Smith & Nephew Hysteroscopic Fluid Management System
Glossary of Symbols

- **Pressure**
- **Total volume**
- **Start/Stop**
- **Reset button**
- **Flow**
- **Service required**
- **Up and Down buttons**
- **Equipotentiality**
- **Menu button**
- **Scope**
- **On/Off button**
- **Drape**
- **Power plug**
- **Handpiece**
- **Fluid deficit**
- **EU: Not for general waste**
- **Fluid deficit rate alarm**
- **Latex free**

EQUIPMENT CLASSIFICATION --
Patient Isolation Type
BF Applied Part

Alternating current

Keep dry

This end up

Fragile; handle with care

Indicates explosion risk in the presence of flammable anesthetics

UL Classification

EU: Not for general waste

Latex free
Preface

This manual contains information required to operate and maintain the Smith & Nephew Hysteroscopic Fluid Management System. It is essential that all the information in this manual be read and understood before using or maintaining the system.

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Device Description
The Smith & Nephew Hysteroscopic Fluid Management System consists of an irrigation pump with a fluid monitor unit used for hysteroscopic procedures. The product is designed to pump fluid and measure the amount of fluid used in these procedures.

Indications for Use
The Hysteroscopic Fluid Management System is a device intended to provide liquid distension of the uterus for diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

Contraindications
Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. Relative contraindications to endometrial ablation: surgical skill ("acute technical"). Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken before adequate training, preceptorship, and clinical experience. Additionally, tissue sampling is required prior to destruction of the endometrium. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:

- Adenomatous endometrial hyperplasia
- Uterine leiomyoma
- Severe adenomyosis
- Pelvic pain (subtle PID)
- Uterine anomalies

Relative contraindications to hysteroscopic myomectomy:

- Surgical skill (see above)
- Severe anemia
- Inability to circumnavigate the myoma (re: myoma size), predominantly intramural myomas with small submucous components.

Warnings
- This manual does not provide a detailed description of procedure techniques, nor is it suitable for introducing a beginner to this surgical technique. Medical accessories and devices may be used only by physicians and medical assistants under the direction of a physician with the appropriate technical qualification.
- Read these instructions completely prior to use.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics.
- Condensation/water penetration: Protect the system from moisture. Do not use if moisture has penetrated the system.
- To prevent electrical shock, do not open the irrigation pump control unit or the fluid monitor unit. Refer servicing to authorized service personnel.
- Tube sets are provided sterile and are for single use only. Do not reuse. Do not resterilize. Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use. Discard any opened and unused product.
- Work exclusively with sterile substances, sterile fluids, and sterile accessories.
- The volume of the irrigation fluid entering and leaving the patient has to be strictly monitored. If a low viscosity liquid distension medium is used, intrauterine instillation exceeding 2 liters should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid (e.g. Hyskon) is used, the use of more than 500 ml should be followed with great care. Refer to the labelling of the irrigation fluid used for additional information.
- Only sterile saline can be used with the Smith & Nephew TRUCLEAR® System.
- The system must only be used with hysteroscopes and resectoscopes designed for the intended surgical procedure. The scopes must comply with the most recent versions of EN 60601-2-18.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 60601-1/IEC 60601-1 approved isolation transformer and retest the system.
• The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  – Use of the accessory in the patient vicinity.
  – Evidence that the safety certification of the accessory has been performed in accordance with UL 60601-1/IEC 60601-1.
• The instrument detection process must only be performed outside of the patient. The hysteroscope or resectoscope must be held at the same height as the height at which the procedure is to be performed.
• This system is intended only for use with plastic fluid canisters and fluid bags. Glass canisters or bottles may break, and there is a risk of implosion.
• Use of bags or canisters not approved for this system, or large and/or lopsided loads, may cause the device to tip over.
• In the event the irrigation pump fails during a procedure, a replacement control unit and accessories should be available.
• If a system deficiency is suspected, or if the system fails to monitor the indicated fluid levels, stop using the system until it has been checked by authorized service personnel.
• If obvious defects are present, especially at the power cord receptacle or power cord, the control unit should not be used.
• For protection against fire hazard, replace control unit fuses only with fuses of the same type and rating.
• Stop the device using the Start/Stop button if the scope is changed during surgery.
• Intrauterine distension can usually be accomplished with pressures in the range of 35–75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressure greater than 75–80 mmHg.
• Intrauterine pressure should be maintained as low as possible to allow adequate distension while minimizing the risk of fluid, air, and/or gas intravasation.
• Fluid Overload (Hyperhydration): By passing through the uterus, irrigation fluids may end up in the blood system or in the patient’s tissue, especially in cases of overpressure, a lengthy procedure, or perforation of the uterine cavity. The physician bears responsibility for monitoring and assessment of these and all other potentially related factors.
• An air embolism can be the result of air contained in the tube set. Ensure there is always fluid in the bag to prevent air from being delivered into the patient.

• It is necessary to monitor the amount of irrigation fluid left in the patient and the concentration of sodium in the blood serum. The calculation of the amount of irrigation fluid left in the patient is the physician’s responsibility.

• Resetting the FLUID DEFICIT display is to be done at the physician’s discretion.

• If the intrauterine pressure does not respond to an increase in set pressure, this may indicate a perforation of the uterine cavity. There is danger of internal bleeding. Examine the uterus for possible injuries.

• In the event of a power outage, the deficit and inflow values are lost.

• The complete fluid monitor system is composed of a scale system and a carrier plate stand, each of which includes its own components. To ensure the accuracy of fluid measurement, these individual components must not touch one another.

• Fluid bags must be hung to the rear of the fluid bag deflector to allow for accurate accountability of irrigation fluid usage.

• Ensure that fluid bags hang freely. They must not be supported from the bottom, or the fluid deficit will not be measured accurately.

• When spiking the bag, do not pull or lift the bag as it may result in an inaccurate deficit reading.

• Any contact with the scale system, including a bag or collection system canister exchange, must be performed quickly and with minimal vibration.

• To ensure accurate measurements, do not place any items in areas that are weight-sensitive (fluid bag holder or top of fluid collection system canisters).

• Ensure neither the power cord nor the equipotential cable touch any part of the scale system, including fluid collection system canisters. This may lead to an error in monitoring the fluid deficit. The control unit may only be operated with angular equipotential MC plugs.

• Pressing the On/Off button does not disconnect the control unit from the power source. This requires removing the power plug from the rear of the control unit.

• To avoid the risk of electrical shock, connect the power cord to a properly wired grounding receptacle only.

• Ensure that all components are properly aligned.

• Ensure that the two support poles are properly aligned with the load controller bracket and the bracket is tightened.

• Ensure that the O-ring in the load controller bracket is properly seated and does not touch the scale system support pole.
Precautions

U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Check all user menu settings and values. Internal standard factory settings may be changed at the physician's discretion. The physician is responsible for all settings that pertain to his/her procedure.
- Do not sterilize the control unit or fluid monitor unit.
- Do not step on, stand on, or roll objects over any tubing. Avoid high traffic areas where tubing may be subjected to detachment.
- Ensure that the available mains voltage matches the data listed on the label attached to the back of the control unit. Incorrect voltage can cause errors or malfunction, and may destroy the equipment.
- **Electrical Interference:** This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- **Environmental Protection:** This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- The control unit or fluid monitor unit housing should not be opened except by a qualified service person. Tampering by unqualified persons can damage these devices.
- Handle unit with care. If the unit is dropped or damaged in any way, it must be returned immediately for service.
- The electrical safety conditions should be checked annually to ensure compliance with IEC 60601-1.
- After use, tube sets may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
System Components

Unpack the Components

Carefully unpack and inspect all components shipped with the Smith & Nephew Hysteroscopic Fluid Management System. If any parts are missing or damaged, contact an authorized Smith & Nephew representative. Save the carton and packing materials in the event a component must be returned for repair.

The following components should have been received:

Carton 1  (REF 7210166)
1 ea.  Roller base
5 ea.  Canister holders
1 ea.  Carrier plate
1 ea.  Large washer (size M10)
1 ea.  Socket head screw (size M10)
2 ea.  Allen wrenches (small, large)*
* attached under carrier plate

Carton 2  (REF 7210165)
1 ea.  Preassembled stand system: a scale supporting the carrier plate and scale system support poles, fluid bag deflector, fluid bag holder, and fluid monitor unit.

Carton 3  (REF 7210164)
1 ea.  Control unit

Carton 4  (REF 72200094)
1 ea.  Vacuum regulator

Carton 5  Accessory Kit (REF 7210473)
3 ea.  Power cords (US, UK, International)
1 ea.  Operations/Service Manual (REF 1061372)

Figure 1. Component identification

1  Fluid monitor display
2  Fluid bag holder
3  Fluid bag deflector
4  Control unit
5  Carrier plate
6  Vacuum regulator
7  Scale system support pole
8  Carrier plate support pole
9  Scale with canister holder brackets
10  Canister holder brackets
11  Collection system canister (five total)
12  Locking roller brakes
13  Roller base
14  Canister holder (five total)
15  Load controller bracket
Assemble the Components

Assemble the Roller Base to the Stand
1. Place the roller base on a smooth level surface with the roller brakes facing you.
2. With the fluid monitor display facing you, place the stand assembly into the support hole in the roller base. Position the stand so the canister holder brackets are centered between the legs of the roller base.
3. Center the large washer underneath the base; insert the socket head screw and lightly hand-tighten (Figure 3).

![Figure 3. Washer orientation](image)

Assemble the Carrier Plate to the Support Pole
1. Slide the carrier plate onto the short carrier plate support pole. The two set screws in the carrier plate should be positioned over the corresponding holes in the carrier plate support pole.

   ![Figure 4. Carrier plate](image)

   *WARNING: Ensure that the O-ring in the load controller bracket is properly seated and does not touch the scale system support pole.*

2. Using the small Allen wrench, securely tighten the set screws.
Assemble Remaining Components

1. Stand in front of the carrier plate. Grasp the carrier plate and tilt the stand forward. Gently lay the stand on an even floor surface. The carrier plate handle ① should rest on the floor as shown in Figure 5.

2. Use the large Allen wrench ④ to securely tighten the socket head screw in the center of the base.

3. Raise the assembled stand and lock the roller brakes in place.

4. Adjust the fluid monitor unit to a vertical position and ensure that the cables have not been damaged. If necessary, remove the plastic cap covering the locking screw on the fluid monitor unit mounting bracket. Use the large Allen wrench to tighten or loosen the locking screw as needed to allow for easy repositioning of the unit.

5. Center the irrigation pump control unit on the carrier plate so that the control unit rear panel touches the U-shaped stop bracket on the rear of the carrier plate (Figure 6).

6. Connect the data cable from underneath the carrier plate to the data cable receptacle on the rear of the pump control unit.

7. Connect the power cord to the power cord receptacle on the rear panel of the pump control unit.
   
   **Note:** The power cord should hang freely and be centered in the opening of the fluid bag deflector.

8. Thread an equipotential compensation cable from the bottom through the opening of the carrier plate. Connect the cable to the equipotential compensator terminal on the rear of the pump control unit.

9. Securely clip the equipotential compensation cable to the cable clip under the carrier plate.

   **WARNING:** Ensure neither the power cord nor the equipotential cable touch any part of the scale system, including fluid collection system canisters. This may lead to an error in monitoring the fluid deficit. The control unit may only be operated with angular equipotential MC plugs.

   The scale system includes the collection system canisters and holders, the scale, scale system support pole, fluid bag holders, and the fluid monitor unit.

10. Insert the canister holders into the brackets on the scale. Insert collection system canisters as required.

11. Refer to the Preoperative Setup section of this manual for connecting canisters to each other and to the vacuum regulator.

   **WARNINGS**
   - Ensure that all components are properly aligned.
   - Ensure that the two support poles are properly aligned with the load controller bracket and the bracket is tightened.

12. Connect the vacuum regulator to the carrier plate support pole.

   **Note:** The vacuum regulator clamp must not touch the scale support pole.
Control Unit Front Panel

Figure 7. Smith & Nephew Hysteroscopic Fluid Management System control unit front panel

<table>
<thead>
<tr>
<th>Control</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Start/Stop button</td>
<td>Calibrates/deactivates the unit.</td>
</tr>
<tr>
<td>2 Start/Stop LED</td>
<td>Illuminates when the Start/Stop button is pressed.</td>
</tr>
<tr>
<td>3 Overpressure indicator</td>
<td>Indicates intrauterine pressure of 200 mmHg has been reached.</td>
</tr>
<tr>
<td>4 IU PRESSURE display</td>
<td>Displays the intrauterine pressure.</td>
</tr>
<tr>
<td>5 MAX FLOW display</td>
<td>Indicates the maximum flow rate available.</td>
</tr>
<tr>
<td>6 Roller wheel</td>
<td>Bidirectional wheel to pressurize or depressurize the uterine cavity.</td>
</tr>
<tr>
<td>7 Pressure transducers</td>
<td>Senses the pressure generated by the irrigation pump.</td>
</tr>
<tr>
<td>8 MAX FLOW up/down buttons</td>
<td>Allows adjustment of the maximum flow rate.</td>
</tr>
<tr>
<td>9 Service indicator</td>
<td>Indicates that the system requires service.</td>
</tr>
<tr>
<td>10 Menu button</td>
<td>Allows entry to the user menu.</td>
</tr>
<tr>
<td>11 SET PRESSURE display</td>
<td>Displays the set pressure.</td>
</tr>
<tr>
<td>12 SET PRESSURE up/down buttons</td>
<td>Allows adjustment of the set pressure.</td>
</tr>
<tr>
<td>13 On/Off LED</td>
<td>Indicates on/off status of the unit.</td>
</tr>
<tr>
<td>14 On/Off button</td>
<td>Turns the power to the unit on/off.</td>
</tr>
<tr>
<td>15 Stand-By Mode LED</td>
<td>Indicates the unit is in Stand-By Mode (connected to a power source).</td>
</tr>
</tbody>
</table>
System Components (continued)

Control Unit Rear Panel

Figure 8. Control unit rear panel

Control Function
1. Power cord receptacle
   Connection for hospital-grade power cord.
2. Equipotential compensator terminal
   Connection for equipotential cable.
3. Data cable receptacle
   Connection for fluid monitor display data cable.
4. Service interface receptacle
   Connection for service interface cable.

Fluid Monitor Display

Figure 9. Fluid monitor display front panel
Figure 10. Fluid monitor display rear panel

Control Function
1. FLUID DEFICIT display
   Displays the amount of irrigation fluid lost during the procedure.
2. TOTAL VOLUME display
   Displays the total irrigation fluid volume used during the procedure.
3. Reset button
   Resets the FLUID DEFICIT and TOTAL VOLUME displays.
4. Fluid deficit alarm indicator
   Alerts the user of a potential problem in the uterine cavity.
5. Fluid deficit bar graph
   Presents the deficit value as a percentage of the set deficit alarm value.
6. Mounting bracket with locking screw
   Attaches the fluid monitor display to the scale support pole. The locking screw under the plastic cap is used to adjust the position of the fluid monitor display.
7. Data cables
   Integrated data cables connecting the fluid monitor display to the scale system.
Recommended System Configuration

IEC 60601-1-1 Compliant System Configuration

Figure 10 indicates a system configuration that complies with IEC 60601-1-1 requirements.

WARNING

- If this unit is configured as part of a system, the entire system (TRUCLEAR™ System and Hysteroscopic Fluid Management System) should be tested for compliance with IEC 60601-1-1.

- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 60601-1/IEC 60601-1 approved isolation transformer and retest the system.

- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the patient vicinity.
  - Evidence that the safety certification of the accessory has been performed in accordance with UL 60601-1/IEC 60601-1.

![Diagram of System Failure Flowchart]

Figure 11. IEC 60601-1-1 Compliant System Configuration
Preoperative Setup

WARNINGS

- The complete fluid monitor system is composed of a scale system and a carrier plate stand, each of which includes its own components. To ensure the accuracy of fluid measurement, these individual components must not touch one another.

- Ensure neither the power cord nor the equipotential cable touch any part of the scale system, including fluid collection system canisters. This may lead to an error in monitoring the fluid deficit. The control unit may only be operated with angular equipotential MC plugs.

- Work exclusively with sterile substances, sterile fluids, and sterile accessories.

Power Supply Connection

WARNING: To avoid the risk of electrical shock, connect the power cord to a properly wired grounding receptacle only.

CAUTION: Ensure that the available mains voltage matches the data listed on the label attached to the back of the control unit. Incorrect voltage can cause errors or malfunction, and may destroy the equipment.

Safety Plug

The power cord must be equipped with a safety plug. Use only the supplied power cord for the connection between the power plug and the control unit power receptacle.

U.S. Operation

Only use a certified (UL listed) removable power cord, type SJT, minimum 18 AWG, with three leads. Plugs must comply with NEMA 5-15 and/or IEC 320/CEE22.

A potential equalization connection is only ensured if the control unit is connected via a properly installed hospital-grade receptacle.

Potential Equalization

Integrate the control unit into the potential equalization that corresponds to the electrical system.

WARNING: Ensure neither the power cord nor the equipotential cable touch any part of the scale system, including fluid collection system canisters. This may lead to an error in monitoring the fluid deficit. The control unit may only be operated with angular equipotential MC plugs.

Hang the Fluid Bags

WARNINGS

- The volume of the irrigation fluid entering and leaving the patient has to be strictly monitored. If a low viscosity liquid distension medium is used, intrauterine instillation exceeding 2 liters should be followed with great care due to the possibility of fluid overload. If a high viscosity fluid (e.g. Hyskon) is used, the use of more than 500 ml should be followed with great care. Refer to the labelling of the irrigation fluid used for additional information.

- Only sterile saline can be used with the Smith & Nephew TRUCLEAR System.

- This system is intended only for use with plastic fluid canisters and fluid bags. Glass canisters or bottles may break, and there is a risk of implosion.

- Use of bags or canisters not approved for this system, or large and/or lopsided loads, may cause the device to tip over.

- Fluid bags must be hung to the rear of the fluid bag deflector to allow for accurate accountability of irrigation fluid usage.

- Ensure that fluid bags hang freely. They must not be supported from the bottom, or the fluid deficit will not be measured accurately.

Fluid bags must only be hung on the bag holder hooks. Hang up to four 5-liter bags maximum.

Connect Tube Sets to Devices

The following instructions detail how to connect the items included in the Hysteroscopic Fluid Management System. Refer to Figures 12, 13, and 14 for correct tubing routing and connection points.

WARNING: Tube sets are provided STERILE and are for single use only. Do not reuse. Do not resterilize. Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use. Discard any opened and unused product.
Tube Set Connections Using the TRUCLEAR° System

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Figure 12. TRUCLEAR System tubing and device connections

1. Saline bags
2. Insertion spikes
3. Inflow tube set
9. Control unit head
11. TRUCLEAR handpiece
12. TRUCLEAR handpiece outflow tubing (white connector)
13. TRUCLEAR Hysteroscope with blade and sheath
14. TRUCLEAR Hysteroscope outflow tubing (yellow connector)
15. Patient drape
16. Drape outflow tubing (blue connector)
17. TRUCLEAR Hysteroscope gravity collection system canister
18. Drape vacuum collection system canisters (2)
19. Vacuum collection system canisters (2)
20. Tissue trap
21. Connection tubing
22. Vacuum regulator
23. Stopcock port
24. Connection to vacuum source

WARNING: Only sterile saline can be used with the Smith & Nephew TRUCLEAR System.
Preoperative Setup (continued)

Tube Set Connections Using the TRUCLEAR® Hysteroscopic Instrument Sets

**Figure 13.** Diagnostic hysteroscopy tubing and device connections

1. Fluid bags
2. Insertion spikes
3. Inflow tube set
4. Control unit head
5. TRUCLEAR Hysteroscope with sheath
6. TRUCLEAR Hysteroscope outflow tubing (yellow connector)
7. Patient drape

8. Drape outflow tubing (blue connector)
9. TRUCLEAR Hysteroscope gravity collection system canister
10. Drape vacuum collection system canisters (2)
11. Connection tubing
12. Vacuum regulator
13. Stopcock port
14. Connection to vacuum source

**Note:** Choose the appropriate irrigation fluid for the procedure being performed.

**Note:** Similar tubing connections may be used when other diagnostic scopes are used.
Preoperative Setup (continued)

Tube Set Connections Using the Resectoscope/Hysteroscope

![Diagram of tube set connections]

Figure 14. Resectoscopy tubing and device connections

1. Fluid bags
2. Insertion spikes
3. Inflow tube set
4. Control unit head
5. Resectoscope
6. Resectoscope outflow tubing (yellow connector)
7. Patient drape
8. Drape outflow tubing (blue connector)
9. Drape vacuum collection system canisters (2)
10. Outflow vacuum collection system canisters (2)
11. Tissue trap
12. Connection tubing
13. Vacuum regulator
14. Stopcock port
15. Connection to vacuum source

Note: Choose the appropriate irrigation fluid for the procedure being performed.

Note: Similar tubing connections may be used when other operative scopes are used.
Connect the Inflow Tube Set
The Smith & Nephew inflow tube set consists of three tubing sections (irrigation, roller, and instrument); one pressure chamber; one locking ring; and two insertion spikes to connect the Irrigation section to the fluid bags.

Insert the Roller Tubing Section
When inserting the roller tubing section, do not damage the membranes of the pressure chamber. Insert the pressure chamber only if unpressurized.

Figure 15. Assembled inflow tube set
1. Fluid bags
2. Irrigation spikes
3. Irrigation tubing section
4. Locking ring
5. Roller tubing section
6. Pressure chamber
7. Pressure chamber key
8. Instrument tubing section
9. Pump head

Figure 16. Roller tubing insertion
3. Irrigation tubing section
4. Locking ring
5. Roller tubing section
6. Pressure chamber
7. Pressure chamber key
8. Instrument tubing section
9. Pump head
10. Pressure chamber membranes

1. Remove the transportation safeguard from the pressure chamber.
2. (A) Slide the pressure-free pressure chamber carefully (nose upward) into the slot in the pump head. Listen for a click when locking the pressure chamber into position. When properly inserted, the pressure chamber is flush with the pump head. Ensure the pressure transducer membranes are not damaged.
3. Place the roller tubing section around the roller wheel.
4. (B) Insert the locking ring by pulling on the tubing until the locking ring snaps into place.
Preoperative Setup (continued)

Connect to the Fluid Bags
Use aseptic technique. Grasp an insertion spike by the handle and connect the Irrigation tubing section to the fluid bags. Close tubing clamps.

Note: When connecting or removing tubing to or from a fluid bag, always grasp the insertion spike by the handle.

Connect to the Hysteroscope/Resectoscope
1. Remove the cap from the Instrument tubing section.
2. Connect the blue luer connector on the Instrument tubing section to the hysteroscope inflow stopcock.

Note: The inflow stopcock on the Smith & Nephew TRUCLEAR Operative Hysteroscope is identified with a blue ring.

Connect the Smith & Nephew Outflow Tube Set
The outflow tube set consists of three tubing sections: one for patient drape, one for a Smith & Nephew TRUCLEAR Handpiece, and one for hysteroscope or resectoscope outflow.

Connect the Drape Outflow Tubing
(Blue Connector)
1. Connect one end to the patient drape.
2. Connect the other end to the first of the drape vacuum canisters using the patient port of the canister lid.
3. Using the connection tubing (Figure 12, 13, 14, ©), connect the drape vacuum canister in a series beginning with the canister connected to the patient drape.
4. Connect the last canister in the series to the stopcock port of the vacuum regulator (Figure 12, 13, 14, ©).
5. Open the stopcock to apply vacuum to the canister and patient drape.

Operative Hysteroscopy Procedure Using the Smith & Nephew TRUCLEAR System
Refer to Figure 12 to:
• Connect the handpiece tubing
• Connect the outflow tubing

Connect the Handpiece Tubing
(White Connector)
1. Connect one end to the barbed fitting on the TRUCLEAR Handpiece.
2. Insert a tissue trap into the lid of the first of the collection system canisters designated as vacuum canisters.

Note: Use only one tissue trap.

Diagnostic Hysteroscopy Procedure
Refer to Figure 13 to:

Connect the Outflow Tubing
(Yellow Connector)
1. Connect the end fitted with the yellow luer lock onto the hysteroscope sheath outflow stopcock (identified with a yellow ring on hysteroscope).
2. Connect the other end of the hysteroscope outflow tubing to the collection system canister designated for gravity.

Assemble the Smith & Nephew Hysteroscopic Morcellator

Insert the Blade into the Hysteroscope
1. Open the working channel stopcock on the hysteroscope completely.
2. Insert the Hysteroscopic Morcellator blade into the Smith & Nephew Operative Hysteroscope. Refer to the Instructions for Use for the Smith & Nephew Disposable Hysteroscopic Morcellator Blades (REF 1061210).

Resectoscopy Procedure (Regulated Suction)
Refer to Figure 14 to:

Connect the Resectoscope Outflow Tubing (Yellow Connector)
1. Connect the end fitted with the yellow luer lock onto the resectoscope sheath outflow stopcock (Figure 14, 13).
2. Connect the other end of the resectoscope outflow tubing to the first vacuum canister.
3. Using the connection tubing (Figure 14, 21), connect the resectoscope vacuum canisters in series as shown (Figure 14, 21).
4. Connect the last canister in the series to the hysteroscopic vacuum regulator using the vacuum port on the canister lid.
5. Connect the vacuum regulator to a vacuum source such as wall suction or a stand-alone vacuum pump.
6. Ensure that the vacuum regulator is turned on. In order to achieve vacuum, all canister lids, caps, and interconnecting tubes must be securely attached.

Verify Tubing Connections
Once all tubing is connected, ascertain that all connections are securely attached; that there are no bends, kinks, or sharp turns in the tubing; and that the tubing has not been routed nor supported near sharp objects.

WARNING: Ensure that the O-ring in the load controller bracket is properly seated and does not touch the scale system support pole.

CAUTION: Do not step on, stand on, or roll objects over any tubing. Avoid high traffic areas where tubing may be subjected to detachment.

Note: Ensure that the bags, tubes, collection system canisters, or other parts of the scale system do not come into contact with the irrigation pump control unit, the carrier plate, the carrier plate support pole, or the roller base.

Confirm Scope Connection
1. Verify that the scope inflow stopcock is completely open.
2. Refer to the manufacturer’s Instructions for Use for additional information.

WARNING: The system must only be used with hysteroscopes and resectoscopes designed for the intended surgical procedure. The scopes must comply with the most recent versions of EN 60601-2-18.

Technical Overview
Set pressure can be set in a range from 15–120 mmHg. Nominal flow can be set to between 30–700 ml/min. The pump control unit should only be used with a hysteroscope indicated for hysteroscopic procedures.

Refer to System Safety Features and Accessing the User Menu in this manual for complete information.

Operation
Plug into a Power Source
Plug the pump control unit power cord into an appropriate power source.
A potential equalization connection is only ensured if the control unit is connected via a properly installed hospital-grade receptacle.

WARNING: If obvious defects are present, especially at the power cord receptacle or power cord, the control unit should not be used.

Each time the power cord is plugged into a power source, the Stand-By Mode LED, On/Off LED, and Service Indicator are illuminated; the control unit initializes; and the control unit conducts a self-test.
The Stand-By Mode LED remains illuminated as long as the control unit is connected to a power source.

Turn Pump Control Unit On
Read all warnings and cautions, and to understand all system information including controls, functions, and safety features prior to turning on the control unit.
If the control unit is already plugged in but has been turned off (only the Stand-By Mode LED is illuminated), press the On/Off button to turn the control unit on.
The control unit and fluid monitor unit initialize and the system conducts a self-test. The service indicator on the control unit remains illuminated during this time.
At the end of the brief self-test, the control unit beeps three times, then the fluid monitor unit beeps three times.
Approximately five seconds later the following default values appear in the pump control unit displays:

| IU PRESSURE: | 0 mmHg |
| SET PRESSURE: | 60 mmHg |
| MAX FLOW: | 700 ml/min |

Note: Pressure and flow are reset to default values whenever the control unit is switched on.
The displays on the fluid monitor unit should read:

| FLUID DEFICIT: | 0 ml |
| TOTAL VOLUME: | 0 ml |
| % (DEFICIT bar graph): | Top bar is illuminated. |
Adjust Pump Pressure and Flow Rate

**Pump Pressure**
Use the Up/Down buttons under the SET PRESSURE display:
- Depress button briefly: adjusts set pressure in increments of 5 mmHg.
- Depress button and hold: adjusts set pressure in increments of 10 mmHg.

While increasing the set pressure, the SET PRESSURE display flashes and an alarm sounds when the safety threshold of 100 mmHg is reached. After two seconds, pressure may be increased again to a maximum of 120 mmHg.

**Flow Rate**
Use the Up/Down buttons under the MAX FLOW display:
- Depress button briefly: adjusts flow rate in increments of 10 ml/min.
- Depress button and hold: adjusts flow rate in increments of 20 ml/min.

**Instrument Detection**
The pump control unit optimizes pressure measurement using the instrument detection function. The instrument detection function uses inflow characteristics to ensure that accurate intrauterine pressure is created and maintained.

When using the Smith & Nephew TRUCLEAR™ System, the instrument detection process can be achieved by using either a Smith & Nephew disposable hysteroscopic blade or a Smith & Nephew hysteroscope insert.*

**WARNING:** The instrument detection process must only be performed outside of the patient. The hysteroscope or resectoscope must be held at the same height as the height at which the procedure is to be performed.

**Note:** If instrument detection is performed 12” (30 cm) below patient height, the actual intrauterine pressure will be less than the IU PRESSURE display by 22 mmHg.

**Start Pump Operation**
Refer to the Preoperative Setup section of this manual for instructions on inserting and connecting all tubing, fluid bags, and devices.

1. Open the clamps on the irrigation inflow tubing.
2. Hold the connected hysteroscope assembly at the height of the roller wheel on the fluid management system control unit.
3. Press the Start/Stop button to start the irrigation process:
   - The Start/Stop LED flashes;
   - The control unit beeps once.

4. The instrument detection process runs for approximately 30 seconds. A long beep signals the start of the instrument detection process. The irrigation pressure value is displayed in the IU PRESSURE display during this process.
   - If detection is successful, the control unit emits another long beep, the Start/Stop LED glows continuously and fluid flows continuously. Fluid flow can be interrupted only by closing the hysteroscope inflow stopcock. If an attempt is made to stop the flow using the Stop/Start button, the instrument detection process must be repeated.
   - In case of error or malfunction the IU PRESSURE display depicts IE. The control unit emits five short warning beeps and then switches to the stop mode.
   - When repeating the instrument detection process, ensure both the working channel and inflow stopcocks are completely open, and that the instrument assembly is held at the proper height.
   - If pump is being restarted after a previous successful instrument detection, refer to the Restart Pump Operation section of this manual to eliminate tube priming step.

5. The IU PRESSURE display shows the current measured value.

**Stop Pump Operation**
Press the Start/Stop button again. The irrigation process is stopped. The current measured value continues to be displayed in the IU PRESSURE display.

**Restart Pump Operation**
If pump has been operating and tube set is purged of air, it is possible to restart the pump without the pump air purging cycle.

1. Press and hold the Start/Stop button for >2 seconds; a double “beep” should sound.
2. The Start/Stop LED illuminates and flashes.
3. After a short delay (~ 2 seconds), the instrument detection process is performed.

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*The Smith & Nephew hysteroscope insert is available in the U.S. only*
Operation (continued)

Pump Control Unit Functions

**Pressure Readings and Controls**

This control unit features non-contact pressure readings of the irrigation medium. The non-contact pressure reading is taken by integrating the pressure chamber into the tubing system. The pressure chamber transfers tubing pressure to the control unit’s processing unit via a pressure transducer. The pressure control circuit continuously compares the intrauterine pressure with the set pressure. The function of the control unit is to maintain the set pressure. If the nominal flow is set too low, the set pressure cannot be reached. Watch for possible leaks.

**Default Settings**

To change the default setting for the functions listed below, refer to the appropriate subsection in the Operation section of this manual.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Default</th>
<th>Operation Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set Pressure</td>
<td>60 mmHg</td>
<td>SET PRESSURE display</td>
</tr>
<tr>
<td>Fluid Deficit Alarm</td>
<td>1500 ml</td>
<td>Accessing the User Menu</td>
</tr>
<tr>
<td>Maximum Flow</td>
<td>700 ml/min</td>
<td>MAX FLOW display</td>
</tr>
</tbody>
</table>

**IU PRESSURE Display**

Following the instrument detection process, the IU PRESSURE display shows the current pressure at the hysteroscope tip.

**SET PRESSURE Display**

Set pressure can be adjusted between 15–120 mmHg. Use the Up/Down buttons to change the set pressure. While increasing the set pressure, the SET PRESSURE display flashes and an alarm sounds when the safety threshold of 100 mmHg is reached. After two seconds pressure may be increased again to a maximum of 120 mmHg.

**MAX FLOW Display**

For optimal performance, the MAX FLOW setting should be kept at maximum (700 ml/min). The flow can be adjusted between 30–700 ml/min. Use the flow Up/Down buttons to change the flow. The MAX FLOW display shows the set value.

**Fluid Monitor Unit Functions**

**WARNINGS**

- It is necessary to monitor the amount of irrigation fluid left in the patient and the concentration of sodium in the blood serum. The calculation of the amount of irrigation fluid left in the patient is the physician’s responsibility.
- To ensure accurate measurements, do not place any items in areas that are weight-sensitive (fluid bag holder or top of fluid collection system canisters).
- Resetting the FLUID DEFICIT display is to be done at the physician’s discretion.
- In the event of a power outage, the deficit and inflow values are lost.

**Default Settings**

To change the default setting for the functions listed below, refer to the appropriate subsection in the Operation section of this manual.

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Following the instrument detection process, the IU PRESSURE display shows the current pressure at the hysteroscope tip.

**SET PRESSURE Display**

Set pressure can be adjusted between 15–120 mmHg. Use the Up/Down buttons to change the set pressure. While increasing the set pressure, the SET PRESSURE display flashes and an alarm sounds when the safety threshold of 100 mmHg is reached. After two seconds pressure may be increased again to a maximum of 120 mmHg.

**MAX FLOW Display**

For optimal performance, the MAX FLOW setting should be kept at maximum (700 ml/min). The flow can be adjusted between 30–700 ml/min. Use the flow Up/Down buttons to change the flow. The MAX FLOW display shows the set value.

**WARNING:** If the intrauterine pressure does not respond to an increase in set pressure, this may indicate a perforation of the uterine cavity. There is danger of internal bleeding. Examine the uterus for possible injuries.

**Fluid Monitoring System Capacity**

The combined weight of the fluid bags and collection system canisters should not exceed 92.4 lbs (42 kg). Weight overload may cause damage to the fluid monitor unit.

To check the accuracy of the fluid monitor unit select PO4 in the User Menu.

**Note:** When the procedure is complete, all fluid must be drained from the outflow drape and the tubing system into a collection system canister to accurately measure the fluid deficit.

**Fluid Monitoring System Capacity**

The combined weight of the fluid bags and collection system canisters should not exceed 92.4 lbs (42 kg). Weight overload may cause damage to the fluid monitor unit.

To check the accuracy of the fluid monitor unit select PO4 in the User Menu.

**Note:** The total amount of fluid lost during the procedure is the deficit amount.

**Note:** The accuracy of the fluid deficit monitoring function is ± 3%.

- The FLUID DEFICIT display shows the volume of fluid lost during the procedure. Negative values indicate a mass increase (i.e., through uncontrolled secretion leakage). The alarm threshold for the deficit value can be set in the User Menu.
- The TOTAL VOLUME display is the volume of fluid that is pumped by the system beginning when the reset button is pressed.
- Pressing the reset button sets the total volume and fluid deficit values to 0.
- The fluid deficit rate alarm indicator is illuminated when the deficit measured increases dramatically in a short period of time (300 ml/min). Deficit measurement takes place automatically every 30 seconds.
- The fluid deficit bar graph displays the deficit threshold of the value set in the user menu.
Bag and Canister Recognition System
The system automatically recognizes the exchange of a bag or collection system canister. In the FLUID DEFICIT display, “BAG” is illuminated whenever the scale system recognizes an exchange of a bag or canister, or during any movement of the stand. “BAG” should be displayed for only a short time. The adjusted values are displayed once the bag detection and/or canister exchange is finished (approximately six seconds). If any vibration continues for 30 seconds or more, an alarm sounds.

Hang a Bag During the Procedure
It is not necessary to stop the procedure when adding a bag.
1. Hang bag on one of the four bag hooks.
2. Wait for the “BAG” display to clear.
3. Spike the bag.

WARNINGS
• When spiking the bag, do not pull or lift the bag as it may result in an inaccurate deficit reading.
• Any contact with the scale system, including a bag or collection system canister exchange, must be performed quickly and with minimal vibration.

CAUTION: Leave empty bags hanging in order for FLUID DEFICIT values to remain accurate.

Intrauterine Pressure Exceeds Set Pressure by 20 mmHg
If the intrauterine pressure exceeds the set pressure by 20 mmHg for more than five seconds, the IU PRESSURE display flashes. A continuous alarm sounds during the time the value exceeds the set pressure. The roller wheel may move forward or backward a few times during the pressure reduction process. If it has rotated in the reverse (clockwise) direction for nine seconds, a second alarm sounds and the roller wheel stops.

Intrauterine Pressure Falls Below Set Pressure by 20 mmHg
If the intrauterine pressure falls below the set pressure by 20 mmHg for more than five seconds, the IU PRESSURE display flashes. The roller wheel moves forward and possibly backward a few times while pressure is increased.

Intrauterine Pressure Equals 200 mmHg
If the intrauterine pressure equals 200 mmHg for more than five seconds, the overpressure indicator illuminates, the IU PRESSURE display flashes, a continuous alarm sounds, and the roller wheel stops. Once the intrauterine pressure falls below 200 mmHg, the control unit automaticallyreactivates.

Pressure Chamber not Secured
If the pressure chamber is not fully inserted into the pump head and the Start/Stop button is pressed, the control unit emits three short warning beeps. The roller wheel does not turn, and the Start/Stop LED does not illuminate.

Pressure Measuring System Errors
If the pressure transducer has malfunctioned or if an error in the electronic pressure determination circuit has been detected, the IU PRESSURE display flashes “E01”, an alarm sounds, and the roller wheel stops.

Control Unit Defect
The control unit is defective if any of the following error codes appear in the IU PRESSURE display after starting the system: E01, E03, E50, E51, E58, or E59. Turn off the control unit. Refer to the Troubleshooting section of this manual.

Pressure Control After Restart
Default pressure setting after restart is 60 mmHg.

Deficit Threshold
When the chosen deficit threshold has been reached, an alarm sounds and the FLUID DEFICIT display flashes continuously. The fluid deficit bar graph completely illuminates.
Increase of 100 ml After Exceeding the Deficit Threshold
After every additional increase of 100 ml over the chosen deficit threshold, an alarm sounds.

Deficit Rate Exceeds 300 ml/min
If the deficit rate meets or exceeds 300 ml/min, the deficit rate alarm indicator illuminates, an alarm sounds, and the FLUID DEFICIT display flashes.

Defective Scale
If the scale is defective, the word “SCALE” appears in the TOTAL VOLUME display on the fluid monitor unit. The service indicator on the control unit illuminates, the IU PRESSURE display indicates error code “E02”, and three warning beeps are emitted from the control unit.

100 mmHg Safety Limit
If the user attempts to exceed 100 mmHg while scrolling up or incrementally increasing pressure, the following occurs:
• SET PRESSURE display blinks for two seconds (at 100 mmHg);
• An alarm sounds for two seconds.
Only after two seconds can the user increase the pressure (incrementally or by scrolling).

Fluid Monitor Unit Overload
Weight overload may cause damage to the fluid monitor unit. Should the maximum weight be exceeded for 30 seconds, a long alarm sounds twice and the FLUID DEFICIT display flashes “SCALE” for five seconds. This situation can be corrected by either removing fluid bag(s) or emptying collection system canister(s).

Access the User Menu
Control unit parameters are displayed and changed in the user menu.
• To access the user menu, simultaneously depress the On/Off button and the Menu button. Release the On/Off button and continue to depress the Menu button until a “P” appears in the SET PRESSURE display.
• The menu level is indicated in the SET PRESSURE display.
• The first menu level offers a selection between User Menu and Service Menu. The SET PRESSURE display shows “P” for the user menu and “L” for the service menu (accessible only to service personnel). Use the Up/Down buttons under the MAX FLOW display to alternate between menus.

Available User Menu Levels and Settings
P: User menu
L: Service menu (accessible only to service personnel)
P01: Signal in the pump control unit volume alarm level.
• There are two settings:
  1 = low and 2 = high.
P02: Setting for the deficit threshold alarm level of the fluid monitor display.
• Setting range 0–2000 ml.
  • Depress button briefly: adjusts the deficit threshold setting in increments of 50 ml.
  • Depress button and hold: adjusts the deficit threshold setting in increments of 100 ml.
• Deficit threshold settings will also illuminate in the FLUID DEFICIT display.
P03: Fluid monitor volume display alarm level. There are two settings:
  1 = low and 2 = high.
• Alarm selection also illuminates in the FLUID DEFICIT display.
P04: Check of the mass gauge of the fluid monitor unit.
• FLUID DEFICIT display illuminates in whole numbers (0) and MAX FLOW display illuminates in whole numbers and decimals (0.00).
Cleaning/Service

Cleaning

To Clean

⚠️ **WARNING:** Condensation/water penetration: Protect the system from moisture. Do not use if moisture has penetrated the system.

Clean the Control Unit
1. Press the On/Off button to turn off the control unit.
2. Gently remove the power cord.
3. Wipe the surface of the control unit with a soft cloth moistened with disinfectant. Use a surface disinfectant with a non-alcohol base.

The concentration and application duration of the disinfectant depend on the information provided by the disinfectant manufacturer.

Do not allow moisture to enter the control unit.

⚠️ **CAUTION:** Do not sterilize the control unit or the fluid monitor unit.

Clean the Fluid Monitor Unit and Stand Assembly
1. Ensure the control unit has been turned off the the power cord removed.
2. Wipe the surface of the fluid monitor unit and stand assembly with a soft cloth moistened with disinfectant. Use a surface disinfectant with a non-alcohol base.

The concentration and application duration of the disinfectant depend on the information provided by the disinfectant manufacturer.

Do not allow moisture to enter the fluid monitor unit.

⚠️ **CAUTION:** Do not sterilize the control unit or the fluid monitor unit.

Clean the Vacuum Regulator
Refer to the manufacturer's instructions supplied with the vacuum regulator for cleaning instructions.

Service

Service Philosophy

There are no user-serviceable components inside the Smith & Nephew Hysteroscopic Fluid Management System. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call an authorized Smith & Nephew Customer Service representative prior to returning the device and request a Return Authorization (RA) number. An authorized representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Smith & Nephew. A Smith & Nephew customer service representative can provide additional instructions.

**Note:** Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by Smith & Nephew will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

Replace Fuses

To replace the fuses:

- Remove the power cord from the power receptacle on the back of the control unit.
- Use a small screwdriver to lift the cover on the fuse holder; pull out the fuse holder.
- Replace fuses with the same type and quality as specified in the Technical Specifications section of this manual.

⚠️ **WARNING:** For protection against fire hazard, replace control unit fuses only with fuses of the same type and rating.
Electrical Interference

CAUTION: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

Environmental Protection

CAUTION: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Maintenance

Preventative Maintenance

Recommended Annual Safety Testing

Note: Safety testing should only be performed by authorized service personnel.

Dielectric Strength, Earth Leakage Current, and Protective Earth Testing

Smith & Nephew recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annually to ensure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 60601-1/IEC 60601-1.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

CAUTION: The control unit or fluid monitor unit housing should not be opened except by a qualified service person.

CAUTION: The electrical safety conditions should be checked annually to ensure compliance with IEC 60601-1.

Preparation

Visually inspect the pump control unit to ensure:

- Text and labels on the control unit are legible
- The control unit has not been damaged
- All visible screws, mountings, and assemblies are secure
- The proper alignment of the carrier plate, the load controller bracket, and the collection system canisters
- There is no evidence of contamination

Dielectric Strength Test

Measure insulation (resistance) with 500–700 V DC. The minimum value should be 50 Ω. Do not measure electric strength using high voltage.

Earth Leakage Current Test

Measure leakage current in accordance with IEC 60601-1.

Protective Earth Test

Measure the ground continuity in accordance with IEC 60601-1. The ground continuity should be measured with the power cord connected. The maximum value should be 0.2 Ω.

Recommended Annual Performance Testing

Note: Performance testing should only be performed by qualified hospital personnel.

Basic Function Test

This test should also be performed if the unit has been serviced or if the accuracy of the system is in question.

The following items are required for this test:

- Smith & Nephew Hysteroscopic Fluid Management System
- Smith & Nephew Inflow Tube Set
- Fluid bags
- Graduated beaker with 0.5 liter scaling
- Smith & Nephew Operative Hysteroscope
- Watch or clock with second hand
- Defined weight between 2.2 lbs (1 kg) and 11 lbs (5 kg)
Note: Carefully read the System Safety Features information in the Operation section of this manual before using the system. This information details all safety notes, visual and audible alarms, and error messages.

Preparation
1. Check the roller base wheels for ease of movement.
2. Connect the equipotential compensation cable to the irrigation pump control unit and ensure it runs freely through the opening of the carrier plate and is then clipped securely to the clip under the carrier plate.
3. Connect the power cord to the control unit and ensure it hangs freely and does not come in contact with any part of the scale system.
4. Check the connection of the data cable between the pump control unit and the fluid monitor unit.
5. Check to ensure no objects have been placed on top of the pump control unit.
6. Check to ensure the fluid bags are hung per the Setup section of this manual, and that they meet the requirements specified.
7. Connect the outflow tubing to the hysteroscope inflow stopcock, the outflow drape, and the collection system canisters.
8. Check to ensure the canisters are interconnected and hang freely from the holders.

Check User Menu Settings
1. Enter the User Menu and record the current user-defined settings.
2. Change the settings and exit the User Menu.
3. Enter the User Menu again and verify all user-defined settings are still active.

Insert Tube Set into Pump
1. Slide the pressure-free pressure chamber carefully (nose upward) into the cutout of the pump head. Listen for a click when locking the pressure chamber into position.
   When properly inserted, the pressure chamber is flush with the pump head. Ensure the pressure transducer membranes are not damaged.
2. Wrap the tubing around the roller wheel, pull taut and release. This locks the tubing in place.
3. Spike the bags.
4. Ensure all tube connections are free of mechanical stress and are freely suspended.

Start Pump Operation
If using the TRUCLEAR System, begin with Step 1 otherwise, begin with step 3.
1. Verify the working channel stopcock is completely open.
2. Insert the blade or hysteroscope insert into the hysteroscope working channel.
3. Open the irrigation tube clamps.
4. Verify that the hysteroscope inflow stopcock is completely open.
5. Press the Start/Stop button to start the irrigation process.
   - Instrument detection is performed
   - The Start/Stop LED is illuminated
   - The IU PRESSURE display shows the current measured value
   - The roller wheel begins to turn
   Note: Allow the instrument detection routine to finish.
6. Press the Start/Stop button again to stop the pump.

Verify Control Unit Set Pressure Values
This step verifies the measurement values and tolerance levels indicated in the Technical Specifications section of this manual.

Note: If the specified tolerances and/or parameters are not in range, the control unit should be checked by authorized service personnel.
1. Set the following pump values:
   - Set pressure: 120 mmHg
   - Nominal flow: 500 ml/min
2. Close the hysteroscope inflow valve. Once the roller wheel no longer moves, the IU PRESSURE display must read 120 mmHg ± 2 mmHg.

Fluid Deficit Measurement Test
1. Press the reset button to set the deficit and fluid usage (total volume) back to zero.
2. Remove the large cap on any one of the collection system canisters hanging on a canister holder, and insert the hysteroscope into the canister.
3. Pump approximately 200 ml and stop. The deficit display should show 0 ml.
4. Hold the hysteroscope over a graduated beaker that is not sitting on one of the five canister holders.
5. Transfer approximately 200 ml into the graduated beaker. The deficit display should show 200 ml ± 10 ml.
   If the deficit display shows 200 ml ± 10 ml, the fluid deficit measurement test is successful.

Flow Rate Verification Test
This step verifies the measurement values and tolerance levels indicated in the Technical Specifications section of this manual.

Note: If the specified tolerances and/or parameters are not in range the unit should be checked by authorized service personnel.
**Preparation**

1. Ensure a watch or clock with a second hand is available.
2. Empty the graduated beaker.
3. Set the following pump values:
   - Set pressure: 120 mmHg
   - Nominal flow: 500 ml/min
4. Set the deficit and total volume display to 0 by pressing the reset button.
5. Place the instrument tip into the graduated beaker and completely open the hysteroscope inflow stopcock.
6. Press the Start/Stop button to start the irrigation process.
   - Instrument detection is performed
   - The Start/Stop LED is illuminated
   - The IU PRESSURE display shows the current measured value
   - The roller wheel begins to turn
7. After one minute press the Start/Stop button again.
8. Verify that the control unit has pumped 500 ml (± 25 ml) of fluid into the beaker.

   Once all values have been verified, the flow rate verification test is successful.

**Pressure Measurement Test**

The pressure measurement test evaluates the pressure chamber, pressure transducers, and pressure measurement for proper function. This test requires a complete tube set and a canister filled with water. The height of the water column is used to generate a hydrostatic pressure on the pressure transducer. The height of the water column above the pressure chamber must match the value of the IU PRESSURE display after conversion.

Conversion formula:

\[ X \text{ (cm } H_2O) \times 0.74 = Y \text{ (mmHg)} \]

**Pressure Transducer Tests**

These tests check the proper functioning of each pressure transducer. Figure 18 shows the location of each pressure transducer.

1. Place the irrigation tube in a canister filled with water.
2. Press the Start/Stop button to start the irrigation process.
   - Instrument detection is performed
   - The Start/Stop LED is illuminated
   - The IU PRESSURE display shows the current measured value
   - The roller wheel begins to turn
3. Fill the tube set with water.
4. Press the Start/Stop button to stop the roller wheel.
5. Hold a finger over the end of the instrument tube to close it.
6. Hold the patient end 44 cm above the pressure chamber (h).
7. The IU PRESSURE display should register 33 mmHg (± 2 mmHg).
   - Conversion formula:
     \[ 44 \text{ cm } H_2O \times 0.74 = \text{approximately } 33 \text{ mmHg} \]
8. Change the water column height. The value of the IU PRESSURE display should change accordingly.
   - When the values of the IU PRESSURE display correspond to those of the water column, the pressure measurement test is successful.

**Figure 17.** Pressure measurement test setup

**Figure 18.** Pressure transducer positions

1. Microswitch
2. Upper pressure transducer
3. Lower pressure transducer

1. Remove the pressure chamber from the pump head.
2. Press and hold the microswitch at the pump head.
3. With the other hand, press the Start/Stop button.
4. Press the upper pressure transducer with a finger while still depressing the microswitch.
5. After nearly 5 seconds, “E01” flashes in the IU PRESSURE display and a continuous signal sounds.
6. Remove fingers from the pressure transducer and the microswitch.
7. Press the On/Off button to turn the irrigation pump control unit off; then press the On/Off button again to turn the control unit back on.
8. Repeat the test with the lower pressure transducer. The pressure transducer tests are complete.

**Fluid Monitor Unit Test**

1. Remove any loads from the scale system.
2. Select PO4 in the user menu.
3. FLUID DEFICIT display illuminates in whole numbers (0) and MAX FLOW display illuminates in whole numbers and decimals (0.00).
4. Place a defined weight (between 2.2 lbs [1 kg] and 11 lbs [5 kg]) either on a fluid bag hook or collection system canister holder.
5. The FLUID DEFICIT display should reflect the weight placed on the fluid bag hook or canister holder.
   **CAUTION:** The display must reflect the weight within ±0.022 lbs (0.01 kg). If not, the scale system must be returned to an authorized Smith & Nephew service center for calibration.
6. Exit the user menu.
7. Remove the weight.
   Once all values have been verified, the basic function test is successful.

**Stand System Disassembly**

To return the fluid monitor stand system, carefully follow these steps to disassemble and package the assembly for shipment to Smith & Nephew.

**Note:** Refer to the System Components and Preoperative Setup sections of this manual for component identification and additional information.

1. Disconnect all power to the control unit.
2. Disconnect all tubing and accessories from the control unit.
3. Disconnect the communication cable from the control unit.
4. Remove the control unit from the carrier plate.
5. Remove all collection system canisters and canister holders.
6. Loosen the clamp on the vacuum regulator and remove the vacuum regulator from the stand system.
7. Lay the stand system face-down on the floor.
8. Use the large, 8 mm (5/16”) Allen wrench to remove the large Allen screw and washer from the bottom of the roller base.
   **Note:** The wrench is stored on the underside of the carrier plate.
9. Use the small, 4 mm (5/32”) Allen wrench (T-handle type is best/not supplied) to remove the four set screws from the black base support pole bushing.
   **Note:** The wrench is stored on the underside of the carrier plate.
10. Pull the pole out of the roller base, leaving the bushing in the base.
   **CAUTION:** Moving the scale system back and forth damages the weighing unit, causing inaccurate deficit readings.
11. Tap the bottom of the bushing to release it from the roller base. A rubber mallet is recommended.
   **CAUTION:** Do not damage the bushing.
12. Reattach the bushing to the support pole. Ensure that the four set screws fit exactly into the indentations on the support pole. Hand-tighten the screws for a secure fit.
13. Use the small, 4 mm (5/32”) Allen wrench to remove the carrier plate.
14. Place the stand system securely into the shipping box provided by the manufacturer. Ensure that the fluid monitor unit is rotated counterclockwise 180° to prevent severing the data cables, and that both the fluid monitor unit and the fluid bag deflector are secured using the supplied packaging foam.
   **Note:** The system’s shipping boxes should be kept in good condition with all materials needed to secure the scale system and the fluid monitor control unit inside. In any case where the boxes are misplaced or damaged, contact the manufacturer to arrange for boxes to be shipped. Do not use bubble wrap or any other method to ship this system.
   **Note:** Retain the roller base, carrier plate, collection system canisters, and canister holders. They are needed for the installation of the replacement scale system.
## Troubleshooting

<table>
<thead>
<tr>
<th>Signal</th>
<th>Error and Cause</th>
<th>Solution/Device Response</th>
</tr>
</thead>
</table>
| • Audible signal (three short beeps) | Pressure chamber of irrigation inflow tube set not properly positioned. | • Check position of pressure chamber.  
• A click indicates the correct fit of tube set pressure chamber. |
| • Audible signal for duration of exceeding pressure parameter  
• IU PRESSURE display flashes | Set pressure has been exceeded.  
IU pressure has exceeded permissible tolerance value of 20 mmHg for longer than 5 seconds. | • Electronic control system of pump control unit automatically reduces pressure by reversing pump motor. The duration of the roller wheel reverse rotation (clockwise) is limited to nine seconds.  
Then the error code E01 is displayed. |
| • IU PRESSURE display flashes for duration that IU pressure is below set pressure | Set pressure has not been reached.  
IU pressure has not reached the permissible tolerance value of 20 mmHg for longer than 5 seconds. | • Electronic control system of pump control unit automatically increases pressure by activating the pump motor. |
| • Audible signal for duration of exceeding pressure parameter  
• IU PRESSURE display flashes  
• Overpressure indicator illuminated | Overpressure alarm, 200 mmHg. IU pressure was equal to or exceeded 200 mmHg for longer than 5 seconds. | • Electronic control system of pump control unit automatically turns off pump motor and turns it back on once value falls below 200 mmHg. |
| • Audible signal (three short beeps)  
• Deficit value flashes | Deficit threshold set by the operator has been reached. | • None |
| • Audible signal (three short beeps)  
• Deficit value flashes | 100 ml alarm above the deficit threshold, additional increase of the deficit after exceeding the deficit threshold every 100 ml. | • None |
| • Audible signal (three short beeps)  
• Deficit value flashes  
• Deficit rate indicator illuminated | Fluid deficit alarm.  
The fluid deficit is equal to or larger than 300 ml/min. | • None |
| • Audible signal (two long beeps)  
• SCALE flashes in IU PRESSURE display for five seconds | Scale overloaded, the usable load limit value of 42 kg was exceeded for 30 seconds. | • Unload the scale. The overload counter is set in the unit. |
### Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Error and Warning Messages</th>
<th>Error and Cause</th>
<th>Solution/Device Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>E01:</strong></td>
<td>Service indicator illuminated. Pressure measuring failure or malfunction.</td>
<td>Remove inflow tube set and unplug unit from power source for 5 minutes. Plug unit back into power source. If error E01 occurs again, contact Smith &amp; Nephew for service replacement unit.</td>
</tr>
<tr>
<td>• Continuous warning signal</td>
<td>Pressure transducer defective.</td>
<td></td>
</tr>
<tr>
<td>• E01 flashes in IU PRESSURE display</td>
<td>Roller wheel reversal time limit of nine seconds has been exceeded.</td>
<td></td>
</tr>
<tr>
<td><strong>E02:</strong></td>
<td>Service indicator illuminated. Breakdown of the scale or fluid monitor unit.</td>
<td>Contact Smith &amp; Nephew for service replacement unit. Refer to the Troubleshooting Flow Diagram.</td>
</tr>
<tr>
<td>• Continuous audible signal</td>
<td>Data cable or scale defective.</td>
<td></td>
</tr>
<tr>
<td>• E02 flashes in IU PRESSURE display</td>
<td>Data cable may be disconnected or loose.</td>
<td>Attach or tighten data cable.</td>
</tr>
<tr>
<td><strong>E50:</strong></td>
<td>Service indicator illuminated. Communication error.</td>
<td>Contact Smith &amp; Nephew for service replacement unit. Refer to the Troubleshooting Flow Diagram.</td>
</tr>
<tr>
<td>• Audible signal (one short beep)</td>
<td>Malfunctioning communication between modules.</td>
<td></td>
</tr>
<tr>
<td>• E50 flashes in IU PRESSURE display</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E51:</strong></td>
<td>Service indicator illuminated. Communication errors.</td>
<td>Contact Smith &amp; Nephew for service replacement unit. Refer to the Troubleshooting Flow Diagram.</td>
</tr>
<tr>
<td>• Audible signal (two short beeps)</td>
<td>Electronics failure or malfunction.</td>
<td></td>
</tr>
<tr>
<td>• E51 flashes in IU PRESSURE display</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E58:</strong></td>
<td>Keyboard error.</td>
<td>Contact Smith &amp; Nephew for service replacement unit. Refer to the Troubleshooting Flow Diagram.</td>
</tr>
<tr>
<td>• Service indicator illuminated</td>
<td>Defective button.</td>
<td></td>
</tr>
<tr>
<td>• Audible signal (nine short beeps)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• E58 flashes in IU PRESSURE display</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E59:</strong></td>
<td>Audible signal (10 short beeps)</td>
<td>New calibration required. Turn the control unit off and then back on.</td>
</tr>
<tr>
<td>• E59 flashes in IU PRESSURE display</td>
<td>Initial calibration interrupted by external factors.</td>
<td></td>
</tr>
<tr>
<td>• Safe status, only the On/Off button is active</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IE:</strong></td>
<td>IE is depicted in the IU PRESSURE display.</td>
<td></td>
</tr>
<tr>
<td>• Audible signal (five short beeps)</td>
<td>Hysteroscope is not held at proper height.</td>
<td>Check that the instrument is held at patient height and repeat the instrument detection process. If “IE” persists, lower the height of the instrument.</td>
</tr>
<tr>
<td>• Control unit switches to STOP mode</td>
<td>Hysteroscope inflow channel is too small.</td>
<td>Use an appropriately sized hysteroscope (5 mm or larger).</td>
</tr>
<tr>
<td></td>
<td>Hysteroscope inflow stopcock not fully opened.</td>
<td>Ensure inflow stopcock is fully opened.</td>
</tr>
<tr>
<td></td>
<td>Inflow tube set is restricted.</td>
<td>Check inflow tube set for restriction.</td>
</tr>
<tr>
<td></td>
<td>Hysteroscope inflow channel is damaged.</td>
<td>Contact hysteroscope manufacturer for repair or replacement.</td>
</tr>
</tbody>
</table>
Troubleshooting Flow Diagram

Although the control unit and the stand system are supplied together, they may be replaced separately. The following flow diagram describes a possible troubleshooting scenario but does not cover all possible situations. If there is an issue which is not described, or if additional information is required, contact Smith & Nephew Customer Service for assistance.

Start

System fails to initialize – service indicator illuminated

Obtain RA for Service Exchange

Receive replacement control unit and monitor system

Replace control unit

Functionality restored?

Yes

Return defective control unit and unopened monitor system → End

No

Replace monitor system

Functionality restored?

Yes

Replace original control unit → End

No

Check all cabling – replace as necessary

Functionality restored?

Yes

Return defective monitor system and replacement control unit → End

No

End
Technical Specifications

Power Supply: 100–240 V~
Frequency: 50/60 Hz
Maximum Power Consumption: 57 VA
Maximum Current: 680 mA, 100 V
340 mA, 240 V
Protection Class: I
Protection Level: BF
Protection for Humidity: IP41 (Pump control unit)
Protection for Humidity: IP21 (Fluid monitor unit)
Fuses (two required): T3, 15 A, UL-recognized
Ground: Equipotential equalization terminal
Alternating Voltages: 110 V
50/60 Hz
Dimensions: width x height x depth
Pump Control Unit: 13.0” x 6.1” x 15.4”
(330 x 155 x 390 mm)
Fluid Monitor Unit: 28.0” x 55.1” x 31.9”
(710 x 1400 x 810 mm)
Weight:
Pump Control Unit: 15.4 lbs (7 kg)
Fluid Monitor Unit: 57.2 lbs (26 kg)
Maximum System Weight with all Components and Canisters:
154 lbs (70 kg)
Scale System Load Range: 0–92.4 lbs (0–42 kg)
Accuracy of the FLUID DEFICIT Display: ± 10 ml,
± 3% of the output
Pressure Range: 15–120 mmHg
Accuracy of Pressure Measurement: ± 1.5% of final value
Overpressure Safety: Motor deactivates at 200 mmHg
Flow Rate Range: 30–700 ml/min
Accuracy of Flow Rate: ± 3% of max value

Ordering Information

Hysteroscopic Fluid Management System Accessories

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
<th>REF</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7209822</td>
<td>Inflow Tube Set</td>
<td>8005600</td>
<td>U.S. Power Cord</td>
</tr>
<tr>
<td>7209823</td>
<td>Outflow Tube Set</td>
<td>8013378</td>
<td>U.K. Power Cord</td>
</tr>
<tr>
<td>7209825</td>
<td>Inflow/Outflow Tube Set</td>
<td>8013380</td>
<td>International Power Cord</td>
</tr>
<tr>
<td>72200094</td>
<td>Vacuum Regulator</td>
<td>72200024</td>
<td>Bemis Collection System Canisters</td>
</tr>
</tbody>
</table>
Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The Smith & Nephew Hysteroscopic Fluid Management System is intended for use in the electromagnetic environment specified below. The customer or the user of the Smith & Nephew Hysteroscopic Fluid Management System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Hysteroscopic Fluid Management System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The Hysteroscopic Fluid Management System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
The Smith & Nephew Hysteroscopic Fluid Management System is intended for use in the electromagnetic environment specified below. The customer or the user of the Hysteroscopic Fluid Management System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<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)</td>
<td>IEC 6000-4-2</td>
<td>+/- 6kV contact</td>
<td>+/- 6kV contact</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- 8kV air</td>
<td>+/- 8kV air</td>
</tr>
<tr>
<td></td>
<td></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>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>IEC 6000-4-4</td>
<td>+/- 2kV for power supply lines</td>
<td>+/- 2kV for power supply lines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- 1kV for input/output lines</td>
<td>+/- 1kV for input/output lines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>IEC 6000-4-5</td>
<td>+/- 1kV differential mode</td>
<td>+/- 1kV differential mode</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- 2kV common mode</td>
<td>+/- 2kV common mode</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>IEC 6000-4-11</td>
<td>&lt;5% $U_T$ (&lt;95% dip in $U_T$) for 0.5 cycle</td>
<td>&lt;5% $U_T$ (&lt;95% dip in $U_T$) for 0.5 cycle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40% $U_T$ (&lt;60% dip in $U_T$) for 5 cycles</td>
<td>40% $U_T$ (&lt;60% dip in $U_T$) for 5 cycles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70% $U_T$ (&lt;30% dip in $U_T$) for 25 cycles</td>
<td>70% $U_T$ (&lt;30% dip in $U_T$) for 25 cycles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;5% $U_T$ (&lt;95% dip in $U_T$) for 5 sec</td>
<td>&lt;5% $U_T$ (&lt;95% dip in $U_T$) for 5 sec</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hysteroscopic Fluid Management System requires continued operation during power mains interruptions, it is recommended that the Hysteroscopic Fluid Management System be powered from an uninterruptible power supply or a battery.</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>IEC 6000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
</tr>
<tr>
<td></td>
<td></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>
</tr>
</tbody>
</table>

**Note:** $U_T$ is the a.c. mains voltage prior to application of the test level.
Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Smith & Nephew Hysteroscopic Fluid Management System is intended for use in the electromagnetic environment specified below. The customer or the user of the Hysteroscopic Fluid Management System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Hysteroscopic Fluid Management System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 KHz to 80 MHz</td>
<td></td>
<td><strong>Recommended separation distance</strong></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td></td>
<td>d = 1.2√p</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 1.2√p</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800 MHz to 2.5 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2.3√p</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>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).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

**Note 1:** At 80 MHz and 800 MHz, 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.

*Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts 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 Hysteroscopic Fluid Management System is used exceeds the applicable RF compliance level above, the Hysteroscopic Fluid Management System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Hysteroscopic Fluid Management System.*

*Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*
## Guidance for Separation Distances

### Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Smith & Nephew Hysteroscopic Fluid Management System

The Hysteroscopic Fluid Management System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Hysteroscopic Fluid Management System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hysteroscopic Fluid Management System as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 KHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = 1.2\sqrt{p})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Aseptic
Refer to Sterile.

Contamination
Pollution of rooms, water, foods, objects, or persons due to micro-organisms or radioactive materials, biological poisons, or chemical agents.

Contraindication
Circumstances (e.g., age, pregnancy, certain illness, medication) prohibiting the use of an otherwise indicated measure.

Deficit/Deficit Amount
The total volume of fluid that is lost during a procedure.

Embolism
Sudden blood vessel closure due to an embolus (a loose clot or air bubble or other particle).

Endoscope
A narrow, telescope-like medical instrument used to examine the interior of a bodily organ or to perform minor surgery.

Flow Rate
Amount (expressed in ml) of irrigation fluid flowing through the tube set per minute.

Fluid Monitoring
Measurement and calculation of fluid volume.

Hyponatremia
A low concentration (<130 mmol/l) of sodium in the blood.

Hysteroscope
An endoscope used for direct visual examination of the uterine cavity.

Hysteroscopy
A procedure that involves inserting a hysteroscope through the vagina and cervix into the uterine cavity. The cavity is then distended with fluid (i.e., saline solution).

Inflow
Irrigation fluid that flows from bags hung on the Hysteroscopic Fluid Management System stand through the irrigation pump and into the operative hysteroscope.

Irrigation Fluid
Refer to Inflow.

Intrauterine (IU) Pressure
Pressure in uterine cavity.

Intravasation
Entry of foreign matter into a blood vessel.

Outflow
Fluids (secretion volume) from the patient drape, TRUCLEAR™ Handpiece, and hysteroscope that flow or are suctioned into the collection system canisters. The total volume of outflow is continuously weighed by the scale system.

SAL
Sterility assurance level. Measurement unit for sterility. The SAL of a product is defined as the probability of any given unit being non-sterile after exposure to a validated process.

Saline/Saline Solution
An isotonic solution of sodium chloride and distilled water.

Sterile
Free of or using methods to keep free of pathological microorganisms, e.g., “a sterile operating area;” “aseptic surgical instruments;” “aseptic surgical techniques.” [syn: aseptic].

Sterility
The state of being free of pathogenic organisms [syn: asepsis, antisepsis, sterileness].

Uterine Cavity
The space inside the uterus between the cervical canal and the Fallopian tubes.

Uterus
A muscular, hollow, pear-shaped structure, partly covered by peritoneum; the uterine cavity is lined by a mucous membrane (the endometrium).
Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Units Warranty

The Smith & Nephew Hysteroscopic Fluid Management System replacement units are warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Smith & Nephew offers a 24-hour Service Replacement Program for its products to minimize downtime in the operating room. Our goal is to ship a service replacement unit within 24 hours** of the call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service at +1 800 343 5717 in the U.S., or contact an authorized representative.

** 24-hour shipment is not offered in all countries.

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully disinfected, repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or an authorized representative can provide shipping information.

*Trademark of Smith & Nephew.
Covered by U.S. patent numbers 7,226,459, 7,249,602, and 7,510,563. Other patents pending.