OPERATOR'S MANUAL - DRAFT
AutoElite Thrombectomy System Console

DEVICE DESCRIPTION
The AutoElite Thrombectomy System (AutoElite System or 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. An additional feature includes injection of physician-specified fluid using the Power Pulse technique for specific Thrombectomy Sets. The AngioJet System consists of a single-use Thrombectomy Set (several models available) and a free-standing mobile Console.

AutoElite Thrombectomy System Console (AutoElite Console or Console)
The Console is a multiple-use device that controls the Thrombectomy Set. It drives the pump, regulates fluid inflow and outflow, and provides the operator with System setup prompts, total run time, total infused fluid volume, and System malfunction information. The Console provides a user-interface controlled by a touchscreen and is activated by pressing a foot switch.

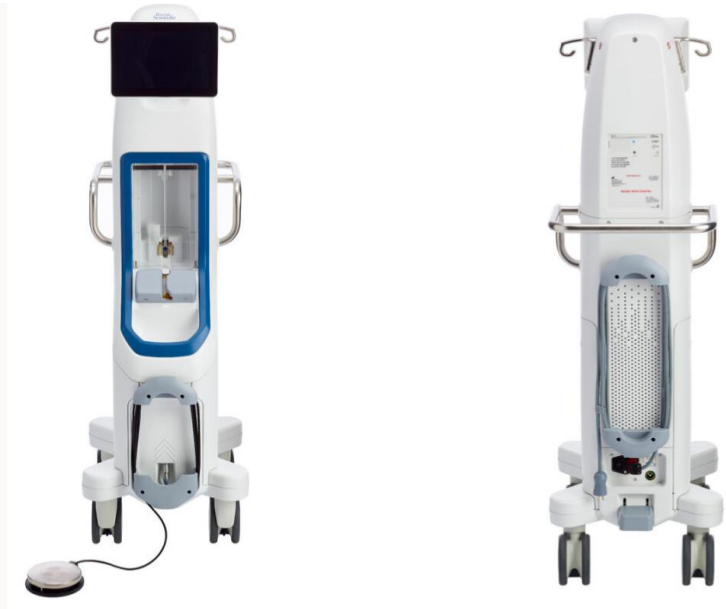

Figure 1. AutoElite Console

AngioJet Thrombectomy Set (Thrombectomy Set)

A bag of 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. Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body. The waste tubing transports the thrombus debris from the catheter to the waste bag for ultimate disposal. An additional feature includes injection of physician-specified fluid using the Power Pulse technique for specific Thrombectomy Sets.

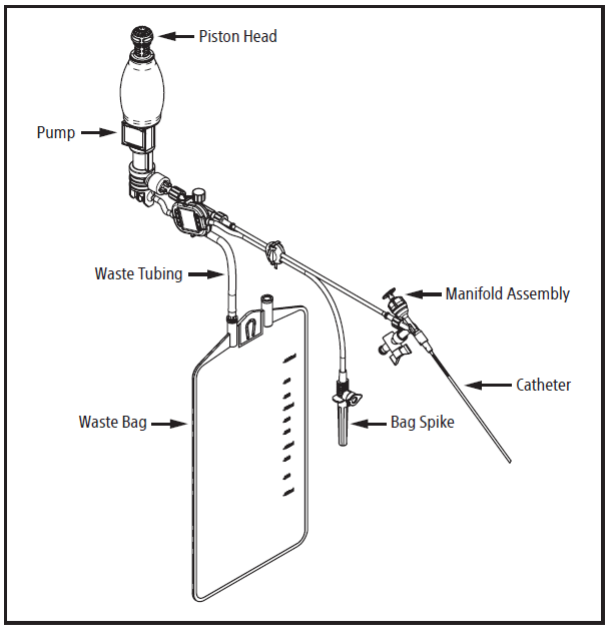

Figure 2. AngioJet Thrombectomy Set (for reference only)

Essential Performance
The AutoElite Console essential performance consists of two clinical functions:

1. Generate a localized low-pressure zone for thrombus aspiration, break-up, and removal.
2. Infusion of physician-specified fluid in a thrombosed vessel (Power Pulse mode).

To achieve the System's essential performance, the AutoElite Console operates the Thrombectomy Set within the operating ranges specified by the Thrombectomy Set. The System verifies performance by conducting both power-up self-tests and continuous monitoring during operation and will halt operation if the System operates out of the specified range(s). There are no user-configurable parameters that would impact clinical performance of the Thrombectomy Set.

Contents
One (1) Console

User Information
The AutoElite System should only be used by physicians who have a thorough understanding of thrombectomy treatments and percutaneous interventional procedures.

INTENDED USE
The AutoElite Console is intended to be used with the AngioJet Thrombectomy Sets for the percutaneous removal of thrombus in the treatment of vascular disease.

INDICATIONS FOR USE
The AutoElite Console is intended for use only in conjunction with a AngioJet Thrombectomy Set. Refer to the individual Thrombectomy Set Instructions for Use for specific clinical applications.

CLINICAL BENEFIT STATEMENT
Refer to the individual Thrombectomy Set Instructions for Use for clinical benefit statement.

CONTRAINDICATIONS
Refer to the individual Thrombectomy Set Instructions for Use for specific contraindications.

WARNINGS
• To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
• Refer to the individual Thrombectomy Set Instructions for Use for specific warnings and precautions.
• Use of the Thrombectomy Set may result in hemolysis which should be monitored to manage possible renal, pancreatic, or other adverse events. Thrombectomy Set Instructions for Use lists maximum recommended operating times for the specific Thrombectomy Set model. Evaluate the patient's risk tolerance for hemolysis (such as body size, thrombus burden, and renal function) prior to the procedure. Consider appropriate hydration prior to, during, and after the procedure.
• Do not attempt to bypass any of the Console safety features.
• The AutoElite System should not be used adjacent to or stacked with other equipment, and if adjacent use is necessary, the Console should be observed to verify normal operation in the configuration in which it will be used.
• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than distances specified in Table 3 and Table 4 to any part of the AutoElite System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
• Use of accessories and cables other than those provided by Boston Scientific could result in increased electromagnetic emissions or decreased electromagnetic immunity of the AutoElite System and/or result in improper operation.
• No modification of this equipment is allowed. The Console contains limited user-serviceable parts. Refer service of other parts to qualified personnel.

PRECAUTIONS
• Use the Console only with an AngioJet Thrombectomy Set.
• The AutoElite 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 AutoElite System near sensitive equipment when operating.
• Visually inspect the Console, foot switch/cable, and power cord prior to use. Use of a damaged Console is not recommended, as performance may be impacted.
• Avoid knocking into or putting weight on the monitor. This may damage the monitor.
• Do not manually manipulate the doors. See *Cleaning* section for proper procedure to clean pump bay and doors.
• Do not reposition or push the Console from any point other than the handle designed for that purpose to avoid overbalancing or tipping.
• If the System continues to run after removal of foot from foot switch, pull the power cord from the wall outlet to deactivate the system.
• If it becomes necessary to replace the fuses, replace with the type and rating specified. Failure to do so may result in device damage or risk of fire.

ADVERSE EVENTS
Refer to the individual Thrombectomy Set Instructions for Use for specific observed and/or potential adverse events.

HOW SUPPLIED

Device Details
This product is supplied nonsterile and is intended for multiple use.

Do not use if package is damaged or unintentionally opened before installation.

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:	70 kPa to 106 kPa

Transport/Storage

Temperature:	Store between 15 °C – 25 °C (59 °F – 77 °F); Excursions permitted to -30 °C to 60 °C (-22 °F – 140 °F)
Relative Humidity:	Up to 85 % (noncondensing)
Atmospheric:	50 kPa to 106 kPa

OPERATIONAL INSTRUCTIONS

USING THE AUTOELITE CONSOLE

Required Items (not included in the package)

• AngioJet Thrombectomy Set
• Heparinized saline in a bowl for wipe-downs and Thrombectomy Set priming (2000 units per liter [U/L] suggested)
• Heparinized saline to be hung on the Console and to be connected to the Thrombectomy Set for operation (5000 U/L suggested)

Optional Items (not included in package)

• AngioJet Power Pulse Kit Y-Set (for Power Pulse Mode operation)
• Physician-specified fluid (for Power Pulse Mode operation)

Pre-Procedure Information

A thorough understanding of each component in the AutoElite System is required for proper operation. Read this manual and the Thrombectomy Set(s) Instructions for Use before using any part of the AutoElite System.

To learn more about Console operation, from the home screen, navigate to “Tutorials**”**. Tap a topic and use the left/right arrows or swipe to navigate through the information.

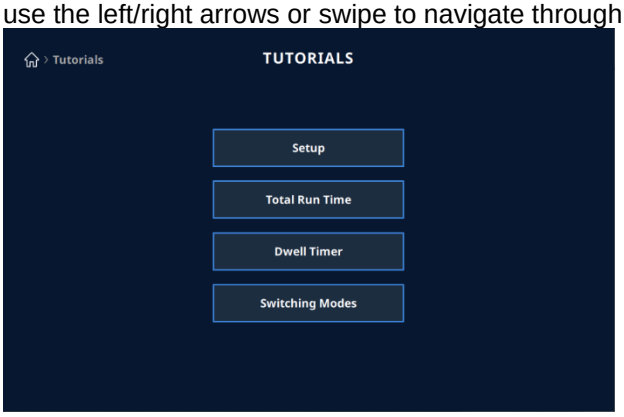

Figure X.

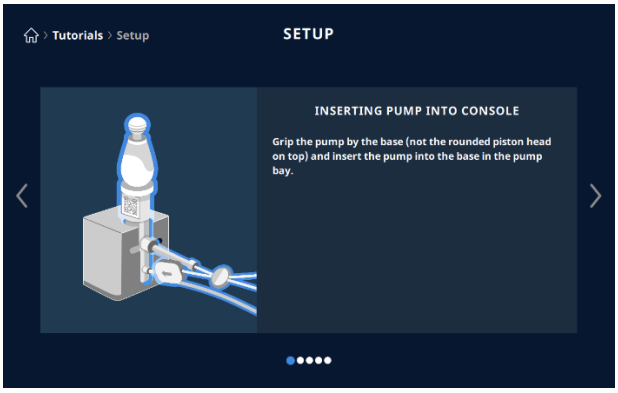

Figure X.

If operation halts due to improper AutoElite System preparation or abnormal component operation, error messages and/or troubleshooting steps may appear. Follow the prompts on the screen. Refer to **Error Messages** in the *Maintenance, Troubleshooting, and Service* section for more information.

If using the Power Pulse Kit, prepare Power Pulse Kit according to the Power Pulse Kit Instructions for Use.

Recommended Maximum Total Run Time
Hemolysis occurs during Thrombectomy Set operation. The amount of hemolysis increases the longer the catheter is operated in the patient.

Boston Scientific recommends using the Thrombectomy Set within a specific time range based on Thrombectomy Set type and the presence of blood flow through the vessel to mitigate potential harm to the patient from hemolysis. The Total Run Time is the total amount of time the Thrombectomy Set has been activated (excluding priming). This Total Run Time includes operating time in Power Pulse Mode and Thrombectomy Mode combined, as both cause hemolysis. This will be tracked on the progress bar at the bottom of the procedure operating screen.

The Thrombectomy Set has recommended maximum total run times for operation in either a totally occluded or partially occluded vessel. The recommended maximum total run time for a totally occluded vessel is longer as there is less systemic hemoglobin release during catheter operation. Recommended maximum total run time should be determined based on vessel occlusion status at the start of the procedure. Both recommended maximum total run times for the procedure will be shown on the procedure operating screen and can also be found in the individual Thrombectomy Set Instructions for Use.

Note: Physician judgment should take priority when determining the run time for each procedure.

Console Preparation
Preparation of the AutoElite System requires the assistance of a sterile and a nonsterile user. 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 user except where otherwise noted.

The AutoElite System is designed to be interactive. The touchscreen provides prompts to guide the user through setup and provides troubleshooting steps when necessary. Additional information can be found by tapping the question mark icon **(?)** when available**.**

Precaution: Visually inspect the Console, foot switch/cable, and power cord prior to use. Use of a damaged Console is not recommended as performance may be impacted.

Precaution: Do not reposition or push the Console from any point other than the handle designed for that purpose to avoid overbalancing or tipping.

1. Position console in desired location near patient table.

2. Apply the brakes to prevent Console movement during operation (see Figure X).

Figure X.
The rear brake prevents the Console from moving or to lock the rear wheel orientation. The lowest position locks the rear casters in place and the upper position locks them in a straight configuration.

3. Plug in the Console and ensure the rear power switch (located next to the power cord) is turned on.

Figure X.

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

5. Heparinize sterile saline using the recommended 5000 U/L concentration. A 1.0 L bag is recommended. Hang the saline on either bag hook at the top of the Console.

6. Press the on/off button near the top of the Console (see Figure X).

Figure X.

The touchscreen will display AUTOELITE while the Console performs a self-test (see Figure X).

Figure X

The doors will open, indicating a successful self-test. An appropriate error message will be shown if any abnormality is detected. The touchscreen will then display the Home screen.

7. Tap the "NEW PROCEDURE" button on the Home screen (see Figure X).

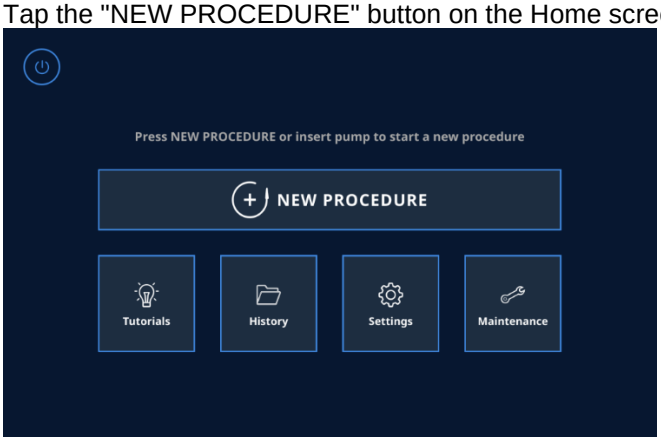

Figure X.

Load Pump

1. Sterile user: Remove the catheter and sufficient tubing from the sterile package and inspect for damage. Hand the tray with the rest of the Thrombectomy Set to the nonsterile user (see Figure X)

Figure X.

2. Nonsterile user: Remove the rest of the Thrombectomy Set from the tray by gripping the pump (not the piston head), then inserting the pump into the Console as shown (see Figures X and X).

Figure X.

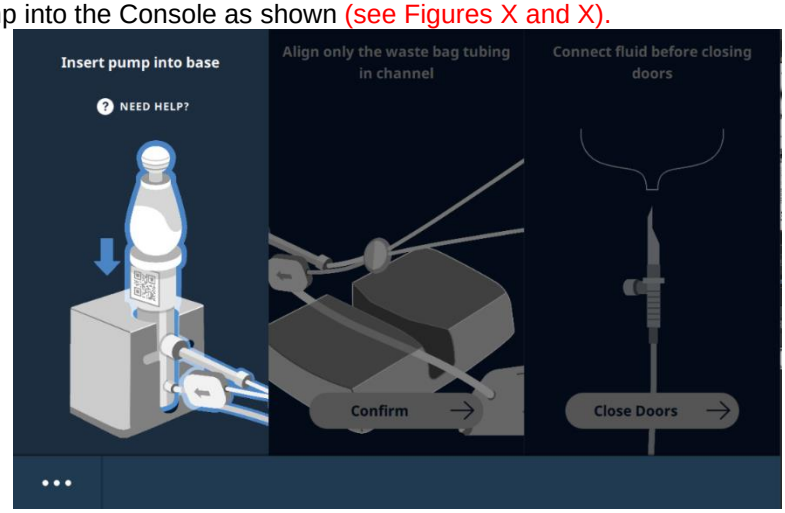

Figure X.

The Console will identify the Thrombectomy Set and all operating information from the pump. After the Console successfully identifies the Thrombectomy Set, the touchscreen will display the model in the lower right corner. (Figure X).

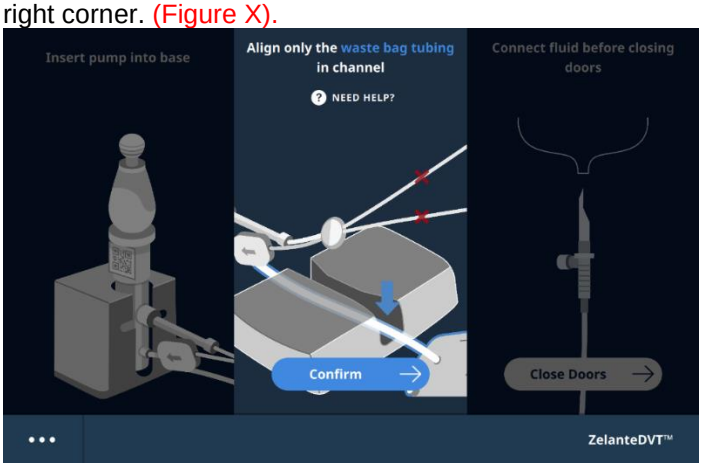

Figure X.

Note: The Console contains a 13.56 MHz RFID (radio frequency identification) tag reader which is used to identify and read the operating information of the Thrombectomy Set. The maximum power of the RFID reader is fixed at 100 mW. RF power is only enabled upon insertion of the Thrombectomy Set and only while reading the tag.

3. Insert the waste tubing in the roller pump channel as shown (see Figure X and X).

Figure X.

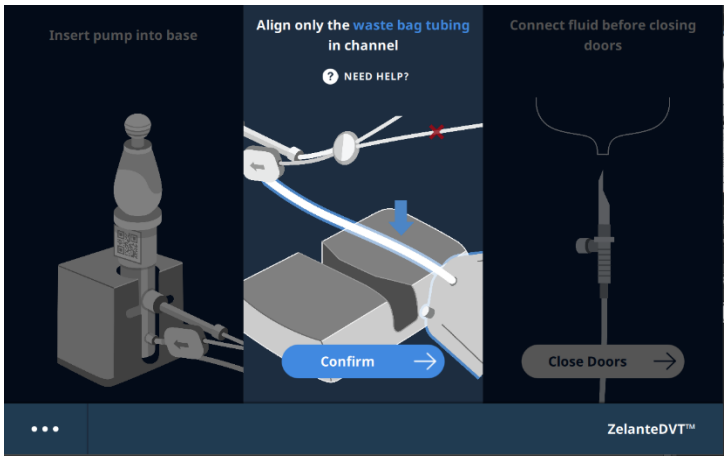

Figure X

4. Tap the "Confirm" button on the touchscreen.

5. Remove the cap from the Thrombectomy Set bag spike and insert the spike into the saline bag. Ensure hands are clear of the Pump Bay Doors and Roller Pump Clamp and tap the "Close Doors" button on the touchscreen (see Figure X).

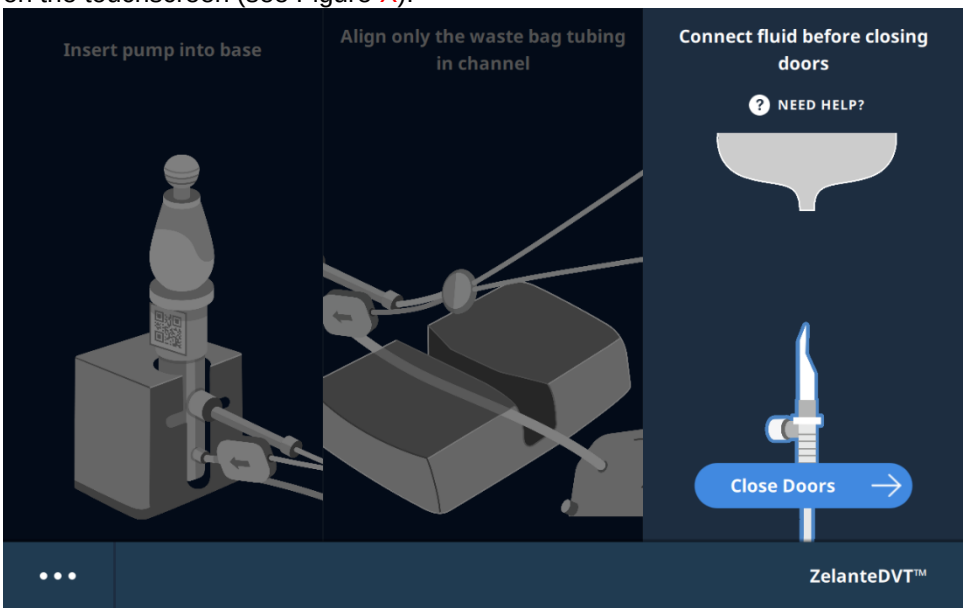

Figure X.

Note: The Power Pulse Kit accessory is available to assist with connection to physician-specified fluid. See Power Pulse Kit Instructions for Use for Power Pulse Kit setup.

After the doors close the Console will automatically detect saline.

Prime the Catheter

The touchscreen displays guidance on how to prime the catheter (see Figure X).

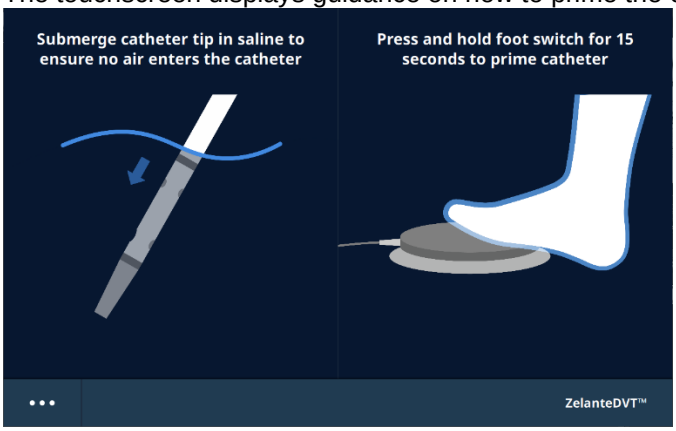

Figure X.

1. Completely submerge the catheter tip in heparinized saline. Press and hold the foot switch for the displayed time to prime the catheter (see Figure X and X).

Figure X.

Figure X.

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

2. Continue priming until the time display reaches zero seconds (see Figure X and X).

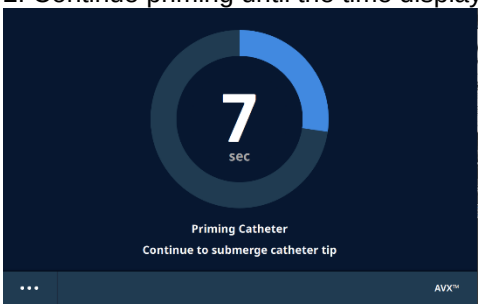

Figure X.

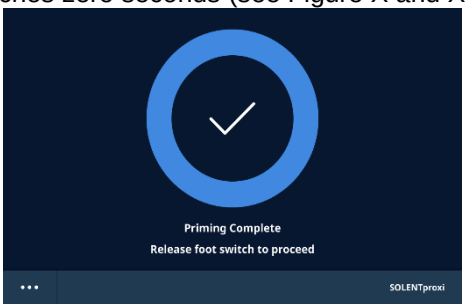

Figure X.

3. Once the time display reaches zero seconds, priming is complete. Release the foot switch.

If the Thrombectomy Set is enabled for Power Pulse Mode, the mode selection screen will appear. Select the first intended mode of operation by tapping the mode tile (see Figure X). Otherwise, the procedure operation screen will appear and Thrombectomy Mode will be enabled.

Note: If Power Pulse Mode is selected, confirm that physician-specified fluid is connected.

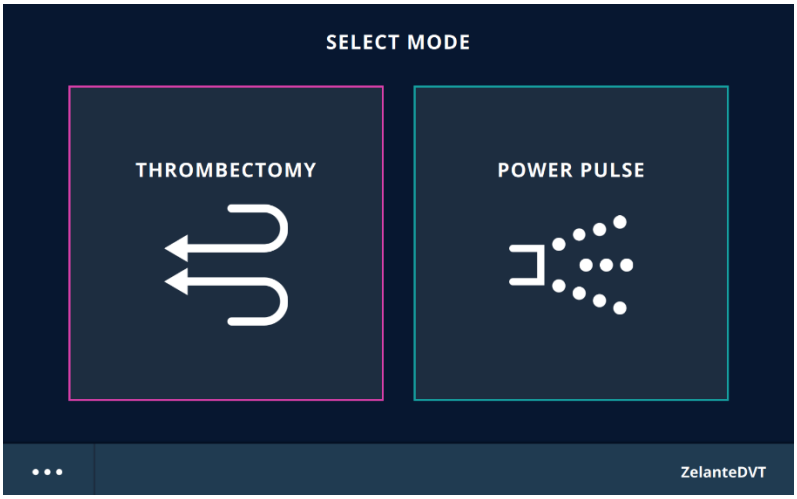

Figure X.

If using Power Pulse Mode, go to the *Power Pulse Spray Infusion Procedure* section in this manual.

If using Thrombectomy Mode, go to the *Thrombectomy Set Operational Procedure* section in this manual.

Refer to the individual Thrombectomy Set Instructions for Use for catheter advancement.

Time and Volume Tracking

The console keeps track of the run times and volumes infused during operation in Thrombectomy Mode and Power Pulse Mode. Displayed run times and volumes are estimations of the Thrombectomy Set output in the respective Operating Mode and are provided as reference only. The amount of fluid delivered can be confirmed by a visual inspection of the fluid delivery source. To indicate the current active operating mode, the active operating mode box will be highlighted with the associated mode color. After switching modes, the active operating mode name will alternate with “ENABLED” until the foot switch is pressed (see Figure X and X).

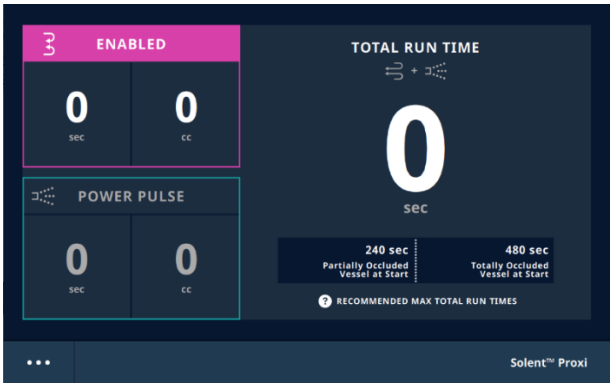

Figure X.

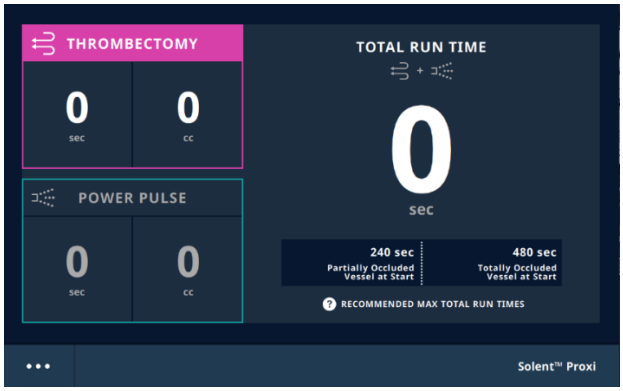

Figure X.

<u>Total Run Time</u>

The Total Run Time is the total amount of time the catheter has been activated (excluding priming). This value includes operating time in Power Pulse Mode and Thrombectomy Mode. The progress bar tracks total run time showing Thrombectomy run time and Power Pulse run time in the associated colors.

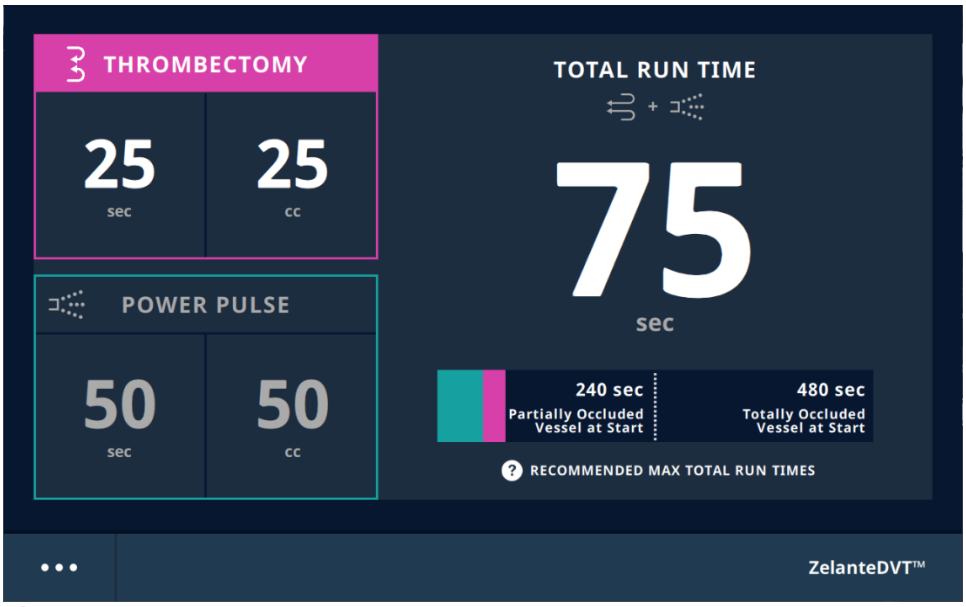

Figure X.

Recommended Max Total Run Time Exceeded – Partially Occluded Vessel

When the total run time exceeds the partially occluded vessel recommended max total run time, the partially occluded run time label text will pulse and a chime will sound. A bell icon ( ) will appear next to the Partially Occluded Recommended Max Total Run Time label (Figure X).

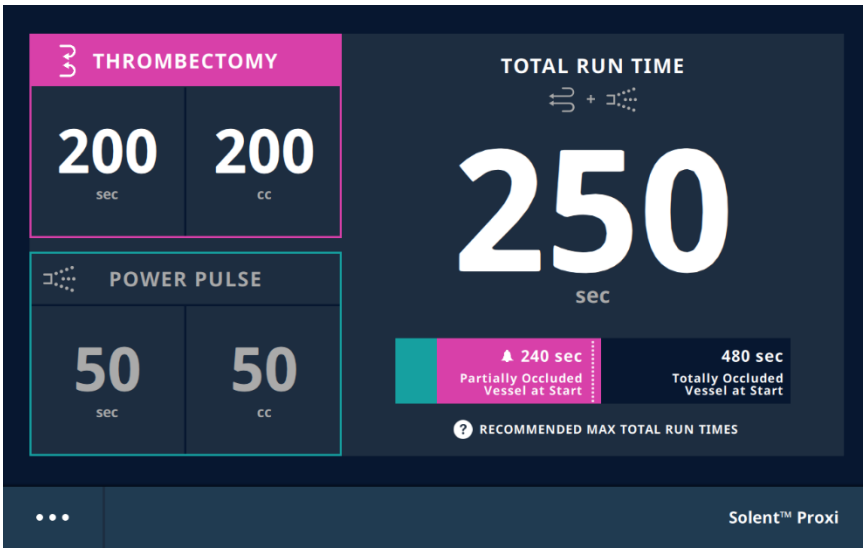

Figure X.

Recommended Max Total Run Time Exceeded – Totally Occluded Vessel

When the total run time exceeds the totally occluded vessel recommended max total run time, elements on the screen will turn orange and a chime will sound. A bell icon ( ) will appear next to the Totally Occluded Recommended Max Total Run Time label. The amount of time the catheter is used beyond the recommended max run time is shown in a box above the progress bar (Figure X).

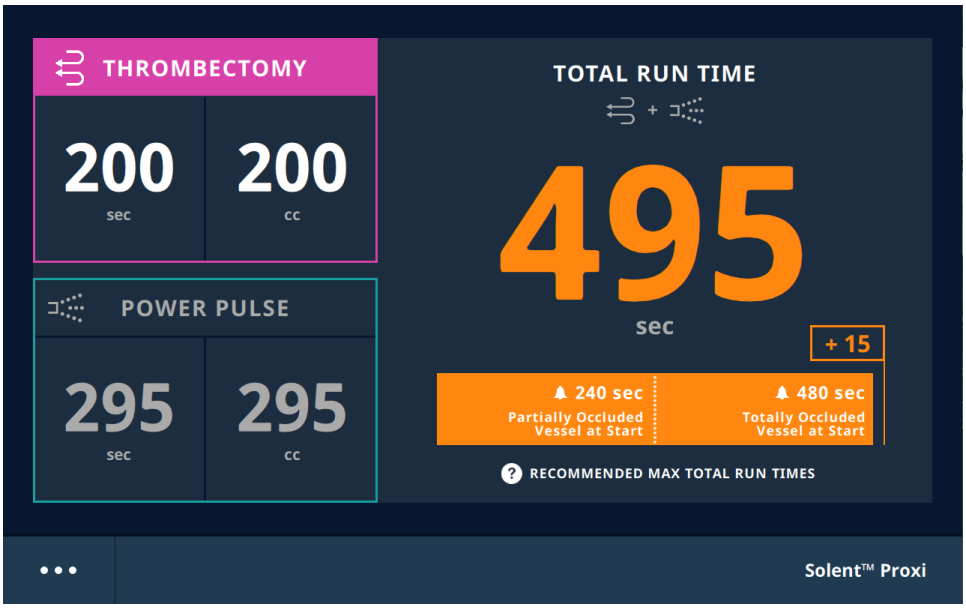

Figure X.

Warning: Use of the Thrombectomy Set may result in hemolysis which should be monitored to manage possible renal, pancreatic, or other adverse events. Thrombectomy Set Instructions for Use lists maximum recommended operating times for the specific Thrombectomy Set model. Evaluate the patient's risk tolerance for hemolysis (such as body size, thrombus burden, and renal function) prior to the procedure. Consider appropriate hydration prior to, during, and after the procedure.

Power Pulse Spray Infusion Procedure
Refer to the individual Thrombectomy Set Instructions for Use in the *Power Pulse Spray Infusion Procedure* section for further operating instructions.
Figure X. AutoElite Display

Dwell Timer
Dwell Timer is available for use to track dwell time after infusion of physician-specified fluid.

1. Tap the Dwell Timer button to open the Dwell Timer screen.

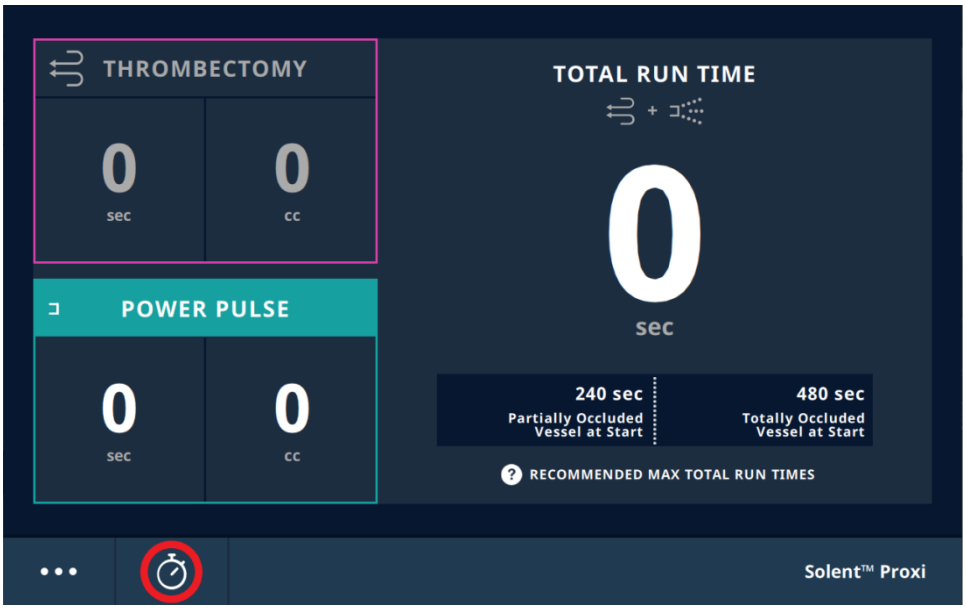

Figure X.

2. To start the Dwell Timer, tap the Start button.
   Note: Tap the “Include time elapsed…” toggle to include the amount of time since the foot switch was released.

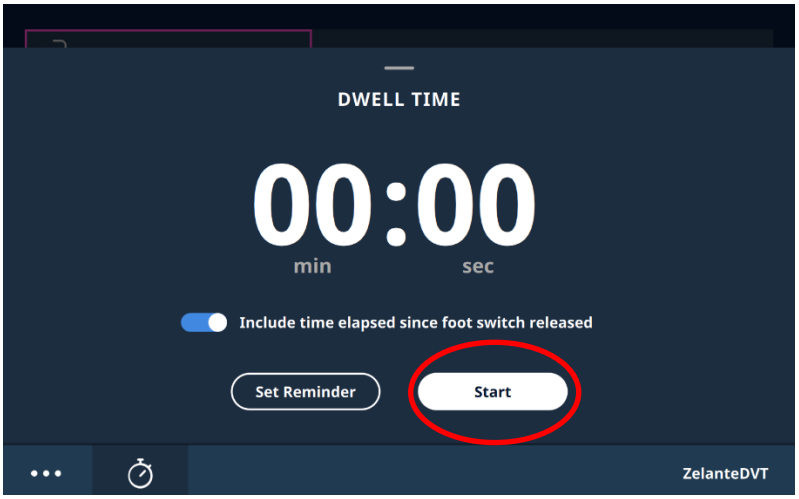

Figure X.

3. To set a reminder, tap the Set Reminder button.
   Note: A default reminder time can be set before the procedure from the Settings screen (Figure X). Reference the *Settings* section for more information.

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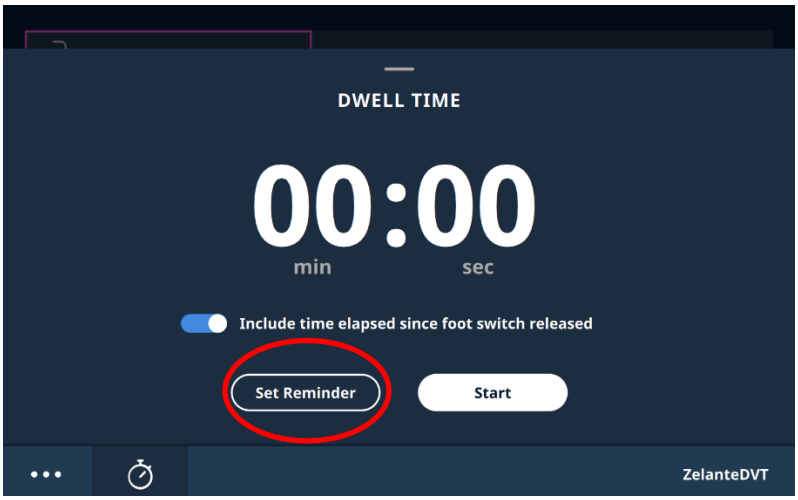


Figure X.

   a. Set the desired reminder time using the up and down arrows (Figure X).
   b. Press “Set” to set the reminder time.

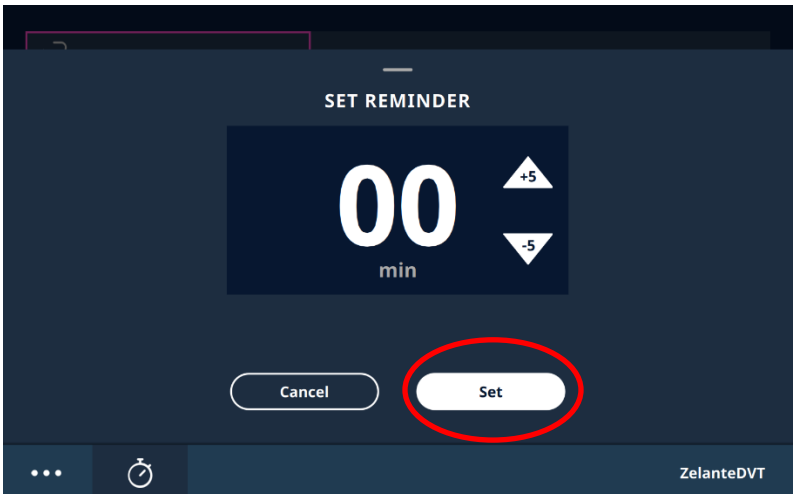


Figure X.

Track Dwell Time

If a reminder has been set, a progress bar will appear. When the dwell time reaches the reminder time, the progress bar will turn blue, and a chime will sound. The Dwell Timer will continue to count after the reminder time has been reached. To change the reminder time, tap **Change Reminder**.

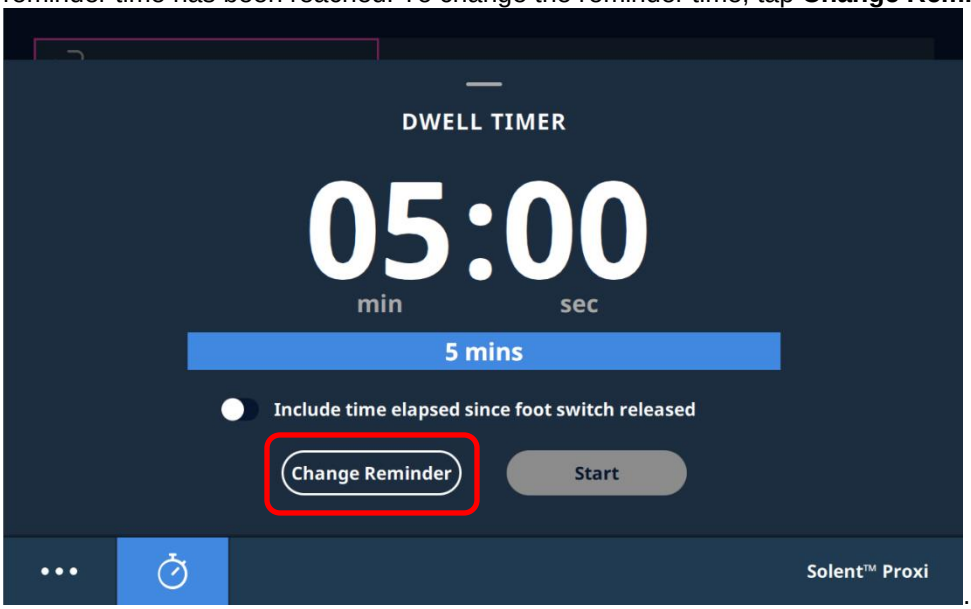


Figure X.

Note: Stepping on the foot switch while in Power Pulse Mode will pause the Dwell Timer. The Timer will automatically resume when the foot switch is released.

Hide/Stop Dwell Timer

To hide the Dwell Timer, swipe down from the top or tap the timer icon ( ) at the bottom of the touchscreen. The Dwell Timer will continue to count if the Dwell Timer is hidden.

To stop the Dwell Timer, step on foot switch while in Thrombectomy Mode or end the procedure.

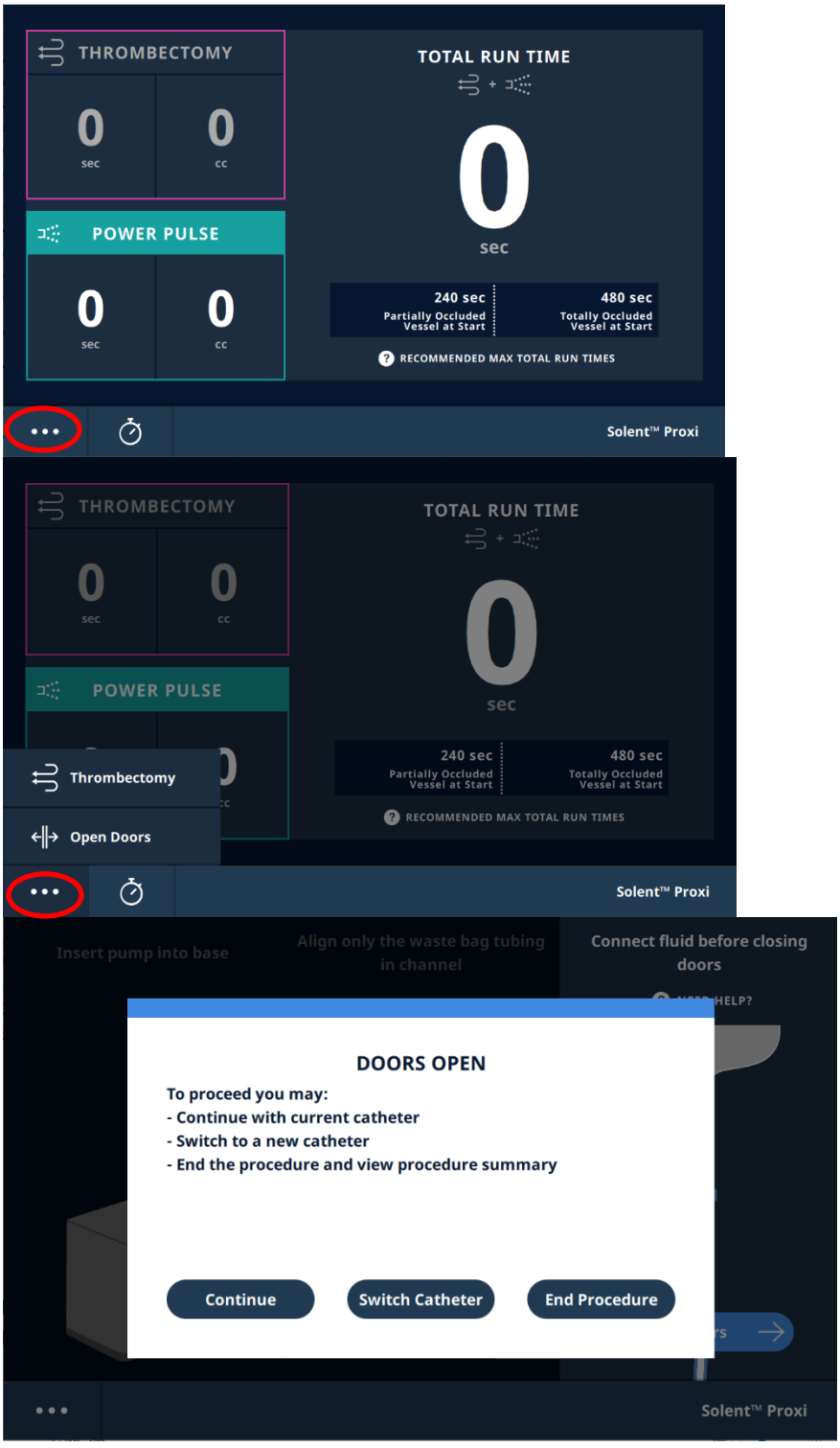
Thrombectomy Set Operational Procedure

Refer to the individual Thrombectomy Set Instructions for Use in the *Thrombectomy Set Operational Procedure* section for further operating instructions.

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

Switching Catheters Within Procedure

To switch catheters, tap Additional Options  in the lower-left corner of the touchscreen. Then tap **Open Doors**. Next, tap **Switch Catheter**.

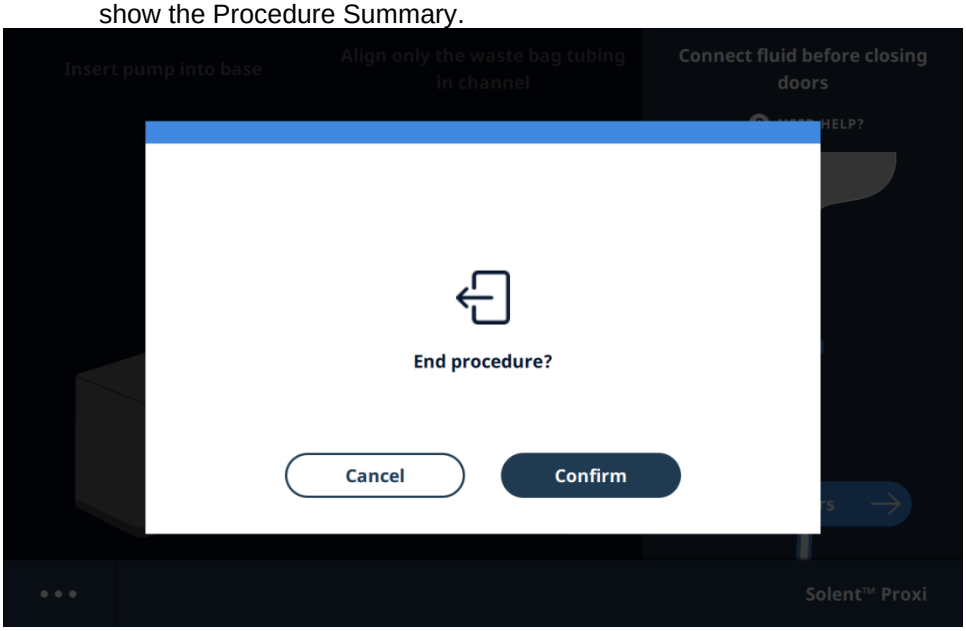


Note: Total Run Time for the new catheter will include the Total Run Time from previous catheters used during the procedure as run time should be tracked for the patient rather than for the catheter.

Recovering a Procedure
In the event of a power loss or error requiring Console reboot, the procedure status will be maintained if the Console is powered back on within five minutes. The catheter tip may be left inside the patient at the physician's discretion; the Console will provide prompts to continue the procedure upon restoration of power.

AutoElite System End Procedure

1. To end the procedure, tap Additional Options in the lower-left corner of the touchscreen. Then tap **Open Doors**. On the pop-up, tap **End Procedure**. Tap **Confirm** to end the procedure and to show the Procedure Summary.



Note: Ending the procedure will reset all run times. Starting a new procedure with the same catheter will recover the previous run times. To switch catheters, see *Switching Catheters within Procedure* section.

2. Remove the Thrombectomy Set from the Console.
    a. Remove the pump from the pump bay
    b. Remove the saline supply from the bag hook. Dispose of the saline supply together with the Thrombectomy Set.
    c. See the individual Thrombectomy Set Instructions for Use for proper disposal instructions.

3. Press the **On/Off** button ( ) on the Console or on the **Home** screen. Tap **Confirm** to turn off the Console.

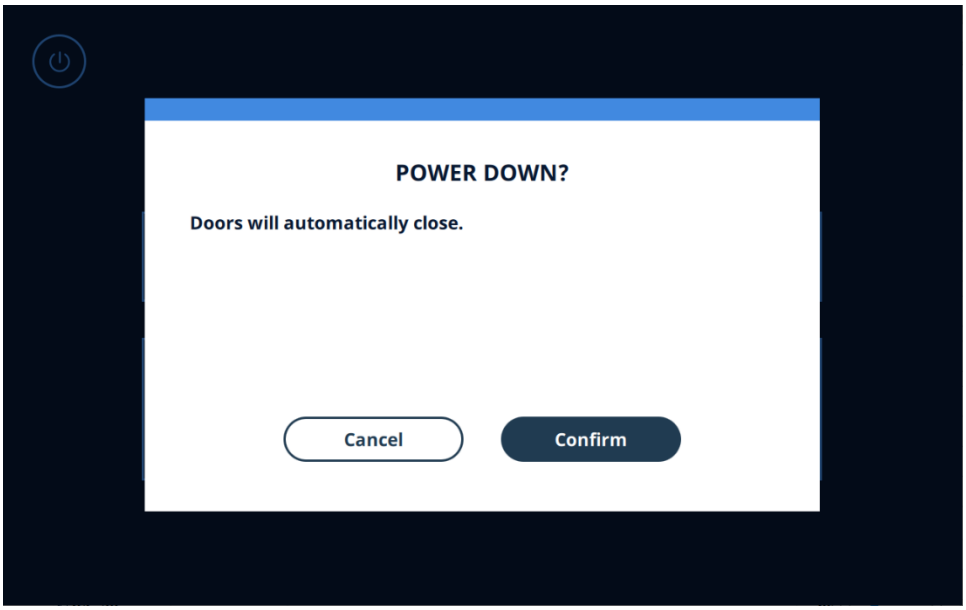


Figure X.

4. Unplug the power cord from the wall outlet. Coil the power cord around the rear cord wraps (Figure X).

Figure X.

5. Place the foot switch into the holder. Coil the foot switch cord around the front cord wraps (Figure X).

Figure X.

Follow proper precautions for the handling of infectious waste. Reuse of the Thrombectomy Set is prohibited.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and relevant local regulatory authority.

Cleaning the Console
Thorough cleaning is required after every use due to potential exposure to infectious material. All accessible Console surfaces, foot switch/cord, and power cord should be cleaned.

Touchscreen

• Do not wipe the screen with a cloth or sponge that could scratch the surface.
• To clean the touchscreen, it is recommended to use window or glass cleaner applied to a clean cloth or sponge. Never apply the cleaner directly to the touchscreen. Do not use alcohol (methyl, ethyl or isopropyl), thinner, benzene, or other abrasive cleaners.

General Cleaning for Console (Excluding the Touchscreen)

The following solutions are acceptable for cleaning:

- 70% max isopropyl alcohol (IPA)
- 10% max bleach (sodium hypochlorite)
- Soapy water

Apply cleaning solution to cloth for cleaning, do not spray directly on the Console.

To clean behind the pump bay doors, power on the Console. From the **Home** screen, navigate to **Maintenance** and then **Pump Bay Cleaning**. Then, close one door at a time to clean behind it. Do not manually manipulate the doors.

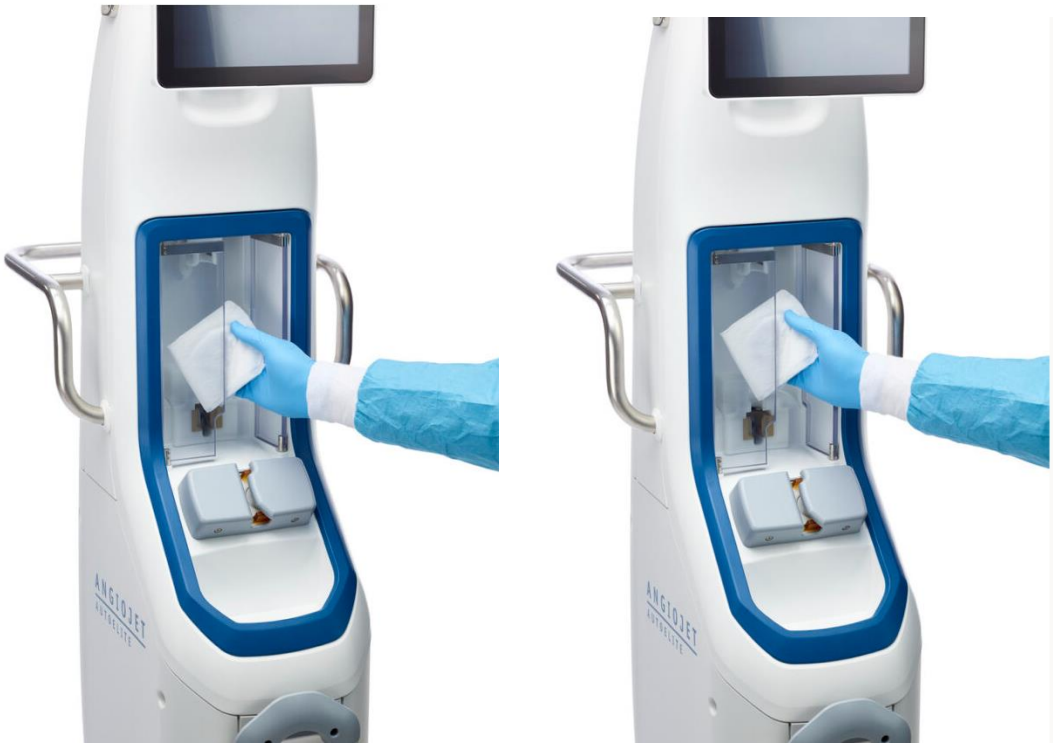


Figure X.

CLEANING AND DISINFECTION INSTRUCTIONS

Caution: (Can this be a note?)

• To avoid the potential for electric shock, turn the power switch off and disconnect the power cord from the hospital's electrical outlet before cleaning and disinfecting the console. The power cord and gas supply hose may remain connected to the back of the console.
• To avoid damage to the console:
  - Do not allow fluids to enter the enclosure or any connectors.
  - Do not immerse the console enclosure into fluids.
  - Do not use solvents or abrasive cleaners.

- Do not spray directly on to the console.

The console has been tested and demonstrated to be compatible with the following cleaning and disinfection solutions:

• 70% Isopropyl Alcohol (IPA)
• Bleach (0.5% to 1% Sodium Hypochlorite)
• Super Sani-Cloth™ Germicidal Wipes

Cleaning Instructions

1. Use Super Sani-Cloth Germicidal Wipes, or a pre-saturated wipe containing one of the following:
   a. 70% IPA
   b. Bleach (0.5% to 1% Sodium Hypochlorite)
   Or, prepare a clean wipe by soaking with solution (a or b above). Wring excess solution ensuring the wipe remains saturated but not dripping.
2. Wipe each panel (front, sides, top and bottom) of the console for a minimum of one minute until all visible soil is removed.
   • While wiping, give particular attention to crevices and hard to clean areas.
   • Replace soiled wipes as needed and use additional wipes to ensure that all surfaces are uniformly cleaned.
3. Use a clean, lint-free cloth/wipe dampened with water to wipe all accessible surfaces of the device a minimum of two times to remove residual solution. Use additional clean, dampened cloths/wipes as needed.
4. Thoroughly dry all surfaces of the console with a clean, lint-free cloth/wipe.
5. Repeat steps 1 through 4 once. Use a soft-bristled brush, as necessary.
6. Visually inspect the console for the absence or presence of remaining soil in a well-lit area with an unaided eye. While inspecting, give particular attention to verifying soil has been removed from the hard-to-clean areas. If soil is present, then repeat the cleaning steps until all visible soil is removed.

Disinfection Instructions

1. Use Super Sani-Cloth Germicidal Wipes, or a pre-saturated wipe containing one of the following:
   a. 70% IPA
   b. Bleach (0.5% to 1% Sodium Hypochlorite)
   Or, prepare a clean wipe by soaking with solution (a or b above). Wring excess solution ensuring the gauze/wipe remains saturated but not dripping.
2. Thoroughly wipe each panel (front, sides, top and bottom) of the console and allow the surfaces to remain visibly wet for a minimum of two minutes if using Super Sani-Cloth Germicidal Wipes (minimum of ten minutes for other wipes).
   • Thoroughly wipe crevices and hard to disinfect areas.
   • Use additional wipes as necessary to ensure surfaces remain wet.
3. Use a clean, lint-free cloth/wipe dampened with water to wipe all accessible surfaces of the device a minimum of two times to remove residual solution. Use additional clean, dampened, lint-free cloths/wipes as needed.
4. Thoroughly dry all surfaces of the console with a clean, lint-free cloth/wipe.

Disposal of Console

If placing the unit into an electronics recycling stream, notify the receiver of the possible presence of internal biohazardous materials. Use of recycling service suppliers familiar with medical electrical equipment is recommended. Do not dispose of by incineration, burial or placement into common waste stream. Device should be safely disposed of in accordance with hospital, administrative, and/or local government policy.

Contact Boston Scientific Customer Service for product returns.

Biohazardous device (after use)

3.1.1. Statement 1:

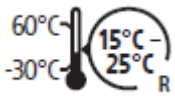
To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:
After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Biohazardous device with electronics/battery

3.3.1. Statement 3:

This device and associated electrical/electronic equipment should not be incinerated.
Do not incinerate any device/component containing a battery and/or electronics.
Improper disposal could result in an explosion.

ANGIOJET ULTRA CONSOLE SYMBOL TRANSLATION KEY

GTIN (new)	Global Trade Item Number
AU REP (replace)	Authorized representative
BR REP (replace)	Authorized representative
	Store at temperature with excursions

REF	Catalog Number
	Follow Instructions for Use
	Contents
EC REP	Authorized Representative in the European Community
	Manufacturer
LOT	Lot Number
	Recyclable Package
AUS	Australian Sponsor Address
ARG	Argentina Local Contact
BRA	Brazil Local Contact
	Do not use if package is damaged
	Humidity limitation
	Atmospheric Pressure Limitation
	Defibrillation-Proof Type CF Applied Part

	CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.
	Separate Collection
	Equipotentiality
	Fuse
	Foot Switch
	Alternating Current
	Temperature limitation
	Date of Manufacture
	Serial Number
	Non-Sterile
	Power On (power: connection to mains)
	Power Off (power: disconnection to mains)
	Standby
	Eject (open/close drawer)
	No Pushing
	Non-Ionizing Electromagnetic Radiation
	Medical Device under EU Legislation
	Unique Device Identifier

	Duty cycle symbol
	ETL Listed Mark

INSTALLATION

If lifting the Console is necessary, it is recommended to use a lifting device or two or more people.

Initial Set-up

1) After removal from crate, inspect the Console for visible damage.
   PRECAUTION: Visually inspect the Console, foot switch/cable, and power cord prior to use. Use of a damaged Console is not recommended, as performance may be impacted.
2) If not already attached, connect the foot switch (figure X).

   a) It is best for the user to be positioned so that the connector and the red dot on the console are at eye level.
   b) Ensure the red dot on the LEMO™ connector aligns with the red dot on the Console. Insert the connector and push until it clicks.
   c) Lightly tug on the cord just below the connector to ensure secure connection.
3) If not already attached, connect the power cord.

   A click will be heard and felt. Lightly tug on the cord just distal to the connector to ensure secure connection.
4) To turn on the Console, confirm the rocker switch is in the “ON” position (Figure X), then press the “POWER” button .

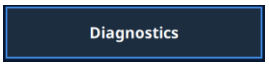
If the Home Screen appears without any error messages, this indicates a successful self-test.

Hardware Test

1. Test the foot switch.

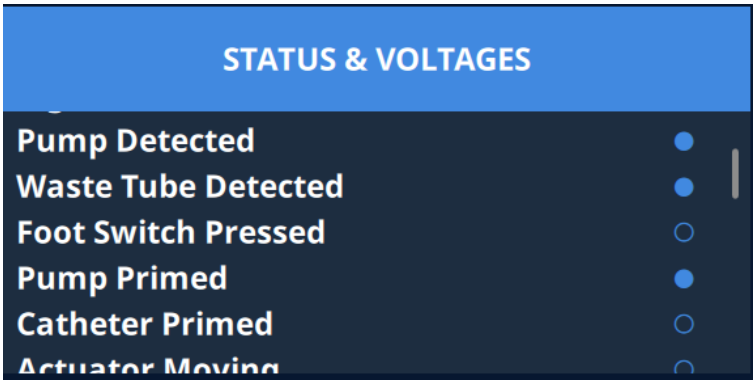
   a. From the Home Screen, tap the Maintenance button 

.

   b. Tap the Diagnostics button 

.

   c. Look under the STATUS & VOLTAGES tab and scroll down until “Foot Switch Pressed” can be seen.



   d. Step on the foot switch and ensure the indicator icon becomes filled in.
   e. Remove foot from foot switch and ensure the indicator icon clears.
   f. If the indicator icons do not respond appropriately, disconnect and reconnect the foot switch. See Initial Set-up above for more detail.

Settings

To adjust console settings, from the home screen, navigate to **Settings**. Tap a settings category and adjust a setting by tapping the toggle or swiping the slider.

MAINTENANCE, TROUBLESHOOTING, AND SERVICE

Preventative Maintenance

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

The Console will indicate when maintenance is recommended. The maintenance interval recommended by Boston Scientific is based on usage and is approximately every five years. Console service is only performed by qualified BSC-approved service personnel except for component replacement described in this manual. All service should be performed outside of the procedure.

IEC 62353 Recurrent Testing

National regulations may require that the user, manufacturer, or manufacturer representative periodically perform and document testing of the device. If such testing is required in your country, follow the testing interval and extent of testing as regulated in your country. If you do not know the national regulations in your country, please contact your Boston Scientific Representative.

If IEC 62353 is a required standard by national regulations but no specific testing or interval is specified, it is recommended to perform testing using the direct method as specified in IEC 62353 at an interval of every 24 months or as per local regulations.

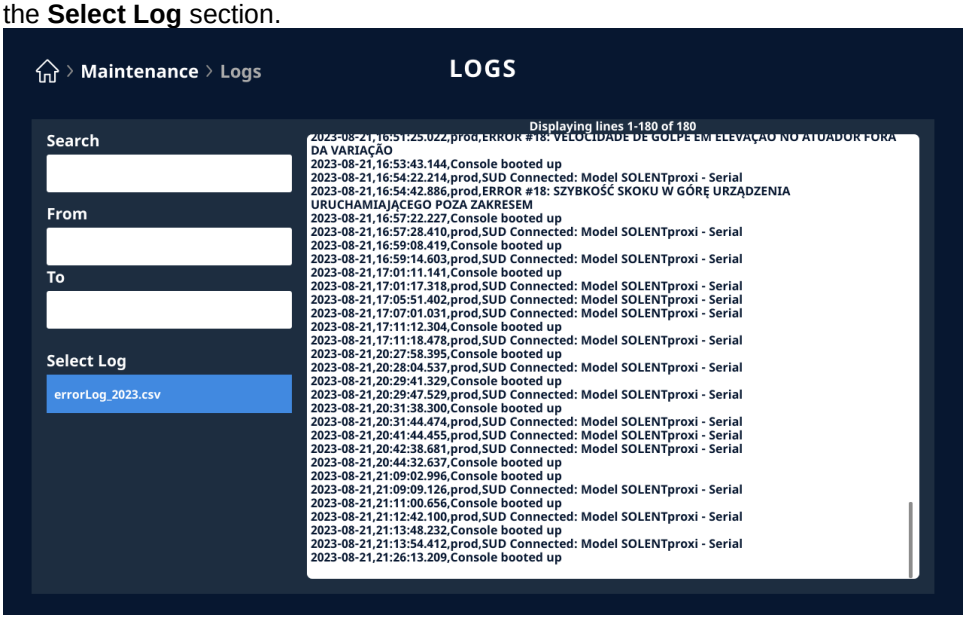
IEC 62353 Test	Limit
Protective Earth Resistance	< 300mΩ (when measured with power cord attached)
Earth Leakage Current	< 5 mA
Touch Current	< 100 µA

If the AutoElite Console exceeds the limits described in table above, immediately discontinue use of the Console and contact your Boston Scientific Representative.

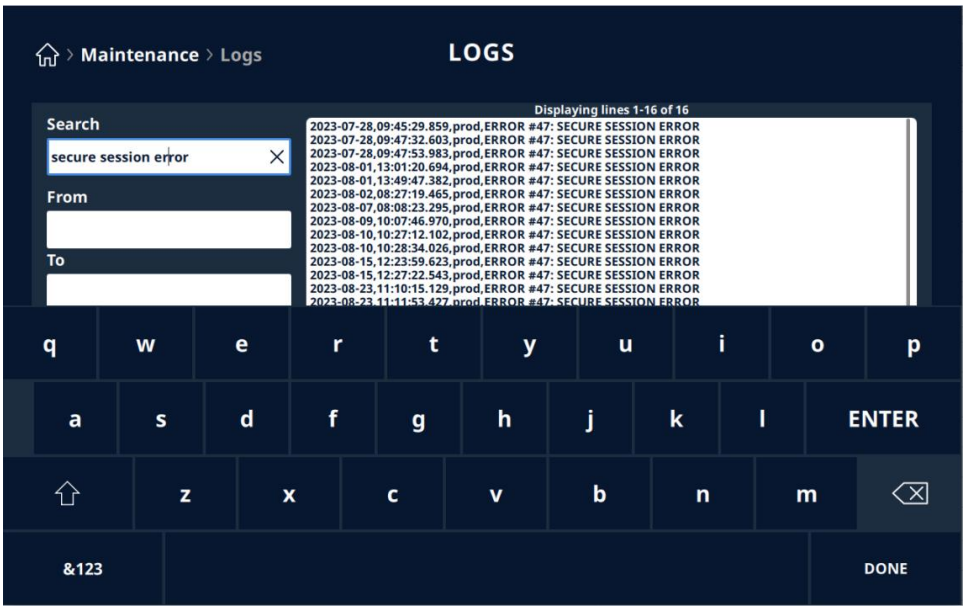
Troubleshooting

Logs

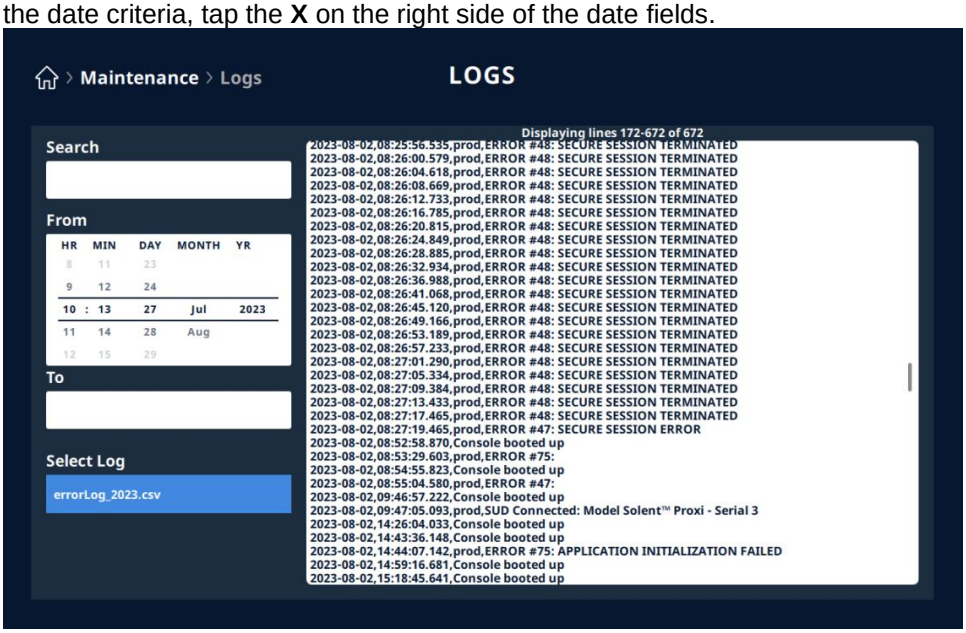
To view the error logs, from the home screen, navigate to **Maintenance**, then **Logs**. The log from the current year will be automatically selected. To view other error logs, select the appropriate log in the **Select Log** section.

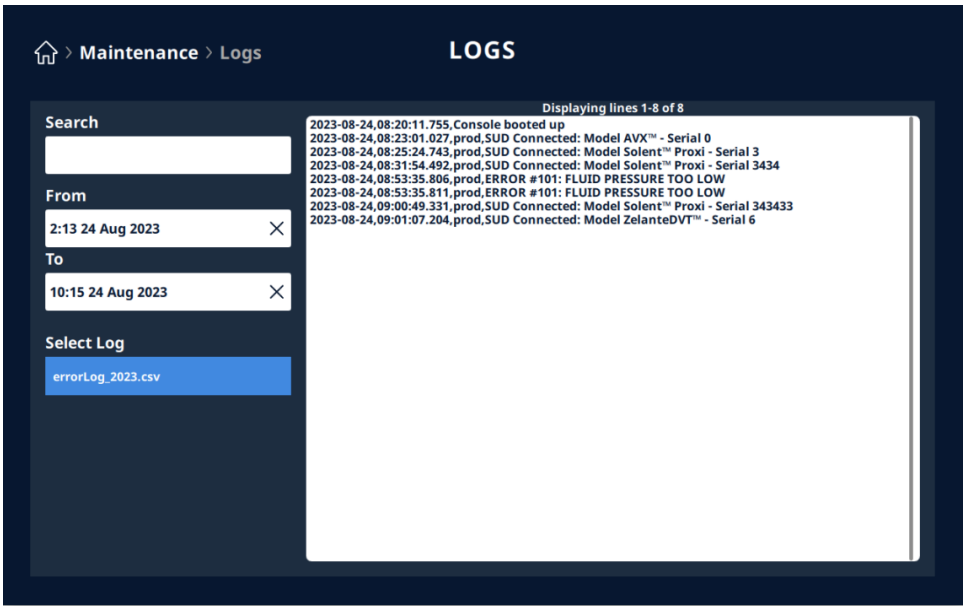


To search for specific events within a log, tap the search bar under **Search**. Enter in search terms with the on-screen keyboard and tap **Enter** to view the results. To clear the search criteria, tap the **X** on the right side of the search bar.



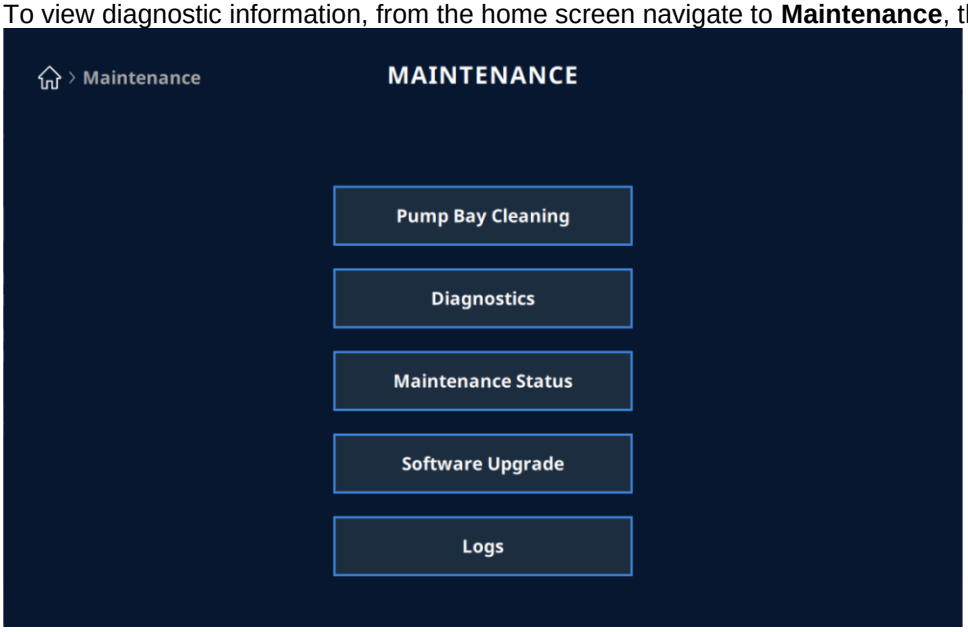
To search by date, set the start date by tapping the field below **From** and select the date using the date picker. Set the end date by tapping the field below **To** and select the date using the date picker. To clear the date criteria, tap the **X** on the right side of the date fields.





Diagnostics

To view diagnostic information, from the home screen navigate to **Maintenance**, then **Diagnostics**.



Error Messages

Error messages and error codes will appear with an orange banner when a fault is detected within the system (see Figure X). The error message will provide guidance for troubleshooting. If the condition persists, the Thrombectomy Set may need to be removed from the Console.

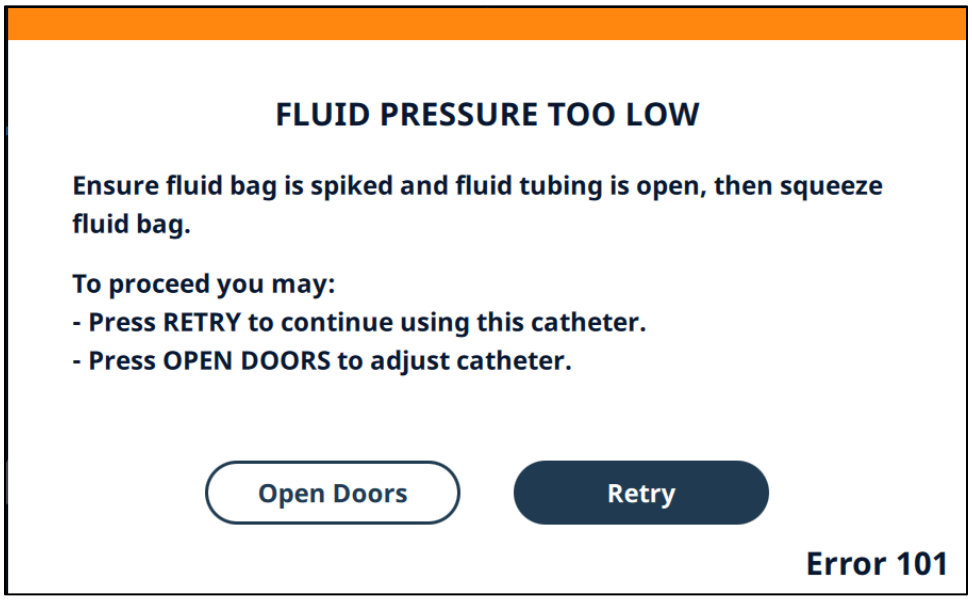


Figure X.

Make note of each error title and number to report to Boston Scientific Technical Assistance. If necessary, refer to the log in the Maintenance screen for errors and error codes that have occurred on the Console.

If the Console becomes unresponsive, cycle the power using the rocker switch next to the power cord.

Then turn on the Console using the ON/OFF button on the front of the Console. If the Console remains unresponsive, contact Boston Scientific Technical Assistance Center (see Table X).

The Boston Scientific phone numbers listed below are not intended to assist with any medical emergencies. Use these contacts only for assistance for technical issues involving the operation of the Console.

Before contacting the Boston Scientific Technical Assistance Center:

- Obtain the Console serial number
- Obtain details of the event or problem

Next, call, email, or fax the Technical Assistance Center according to your geographic region

Table X. Technical Assistance Center Contact Information

Region	Telephone Number	Email
United States, Canada, Puerto Rico, and Caribbean	1 800 949 6708	CEtechsupportUSA@bsci.com
Europe, Middle East, and Africa	00800 5555 7707	CEtechsupportEMEA@bsci.com
Asia Pacific	+65 64 18 8878	CETechSupportAPAC@bsci.com
Latin America		
Argentina, Chile, Bolivia, Uruguay, and Paraguay	+54 1170900232	CustomerServiceArgentina@bsci.com
Brazil	+55 11 99571-3615	CEBrazilTeam@bsci.com
Colombia, Venezuela, Peru, and Ecuador	+52 55 4383 6824	CESupportColombia@bsci.com
Mexico, Panama, Costa Rica, Guatemala, EL Salvador, and Nicaragua	+52 15559924100	CESupportMXC@bsci.com

Part Replacement (in the Torx spec there may be good photos)
It may be necessary to replace components on the AutoElite Console. The user may replace the components outlined in the instructions below. For all other parts, contact Boston Scientific Technical Support using contact information in Table X.

Foot switch

Figure X.

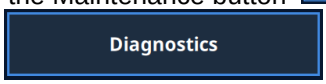
1. On the front of the console, pull back on the outer release sleeve of the LEMO connector.
2. To attach the new foot switch, it is best for the user to be positioned so that the connector and the red dot on the console are at eye level.
3. Ensure the red dot on the LEMO connector aligns with the red dot on the Console. Insert the connector and push until it clicks.

Figure X.

4. Lightly tug on the cord just below the connector to ensure secure connection.
5. Test the foot switch.

   a. From the Home Screen, tap the Maintenance button 

   .

   b. Tap the Diagnostics button 

   .

   c. Look under the STATUS & VOLTAGES tab and scroll down until “Foot Switch Pressed” can be seen.
   d. Step on the foot switch and ensure the indicator icon becomes filled in.
   e. Remove foot from foot switch and ensure the indicator icon clears.
   f. If the indicator icons do not respond appropriately, disconnect, and reconnect.

Fuses

1. Using a #4 Allen wrench remove the screws holding the power input connector in place. See Figure X.

Figure X.

2. Take out the old fuses and put in two new fuses.

3. Put the power input connector and screws back into place.
4. If the console powers up successfully no further testing is needed.

Power cord

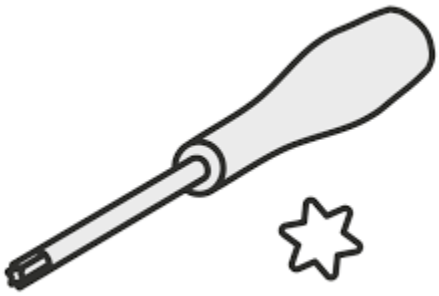
Figure X.

1. Power off the Console. Unplug the power cord from the electrical outlet.
2. The power cord connection to the Console includes a red locking mechanism. To disconnect, grasp the red locking mechanism with a finger and thumb. Pull back on the red locking mechanism to release the cord from the Console.
3. Attach the new power cord to the Console by inserting the end into the power input until the locking mechanism clicks. Connect the power cord to the electrical outlet.
4. Power on the Console. If the Console powers up successfully, no further testing is needed.

Foot switch holder and cord wrap

See Figures 1 and 2.

1. Using a Torx™ T15 (star driver) remove the two screws holding the foot switch feature in place.
2. Remove the damaged foot switch feature and replace with new component.
3. Screw each screw hand tight. Ensure the new part is not loose. No testing is needed.



Power cord wraps

Note: Upper power cord wrap requires a Phillips #2 and the bottom power cord wrap requires a Torx® T15.

1. Using the appropriate tool, remove the two screws holding the cord wrap in place.
2. Remove the damaged cord wrap and replace with a new component.
3. Screw each screw hand tight. Ensure the new part is not loose. No testing is needed.

Bag hanger

Figure X.

1. Using a Torx T15, remove the two screws holding the damaged bag hanger in place.
2. Remove the damaged bag hanger and replace with a new component.
3. Screw each screw hand tight. Ensure the new part is not loose. No testing is needed.

SPECIFICATIONS

Model	AutoElite
Dimensions, D x W x H	23.0 in x 16.7 in x 54.0 in (58.42 cm x 42.42 cm x 137.16 cm)
Weight	162 lb (73.48 kg)
Safe working load	162 lb +/- 5 lb (73.48 kg +/- 2.26 kg)
Voltage requirements	100-240 VAC
Frequency requirements	50/60 Hz
Current requirements	< 10 A RMS
Logic power backup outage	5 min for conditions of power loss
Equipment class	Class 1
Foot switch protection against ingress of liquid	IPX7
Degree of protection against electrical shock	Defibrillation-Proof Type CF Applied Part
RFID Reader Frequency bands	13.56 MHz
RFID Reader Maximum RF power	100 mW (+20 dBm)
Equipment maximum duty cycle	40 min of continuous pumping followed by 60 min of non-pumping
Transport temperature	store between 15°C - 25°C (59°F - 77°F); excursions permitted to -30°C to 60°C (-22°F - 140°F)
Transport relative humidity	Up to 85 % (noncondensing)
Storage temperature	store between 15°C - 25°C (59°F - 77°F); excursions permitted to -30°C to 60°C (-22°F - 140°F)
Storage relative humidity	Up to 85 % (noncondensing)
Operating temperature	10 °C to 40 °C (50 °F to 104 °F)
Operating humidity	30 % to 75 % (noncondensing)
Operating atmospheric pressure	700 hPa to 1060 hPa
Pollution	No greater than degree 2

Installation/overvoltage	No greater than category 2
Fuse	T10AL 250V
Cables	AC adapter cable Maximum cord length 15 ft (4.57 m)
	Foot Switch Maximum cord length 15 ft (4.57 m)
ETL CLASSIFIED C ETL US LISTED Intertek 5028357	Medical Electrical Equipment Conforms to ANSI/AAMI STD ES60601-1, and IEC STD 60601-1-6 Certified to CSA STDs C22.2# 60601-1, and 60601-1-6
FCC ID	2BCX3M001AJAEC
IC ID	31504-M001AJAEC

ELECTRONIC AND ELECTROMAGNETIC GUIDANCE

Table 1. Guidance and manufacturer's declaration — electromagnetic emissions
The AutoElite System is intended for use in the electromagnetic environment specified below. The customer or the user of the AutoElite System should assure that it is used in such an environment.
(In chart, remove AngioJet and change Ultra to AutoElite, 2 instances)

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The AngioJet Ultra System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The AngioJet Ultra System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker/emissions IEC 61000-3-3	Complies	
NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

Table 2. Guidance and manufacturer's declaration — electromagnetic immunity
The AutoElite System is intended for use in the electromagnetic environment specified below. The customer or the user of the AutoElite System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV input AC power ± 1 kV SIP/SOP 100 kHz repetition frequency	± 2 kV input AC power ± 1 kV SIP/SOP 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge: Line-to-line IEC 61000-4-5	± 0.5 kV, ± 1 kV input AC power	± 0.5 kV, ± 1 kV input AC power	Mains power quality should be that of a typical commercial or hospital environment.
Surge: Line-to-ground IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV input AC power	± 0.5 kV, ± 1 kV, ± 2 kV input AC power	
Voltage dips IEC 61000-4-11	0 % U_t for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_t for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Console requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply or a battery.
	0 % U_t for 1 cycle and 70 % U_t for 25/30 cycles Single phase: at 0°	0 % U_t for 1 cycle and 70 % U_t for 25 cycles (50 Hz) and 30 cycles (60 Hz) Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0 % U_t for 250/300 cycles	0 % U_t for 250 cycles (50 Hz) and 300 cycles (60 Hz)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	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	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	
Radiated RF EM fields IEC 61000-4-3	3 V/m between 80 MHz – 2.7 GHz At 80 % AM with 1 kHz modulation frequency	3 V/m between 80 MHz – 2.7 GHz At 80 % AM with 1 kHz modulation frequency	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	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	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	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: ((•))

NOTE 1: U_t 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 Ultra 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 Ultra System is used exceeds the applicable RF compliance level above, the AngioJet Ultra 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 Ultra System.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

(In notes above, remove AngioJet, change Ultra to AutoElite)

Proximity magnetic field IEC61000-4-39	134.2 kHz: 65 A/m, 2.1 kHz pulse modulation 13.56 MHz: 7.5 A/m, 50 kHz pulse modulation	134.2 kHz: 65 A/m, 2.1 kHz pulse modulation 13.56 MHz: 7.5 A/m, 50 kHz pulse modulation	Proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

(This will be added as last row of info before Notes rows)

Federal Communications Commission (FCC):
This device complies with Title 47, Part 15, of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

Industry Canada (IC):
This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by Boston Scientific Corporation could void the user's authority to operate the equipment.

In Canada, for information regarding RF exposure and compliance contact:
Company Name: Boston Scientific Limited
ISED Company Number: 4794B
Contact Name: Abby Chimonides
Address: 2 Paget Road, Unit #2, Brampton, Ontario, L6T 5G3
Telephone No: 905-696-1929
Email: abby.chimonides@bsci.com

Radio Spectrum, EMC, and RF Exposure Compliance Standards

The AutoElite Thrombectomy System complies with the applicable portions of the following spectrum compliance standards:

- EN 300 330 V2.1.1:2017
- EN 301 489-3 V2.3.2:2023-01
- EN IEC 62311:2020
- FCC 15.225:2023
- FCC 15.207:2023
- FCC 2.1091:2023
- RSS-210 Issue 10:2019
- RSS-Gen Issue 5
- RSS-102 Issue 5:2015+A1:2021

Radio Equipment Directive Declaration of Conformity

Boston Scientific hereby declares that the AutoElite Console, Model (Global UPN): M001AJAEC0200 is in conformity with the relevant Union harmonization legislation, Radio Equipment Directive 2014/53/EU.

To obtain a full text Declaration of Conformity, contact Boston Scientific using the information on the back cover of this manual.

WARRANTY
For device warranty information, visit **www.bostonscientific-warranty.com**.

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet at www.IFU-BSCI.com.

Back Cover

EC REP Authorized Representative in the European Community

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Update Australia and Argentina to current symbology.

ARG Argentina Local Contact

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Update symbology to current no-text version

Manufacturer

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