2.5 GHz**
  - Field strength: 3 V/m
  - Separation distance: \( d = 2.3 \sqrt{P} \) meters

Where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.\(^a\)

\(^a\) 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.\(^b\)

\(^b\) 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.