AngioJet™ Ultra 5000A Console
Thrombectomy System Console

Operator's Manual ...........................................3
TABLE OF CONTENTS

DEVICE DESCRIPTION................................................................. 4
  Contents.............................................................................. 4
  AngioJet™ Ultra 5000A Console (Console or AngioJet Ultra Console)............ 4
  Figure 1. AngioJet Ultra Console......................................... 4
  AngioJet Thrombectomy Set (Thrombectomy Set)........................ 5
  Figure 2. Thrombectomy Set............................................. 5

INTENDED USE/INDICATIONS FOR USE................................. 5

CONTRAINDICATIONS............................................................... 5

WARNINGS............................................................................. 5

PRECAUTIONS....................................................................... 5

Disposal............................................................................... 5

POTENTIAL ADVERSE EFFECTS............................................. 5

HOW SUPPLIED..................................................................... 5

HANDLING AND STORAGE...................................................... 5

  Operating Environment.................................................... 5
  Transport Environment.................................................... 5
  Storage Environment...................................................... 5

USING THE ANGIOJET ULTRA CONSOLE............................ 6

  Clinician Use Information................................................ 6
  Prepare Console................................................................ 6
    Figure 3........................................................................ 6
    Figure 4. Reference Only.............................................. 6
  Load Pump........................................................................ 7
    Figure 5........................................................................ 7
    Figure 6........................................................................ 7
    Figure 7........................................................................ 7
    Figure 8........................................................................ 7
    Figure 9. Reference Only.............................................. 8
  Prime the Catheter............................................................ 8
    Figure 10. Reference Only.............................................. 8
    Figure 11...................................................................... 8
    Figure 12...................................................................... 8
    Figure 13. Reference Only.............................................. 8
    Figure 14. Reference Only.............................................. 8
  AngioJet System Dismantling............................................. 9
    Figure 15...................................................................... 9
    Figure 16...................................................................... 9

ANGIOJET ULTRA CONSOLE SYMBOL TRANSLATION KEY........ 9

MAINTENANCE, TROUBLESHOOTING AND SERVICE............... 10

  Alarms and Error Messages.............................................. 10
    Figure 17. Example..................................................... 10
    Figure 18. Example..................................................... 10
  Console Errors.................................................................. 10
    Figure 19. Example..................................................... 10

GLOSSARY OF TERMS............................................................ 10

SPECIFICATIONS.................................................................. 11

ELECTRONIC AND ELECTROMAGNETIC GUIDANCE.................. 11

  Table 1. Guidance and manufacturer’s declaration — electromagnetic emissions 11
  Table 2. Guidance and manufacturer’s declaration — electromagnetic immunity... 12

WARRANTY................................................................. 13
AngioJet™
Ultra 5000A Console
Thrombectomy System Console

Rx ONLY

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

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

DEVICE DESCRIPTION

The AngioJet Thrombectomy System allows for percutaneous removal of thrombus located in peripheral arteries and veins, saphenous vein bypass grafts, native coronary arteries, and native or synthetic AV access conduits. Thrombectomy is accomplished using high-pressure saline jets contained in the catheter shaft. The saline jets create a low-pressure effect to draw thrombus into the catheter, fragment the thrombus, and remove the thrombus from the treatment site. The system consists of a single use Thrombectomy Set (several models available) and a free standing mobile Console.

Contents

One (1) Console
One (1) Operator’s Manual
One (1) Foot switch with cord
One (1) Power cord

AngioJet Ultra 5000A Console (Console or AngioJet Ultra 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 AngioJet System set-up prompts, total infused saline volume, and AngioJet System malfunction information. The Console is activated by pressing a foot switch.

Figure 1. AngioJet Ultra Console
AngioJet™ Thrombectomy Set (Thrombectomy Set)

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.

Figure 2. Thrombectomy Set

INTENDED USE/INDICATIONS FOR USE

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

CONTRAINDICATIONS

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

WARNINGS

- The Console contains no user-serviceable parts. Refer service to qualified personnel.
- Removal of outer covers may result in electrical shock.

- The Console 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 Thrombectomy Set.
- The AngioJet System requires special precautions regarding electromagnetic emissions and immunity and needs to be installed and put into service according to the information included in the Electronic and Electromagnetic Guidance Section.
- This device may cause electromagnetic interference with other devices when in use. Do not place the AngioJet System near sensitive equipment when operating.
- Console bag hooks are intended for physician specified fluid and/or saline bags only. Hanging other objects or applying additional weight to the bag hooks may cause damage.
- When drawer is extended from Console, avoid knocking or leaning on the drawer. This may damage the device.
- Do not move the collection bag during catheter operation as this may cause a waste tubing error.
- Do not reposition or push the Console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.
- In the event the foot switch is stuck in the “on” position (inadvertent activation), press the POWER button or pull the power cord from the wall outlet to deactivate the system. Contact Boston Scientific Customer Service.

Disposal

The user should follow local and national regulations for disposal of electronics when disposing of this unit. Contact Boston Scientific Customer Service for product returns.

POTENTIAL ADVERSE EFFECTS

Refer to the individual Thrombectomy Set Directions for Use manual for specific observed and/or potential adverse events.

HOW SUPPLIED

This product is supplied non-sterile and is intended for multiple use.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

Operating Environment

Temperature: 10 °C to 40 °C (50 °F to 104 °F)
Relative Humidity: 30% to 75% (noncondensing)
Atmospheric Pressure: 700 hPa to 1060 hPa

Transport Environment

Temperature: -25 °C to 55 °C (-13 °F to 131 °F)
Relative Humidity: 10% to 95% (noncondensing)
Atmospheric Pressure: 500 hPa to 1060 hPa

Storage Environment

Temperature: -25 °C to 55 °C (-13 °F to 131 °F)
Relative Humidity: 10% to 95% (noncondensing)
Atmospheric Pressure: 500 hPa to 1060 hPa

Electronic and Electromagnetic Emissions and Immunity

This product is supplied non-sterile and is intended for multiple use.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.
**USING THE ANGIOJET™ ULTRA CONSOLE**

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

**Icons**
- **Action Required**
- **Prime Catheter**
- **Install Pump**
- **System Ready**
- **Connect Saline**
- **Contact Boston Scientific Customer Service**

**Status Panel**
- Provides instructions, procedure status, and alarm resolution strategies.

**Power Button**
- Press to activate or deactivate the control panel.

**Alarm Reset Button**
- Press to continue operation after following on-screen troubleshooting steps.

**Catheter Button**
- Displays catheter model installed in the Console. Press this button to see a 3-second display of catheter model. Additional functions allowed based on catheter model (refer to individual Thrombectomy Set Directions for Use).

**Scroll Buttons**
- These buttons are active only for selection or when there is more text to be displayed.

**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.

---

**Clinician Use Information**

A thorough understanding of the AngioJet System components is required for proper operation. Read this manual and the Directions for Use supplied with the Thrombectomy Set before attempting to use any of the components of the AngioJet System.

Improper AngioJet System preparation or abnormal component operation will halt Console operation and troubleshooting steps or error messages may occur. If operation halts, refer to Alarms and Error Messages in the Maintenance, Troubleshooting and Service Section.

**Prepare Console**

**Note:** The AngioJet System is designed to be interactive. The status panel will provide prompts to guide the technician through set-up as well as provide troubleshooting steps when necessary.

Preparation of the AngioJet 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 3).**

**Figure 3.**

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 AngioJet System). Hang the saline bag on the bag hook at the top of the Console.**

**Precaution:** Console bag hooks are intended for physician specified fluid and/or saline bags only. Hanging other objects or applying additional weight to the bag hooks may cause damage.

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 steps (Figure 4).

**Figure 4.** Reference Only
Precaution: When drawer is extended from Console, avoid knocking or leaning on the drawer. This may damage the device.

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 5).

2. Nonsterile technician: Remove the rest of the Thrombectomy Set from the tray by gripping the pump (not the piston head) and insert the pump into the Console (Figure 6).

3. Ensure that the waste tubing aligns with the roller pump (Figure 7).

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

5. Push the drawer button to close the Console drawer (Figure 8).

The Console will load the pump and scan the 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 pull saline into the pump.

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

Prime the Catheter

The status panel displays PRIME indicating that the initial pump prime was successful. The time display shows the time required to complete the priming sequence (Figure 10).

1. Prime the catheter by completely submerging the tip in heparinized saline and pressing the foot switch (Figures 11 and 12).

2. Continue priming until the time display reaches zero seconds. The status panel displays PRIME COMPLETE (Figure 13).

3. Confirm AngioJet™ System set-up is successfully completed by removing foot from foot switch. The status panel displays READY and green icon is illuminated (Figure 14).
The AngioJet™ 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 switch is activated.

**Note:** Once the foot switch is released, the system will continue to complete the current pump stroke.

**Caution:** Do not move the collection bag during catheter operation as this may cause a waste tubing error.

**Precaution:** In the event the foot switch is stuck in the “on” position (inadvertent activation), press the POWER button or pull the power cord from the wall outlet to deactivate the system. Contact Boston Scientific Customer Service.

**AngioJet 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. Wait for drawer to fully retract, then unplug the power cord from the wall outlet. Coil the foot switch cord around the hook and foot switch bracket (5 turns) and place the foot switch into the bracket. Coil the power cord around the hook and bracket for proper storage (Figure 15).

**Figure 15.**

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 16).

**Figure 16.**

**ANGIOJET ULTRA CONSOLE SYMBOL TRANSLATION KEY**

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow instructions for use</td>
</tr>
<tr>
<td></td>
<td>Contents</td>
</tr>
<tr>
<td>EC</td>
<td>EU Authorized Representative</td>
</tr>
<tr>
<td>REP</td>
<td>Legal Manufacturer</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot</td>
</tr>
<tr>
<td></td>
<td>Recyclable Package</td>
</tr>
<tr>
<td>AUS</td>
<td>Australian Sponsor Address</td>
</tr>
<tr>
<td>ARG</td>
<td>Argentina Local Contact</td>
</tr>
<tr>
<td>BRA</td>
<td>Brazil Local Contact</td>
</tr>
<tr>
<td></td>
<td>Do not use if package is damaged.</td>
</tr>
<tr>
<td></td>
<td>Humidity limitation</td>
</tr>
<tr>
<td></td>
<td>Defibrillation-Proof Type CF Applied Part</td>
</tr>
<tr>
<td></td>
<td>CAUTION</td>
</tr>
<tr>
<td></td>
<td>Attention: Consult ACCOMPANYING DOCUMENTS.</td>
</tr>
<tr>
<td></td>
<td>Separate Collection</td>
</tr>
</tbody>
</table>
### EQUIPMENT SYMBOLS AND TRANSLATION KEY

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Equipotentiality" /></td>
<td>Equipotentiality</td>
</tr>
<tr>
<td><img src="image" alt="Fuse" /></td>
<td>Fuse</td>
</tr>
<tr>
<td><img src="image" alt="Foot Switch" /></td>
<td>Foot Switch</td>
</tr>
<tr>
<td><img src="image" alt="Alternating Current" /></td>
<td>Alternating Current</td>
</tr>
<tr>
<td><img src="image" alt="Temperature limitation" /></td>
<td>Temperature limitation</td>
</tr>
<tr>
<td><img src="image" alt="Date of Manufacture" /></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td><img src="image" alt="Serial Number" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image" alt="Non-Sterile" /></td>
<td>Non-Sterile</td>
</tr>
<tr>
<td><img src="image" alt="ON (power: connection to mains)" /></td>
<td>ON (power: connection to mains)</td>
</tr>
<tr>
<td><img src="image" alt="OFF (power: disconnection to mains)" /></td>
<td>OFF (power: disconnection to mains)</td>
</tr>
<tr>
<td><img src="image" alt="Standby" /></td>
<td>Standby</td>
</tr>
<tr>
<td><img src="image" alt="Eject (open/close drawer)" /></td>
<td>Eject (open/close drawer)</td>
</tr>
<tr>
<td><img src="image" alt="Pushing Prohibited" /></td>
<td>Pushing Prohibited</td>
</tr>
<tr>
<td><img src="image" alt="Non-Ionizing Electromagnetic Radiation" /></td>
<td>Non-Ionizing Electromagnetic Radiation</td>
</tr>
</tbody>
</table>

### MAINTENANCE, TROUBLESHOOTING AND SERVICE

Refer to your Limited Warranty and Disclaimer and/or Certificate of Extended Warranty, if applicable, for information on servicing the AngioJet Ultra Console. Boston Scientific 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.

#### Alarms and Error Messages

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

The Console status panel will display alarm resolution messages and prompts (Example shown in Figure 17). 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 17** Example

The Console allows multiple attempts to correct most alarm conditions. If the alarm persists, the Console may prompt the user to replace the Thrombectomy Set (Figure 18).

**Figure 18** Example

**Console Errors**

A Console failure will result in a system error (wrench icon lights red, shown in Figure 19). Turn off the power, then restart before contacting Boston Scientific Customer Service for further instructions.

Make note of each system error title and number to report to Boston Scientific Customer Service.

**Figure 19** Example

**GLOSSARY OF TERMS**

**Alarm:** A recoverable or nonrecoverable fault occurring when one of the Console safety sensors responds to abnormal operation of a component. Check Catheter Alarm: A recoverable condition occurring when an abnormally high pressure has been detected. Replacement of the Thrombectomy Set may be necessary.
Check Saline Supply Alarm: A recoverable condition occurring when an abnormally low pressure has been detected. Replacement of the Thrombectomy Set may be necessary.

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

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.

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.

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

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

SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Number</td>
<td>5000A</td>
</tr>
<tr>
<td>Dimensions, D x W x H</td>
<td>25 in x 16.5 in x 54 in (63.5 cm x 42 cm x 137 cm)</td>
</tr>
<tr>
<td>Weight</td>
<td>140 lbs (63.5 kg)</td>
</tr>
<tr>
<td>Voltage requirements</td>
<td>100/120/220/240 VAC</td>
</tr>
<tr>
<td>Frequency requirements</td>
<td>50/60 Hz</td>
</tr>
<tr>
<td>Power requirements</td>
<td>900 VA</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>Defibrillation-Proof Type CF Applied Part</td>
</tr>
<tr>
<td>Enclosure protection against ingress of liquid</td>
<td>IPX 1</td>
</tr>
<tr>
<td>Foot switch protection against ingress of liquid</td>
<td>IPX 8</td>
</tr>
<tr>
<td>Mode of (electrical) operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Transport temperature</td>
<td>-25 °C to 55 °C (-13 °F to 131 °F)</td>
</tr>
<tr>
<td>Transport relative humidity</td>
<td>10% to 95% (noncondensing)</td>
</tr>
<tr>
<td>Transport atmospheric pressure</td>
<td>500 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-25 °C to 55 °C (-13 °F to 131 °F)</td>
</tr>
<tr>
<td>Storage relative humidity</td>
<td>10% to 95% (noncondensing)</td>
</tr>
<tr>
<td>Storage atmospheric pressure</td>
<td>500 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Operation temperature</td>
<td>10 °C to 40 °C (50 °F to 104 °F)</td>
</tr>
<tr>
<td>Operation humidity</td>
<td>30% to 75% (noncondensing)</td>
</tr>
<tr>
<td>Operation atmospheric pressure</td>
<td>700 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Pollution</td>
<td>No greater than degree 2</td>
</tr>
<tr>
<td>Installation/Overvoltage</td>
<td>No greater than category 2</td>
</tr>
<tr>
<td>Fuse</td>
<td>100/120V, T10AL, 250V, 5 mm x 20 mm</td>
</tr>
<tr>
<td></td>
<td>220/240V, T6.3AL, 250V, 5 mm x 20 mm</td>
</tr>
<tr>
<td>Cables</td>
<td>AC adapter cable</td>
</tr>
<tr>
<td></td>
<td>Maximum Cord Length 10 ft (3.05 m)</td>
</tr>
<tr>
<td>Foot Switch</td>
<td>Maximum Cord Length 15 ft (4.57 m)</td>
</tr>
</tbody>
</table>


**Note:** If it becomes necessary to replace the fuse, replace fuse with the type and rating specified. Failure to do so may result in device damage or risk of fire.
The AngioJet™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the AngioJet System should assure that it is used in such an environment.

### IEC 60601 Test Levels

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60061 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td>
<td>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>± 2 kV input AC power ± 1 kV SIP/SOP 100 kHz repetition frequency</td>
<td>± 2 kV input AC power ± 1 kV SIP/SOP 100 kHz repetition frequency</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge: Line-to-line</td>
<td>± 0.5 kV, ± 1 kV input AC power</td>
<td>± 0.5 kV, ± 1 kV input AC power</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge: Line-to-ground</td>
<td>± 0.5 kV, ± 1 kV, ± 2 kV input AC power</td>
<td>± 0.5 kV, ± 1 kV, ± 2 kV input AC power</td>
<td></td>
</tr>
<tr>
<td>Voltage dips</td>
<td>0% U, for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>0% U, for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>0% U, for 1 cycle and 70% U, for 25/30 cycles Single phase: at 0°</td>
<td>0% U, for 1 cycle and 70% U, for 25 cycles (50 Hz) and 30 cycles (60 Hz) Single phase: at 0°</td>
<td></td>
</tr>
<tr>
<td>Voltage interruptions</td>
<td>0% U, for 250/300 cycles</td>
<td>0% U, for 250 cycles (50 Hz) and 300 cycles (60 Hz)</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>30 A/m 50 Hz or 60 Hz</td>
<td>30 A/m 50 Hz and 60 Hz</td>
<td></td>
</tr>
<tr>
<td>Conducted disturbances induced by RF fields</td>
<td>3 V between 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz At 80% AM with 1 kHz modulation frequency</td>
<td>3 V between 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz At 80% AM with 1 kHz modulation frequency</td>
<td>Field strengths 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>Radiated RF EM fields</td>
<td>3 V/m between 80 MHz – 2.7 GHz At 80% AM with 1 kHz modulation frequency</td>
<td>3 V/m between 80 MHz – 2.7 GHz At 80% AM with 1 kHz modulation frequency</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td>Proximity fields from RF wireless communications equipment</td>
<td>380 MHz - 390 MHz: 27 V/m 430 MHz - 470 MHz: 28 V/m 704 MHz - 787 MHz: 9 V/m 800 MHz - 960 MHz: 28 V/m 1700 MHz - 1990 MHz: 28 V/m 2400 MHz - 2570 MHz: 28 V/m 5100 MHz - 5800 MHz: 9 V/m</td>
<td>385 MHz: 27 V/m 450 MHz: 28 V/m 710 MHz: 9 V/m 745 MHz: 9 V/m 780 MHz: 9 V/m 810 MHz: 28 V/m 870 MHz: 28 V/m 930 MHz: 28 V/m 1720 MHz: 28 V/m 1845 MHz: 28 V/m 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz: 9 V/m 5500 MHz: 9 V/m 5785 MHz: 9 V/m</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE 1:** U<sub>i</sub> is the a.c. mains voltage prior to application of the test level.

**NOTE 2:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 3:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**NOTE 4:** The AngioJet System is intended for use in hospitals and outpatient facilities only. The equipment has not been assessed for use near high frequency surgical equipment and interference may occur. If degradation of performance is observed, move the equipment away from the high frequency surgical equipment or contact Boston Scientific for assistance. For additional corrective actions, refer to “Maintenance, Troubleshooting and Service” Section.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AngioJet System is used exceeds the applicable RF compliance level above, the AngioJet System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AngioJet System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.