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1. DEVICE DESCRIPTION

This manual provides instructions for operating the AngioJet® Ultra Thrombectomy System, with specific focus on the AngioJet Ultra Console.

The AngioJet Ultra System consists of the following components:

A. The AngioJet Ultra Console (Console)

The Console is a multiple-use device that controls the Thrombectomy Set. It drives the pump, regulates fluid inflow and outflow, provides the operator with Ultra System set-up prompts, total infused saline volume, and Ultra System malfunction warnings. The Console is activated by pressing a foot pedal.

B. The AngioJet Ultra Thrombectomy Set

(Thrombectomy Set - Several models available)

The single-use, disposable Thrombectomy Set includes:

- Pump
- Catheter
- Saline delivery and waste tubing
- Collection bag

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.
A bag of sterile, heparinized saline (not included) supplies the pump with saline through the saline delivery tubing. The pump pressurizes the saline. The Thrombectomy Set uses this pressurized, high-velocity saline to create a low-pressure zone at the catheter tip. This allows the catheter to break up and remove thrombus. The waste tubing transports the thrombus debris from the catheter to the collection bag for ultimate disposal.

2. INDICATIONS AND USAGE

The Console is intended for use only in conjunction with an AngioJet Ultra Thrombectomy Set. Refer to the individual Thrombectomy Set Information for Use manual for specific clinical applications.

3. CONTRAINDICATIONS

Refer to the individual Thrombectomy Set Information for Use manual for specific contraindications.

4. WARNINGS AND PRECAUTIONS

- The AngioJet Ultra System should be used only by operators who have received appropriate training on its installation and use.
- Use the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter.
- Do not attempt to bypass any of the Console safety features.
- If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient.
- Physician discretion with regard to the use of heparin is advised.
- Refer to the individual AngioJet Ultra Thrombectomy Set Information for Use manual for specific warnings and precautions.
- Do not move the collection bag during catheter operation as this may cause a collection bag error.
- Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked.
- Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen.
- Refer to individual Thrombectomy Set Instructions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set.
• The Console contains no user-serviceable parts. Refer service to qualified personnel.
• Removal of outer covers may result in electrical shock.
• This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating.
• Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

5. ADVERSE EVENTS

Refer to the individual Thrombectomy Set Information for Use manual for specific observed and/or potential adverse events.
### 6. CONSOLE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model number</td>
<td>5000A</td>
</tr>
<tr>
<td>Dimensions</td>
<td>25” x 16.5” x 54” (63.5 x 42 x 137 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>135 lbs (57 kg)</td>
</tr>
<tr>
<td>Voltage requirements</td>
<td>100/120/220/240 ~</td>
</tr>
<tr>
<td>Frequency requirements</td>
<td>50/60 Hz</td>
</tr>
<tr>
<td>Power requirements</td>
<td>900VA</td>
</tr>
<tr>
<td>Logic power backup outage</td>
<td>60 seconds for conditions of power loss</td>
</tr>
<tr>
<td>Equipment class</td>
<td>Class 1</td>
</tr>
<tr>
<td>Degree of protection against electrical shock</td>
<td>Defibrillator proof type CF equipment</td>
</tr>
<tr>
<td>Enclosure protection against ingress of liquid</td>
<td>IPX1</td>
</tr>
<tr>
<td>Foot pedal protection against ingress of liquid</td>
<td>IPX8</td>
</tr>
<tr>
<td>Mode of (electrical) operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Transport &amp; storage temperature</td>
<td>– 25°C to 57°C</td>
</tr>
<tr>
<td>Transport &amp; storage humidity</td>
<td>10% to 100%</td>
</tr>
<tr>
<td>Transport &amp; storage atmospheric pressure</td>
<td>500hPa to 1060hPa</td>
</tr>
<tr>
<td>Operation temperature</td>
<td>10°C to 40°C</td>
</tr>
<tr>
<td>Operation humidity</td>
<td>30% to 75%</td>
</tr>
<tr>
<td>Operation atmospheric pressure</td>
<td>700hPa to 1060hPa</td>
</tr>
<tr>
<td>Fuse</td>
<td>100/120V, 10A, 250V, 5X20 mm Time lag</td>
</tr>
<tr>
<td></td>
<td>220/240V, 6.3A, 250V, 5X20 mm Time lag</td>
</tr>
</tbody>
</table>

**NOTE:** Replace fuse with the type and rating specified. Failure to do so may result in device damage or risk of fire.

The AngioJet Ultra Console is compliant with EN60601-1, UL60601-1, and CAN/CSA-C22.2 No. 601-1-M90.
A thorough understanding of the Ultra System components is required for proper operation. Read this manual and the Information for Use supplied with the Thrombectomy Set before attempting to use any of the components of the Ultra System.

Improper Ultra System preparation or abnormal component operation will result in error messages. Please refer to Section 7.5 - Alarms and Error Messages of this manual for instructions on what to do if error messages are displayed.

**Time Display:** During catheter priming, the time display counts down to zero. During the procedure, the time display counts up from zero.

**Icons:** Display the progress of set-up and operation steps and also indicate when an alarm or Ultra System error has occurred.

- **Please Wait.**
- **Install Pump.**
- **Connect Saline.**
- **Prime Catheter.**
- **Ultra System Ready.**
- **Contact MEDRAD Technical Support.**
Status Panel: Provides instructions, procedure status, and alarm resolution strategies.

Power Button: Press to activate the control panel.

Alarm Reset Button: Press to clear or override an alarm.

Catheter Button: Displays catheter model installed in the AngioJet Ultra Console. Press this button to see a 3-second display of catheter model.

Scroll Buttons: These buttons are active only when there is more text to be displayed than can fit on the status panel screen. Press the DOWN button to advance one screen forward; press the UP button to return to the previous screen.

Counter Reset Button: Press this button to return the time display and infused volume to zero.

NOTE: You cannot use the COUNTER RESET Button to override the time needed for priming the catheter.

7.1 Prepare Console

NOTE: The Ultra System is designed to be interactive. The status panel will provide prompts to guide the technician through set-up as well as provide error resolution when necessary.

Preparation of the Ultra System requires the assistance of a sterile and a nonsterile technician. The catheter is used within the defined sterile field, the Console and pump are operated outside the sterile field. The following directions are for the nonsterile technician except where otherwise noted.

1. Plug in the Console and ensure the main power circuit breaker switch is turned ON (Figure 4).

2. Heparinize a bag of sterile, room-temperature saline at a suggested rate of 5000 units per liter of saline and mix contents (a 1.0 liter bag is recommended, but is not included with the Ultra System). Hang the saline bag on the saline bag hook at the top of the Console.

3. Press the POWER button on the control panel.
All indicators on the control panel will illuminate. The status panel will display ANGIOJET ULTRA while the Console performs a self-test.

The drawer will open, indicating a successful self-test. The status panel will display the next step (Figure 5).

7.2 Load Pump

1 Sterile technician: Remove the catheter and sufficient tubing for ease of use from the sterile package and inspect for damage. Hand the tray with the rest of the Thrombectomy Set to the nonsterile technician for installation into the Console (Figure 6).

NOTE: If a clamp is used to keep the catheter in the sterile field, ensure that the clamp does not deform the tubing.

2 Nonsterile technician: Remove the pump (not the piston head) from the tray and insert the pump into the Console. Ensure that the waste tubing aligns with the roller pump (Figure 7).

3 Remove the cap from the Thrombectomy Set bag spike and insert the spike into the saline bag.

4 Push the drawer button to close the Console drawer (Figure 8).
The Console will load the pump and process information from a bar code located on the pump. After the Console successfully identifies the catheter, the status panel will display the model of catheter in use (Figure 9).

The Console will automatically prime the pump.

5 Place the foot pedal within easy access of the physician. Choose a location that will minimize accidental activation.

7.3 Prime the Catheter

The status panel displays PRIME indicating that the initial pump prime was successful (Figure 10).

Catheter priming time is determined by the catheter model and is automatically set by the Console.

1 Prime the catheter by completely submerging the tip in heparinized saline and pressing the foot pedal (Figures 11 & 12).
2  Continue priming until the time display reaches zero seconds.

The status panel displays PRIME COMPLETE (Figure 13).

3  Confirm Ultra System set-up is successfully completed by removing foot from foot pedal.

Status panel displays READY and green icon is illuminated (Figure 14).

**The AngioJet Ultra System is now ready to use.**

During operation, the infused volume will be displayed on the status panel, the green icon remains lit, and the time display will keep track of the total time that the foot pedal is activated.

**CAUTION:** Do not move the collection bag during catheter operation as this may cause a collection bag error.
7.4 Ultra System Dismantling

Follow proper precautions for the handling of infectious waste. Reuse of Thrombectomy Set is prohibited due to risk of contamination by blood waste products.

After use, disassemble the components as follows:

1. Push the drawer button to open the drawer.

2. Carefully remove Thrombectomy Set from Console.

3. Unhook the saline supply and collection bag and dispose together with the Thrombectomy Set.

4. Press POWER button to deactivate control panel. Pump drawer will automatically retract when powering down.

5. Unplug the power cord from the wall outlet and coil the cord on the hooks in the power cord and foot pedal recess. Place the foot pedal into the storage bracket at the bottom of the recess.

6. Clean the Console surfaces thoroughly with a standard, mild germicidal cleaning agent. Do not clean with harsh detergent or chemical agents.

NOTE: Check bar code window for saline build-up, clean with long cotton-tipped swab and water, if necessary (Figure 15).
7.5 Alarms and Error Messages

Alarms and error messages indicate improper Ultra System preparation or abnormal component operation.

The Console status panel will display alarm resolution messages and prompts (Example shown in Figure 16). In most instances, alarms will either adjust themselves or prompt the user to repeat a step. Follow the prompts displayed on the status panel for alarm resolution.

![Figure 16 - Example of alarm](image1)

The Console allows multiple attempts to correct most alarm conditions. If the alarm persists beyond the third attempt, it is most likely that the Thrombectomy Set has a defect and the Console will prompt the user to replace the Thrombectomy Set (Figure 17).

![Figure 17 - Example](image2)

7.6 Ultra System Errors

A system failure will result in a system error (wrench icon lights red, shown in Figure 18). Turn off the power, then restart before contacting MEDRAD Technical Service for further instructions.

It is helpful to make a note of each system error title and number to report to MEDRAD Technical Service.

![Figure 18 - Example](image3)

7.7 Maintenance

Refer to your Limited Warranty and Disclaimer and/or Certificate of Extended Warranty, if applicable, for information on servicing the AngioJet Ultra Console. MEDRAD recommends annual inspection and calibration. There are no user serviceable parts inside the Console. The Console cabinet panels should only be opened by trained service personnel.
7.8 Glossary

**Alarm:**
A recoverable or nonrecoverable fault occurring when one of the Ultra System safety sensors responds to abnormal operation of a component.

**Waste Tubing:**
The tubing which is inserted in the roller pump and transports the extracted thrombus from the effluent tubing to the collection bag.

**Collection Bag:**
The bag which collects the extracted thrombus being removed by the Catheter. The bag hangs on the Console.

**Control Panel:**
The operator interface on the upper front of the Console.

**Error:**
A nonrecoverable fault which has occurred because of Thrombectomy Set or Console malfunction.

**Saline Delivery Tubing:**
The tubing which transports saline from the saline bag to the pump.

**Load Pump:**
An indicator instructing the operator to install the pump into the Console.

**Over Pressure Alarm:**
A recoverable condition occurring when an abnormally high pressure has been detected. Replacement of the Thrombectomy Set may be necessary.

**Thrombectomy Set:**
The disposable component of the Ultra System which delivers pressurized saline to the catheter and removes debris from the catheter. It consists of the saline bag spike, saline delivery tubing, pump, catheter, waste tubing, and collection bag.

**Self Test:**
An operation performed by the Console to examine the fidelity and the state of its circuit paths and sensors. An appropriate indicator will be illuminated if any abnormality is detected.

**Total Infused Volume:**
The numerical display on the control panel which displays the total volume of saline infused in cc.

**Under Pressure Alarm:**
A recoverable condition occurring when an abnormally low pressure has been detected.
### 7.9 Symbols

<table>
<thead>
<tr>
<th>No.</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>![on_symbol]</td>
<td>ON (power: connection to mains)</td>
</tr>
<tr>
<td>2</td>
<td>![off_symbol]</td>
<td>OFF (power: disconnection to mains)</td>
</tr>
<tr>
<td>3</td>
<td>![standby_symbol]</td>
<td>Standby</td>
</tr>
<tr>
<td>4</td>
<td>![eject_symbol]</td>
<td>Eject (Open/close drawer)</td>
</tr>
<tr>
<td>5</td>
<td>![information_symbol]</td>
<td>Consult Instructions For Use</td>
</tr>
<tr>
<td>6</td>
<td>![warning_symbol]</td>
<td>See Warnings and Precautions</td>
</tr>
<tr>
<td>7</td>
<td>![heart_symbol]</td>
<td>Defibrillator proof type CF equipment</td>
</tr>
<tr>
<td>8</td>
<td>![ipx1_symbol]</td>
<td>IPX 1 Protection against dripping water</td>
</tr>
<tr>
<td>9</td>
<td>![ipx8_symbol]</td>
<td>IPX 8 Protection against the effects of permanent immersion in water</td>
</tr>
<tr>
<td>10</td>
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<td>Alternating current</td>
</tr>
<tr>
<td>11</td>
<td>![equipotentiality_symbol]</td>
<td>Equipotentiality</td>
</tr>
<tr>
<td>12</td>
<td>![fuse_symbol]</td>
<td>Fuse</td>
</tr>
<tr>
<td>13</td>
<td>![foot_pedal_symbol]</td>
<td>Foot Pedal</td>
</tr>
<tr>
<td>14</td>
<td>![disposal_symbol]</td>
<td>Electrical and electronic equipment should not be disposed of in the normal waste stream</td>
</tr>
</tbody>
</table>

### 8. HOW SUPPLIED

**NON-STERILE, MULTIPLE USE**

**CONTENTS:**
- One (1) Console
- One (1) Console *Operations Manual*
- One (1) Foot pedal with cord
- One (1) Power cord