Auryon Atherectomy System

Operator Manual

CE 2797

Contents

Preface

The Auryon* Atherectomy System is a laser system cleared for use in peripheral arterial disease (PAD) atherectomy. The Auryon Atherectomy System generates pulsed laser radiation delivered to the target site with proprietary fiber optic catheter technology.

The Auryon Atherectomy System includes the laser system and the Auryon Catheter (hereinafter "catheter", "Auryon catheter"). The laser system includes the laser itself, a pump, a reusable canister, a footswitch pedal, control touch panel, Emergency Off (EMO), a key switch, the system aperture (connector housing), LED indicator panel, the system handle, wheels, a rear storage compartment, and a power cord.

For additional information, technical and specific details for use of the Catheters with the laser system, please refer to the Instructions for Use, document IFUE110 or IFUE120 that are provided with the catheter.

Note: do not use any equipment, catheters or other disposables with the laser system that were not provided by AngioDynamics or an AngioDynamics` authorized distributor.

Before operating the system, users should thoroughly read this manual.

The Auryon system is operated by software and contains an RFID.

Notice

Radio Frequency Identification

FCC ID: Z97-1149466

The Auryon Atherectomy System incorporates radio frequency identification (RFID) technology. The RFID card with its FCC ID label is located inside the optical system box. The RFID antenna is located above the catheter`s connector housing. The RFID is used to wirelessly identify and authenticate disposable Auryon catheters. An RFID tag is integrated into each catheter`s connector. The tags contain an integrated circuit and an antenna used to transmit data. The information is read by an RFID reader that stores the information collected from the tags into a database for further analysis. The RFID operates at a frequency of 125kHz and has an operating distance range of 1 ± 0.2 inches (2.5 cm ± 0.5 cm).

For Quality of Service (QoS), the detection, reading, and writing of a tag at a specific antenna has 99% reliability. If two tags are detected in range of the same antenna, both will be ignored until only one tag is detected.

The Auryon System may take up to 5 seconds to process. If the system cannot recognize or read the tag because of a communication issue, the user cannot progress to the next step and should try to reconnect the catheter to the system aperture. If that does not work, then the user should try a new catheter. If neither of these solutions work, contact customer service.

This device complies with 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Notice

The Auryon Atherectomy System contains no user serviceable parts or assemblies.

In the event of fault or suspicion regarding the Auryon Atherectomy System, contact AngioDynamics, Inc. for service or system replacement. Do not attempt to solve the fault on your own.

Service of the Auryon Atherectomy System must be performed only by AngioDynamics or an authorized AngioDynamics representative. Performing unauthorized service or repairs not described in this operator manual or a product manual will void the product's warranty. For service and advice or any issue related to the Auryon Atherectomy System, please call AngioDynamics Inc. at 800-772-6446

EU represented by:

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Haaksbergweg 75
1101 BR
Amsterdam
The Netherlands

1. Glossary

1.1. Alignment
Adjustment of the elements in the system in order to achieve optimization of the system.

1.2. Optical fiber catheter
Disposable device that is inserted into the patient's artery to deliver laser radiation to the targeted lesion.

1.3. Distal end
The end side of the device located away from the point of origin or attachment.

1.4. Electrical socket
Also called an "outlet".

1.5. Fluence
The energy density at the optical fiber catheter output expressed in energy (mJ)/cross section area (mm^2).

1.6. IP68 and IP65
The IP code indicates the protection rating of different devices, wherein the first digit gives solid particle protection, and the second digit indicates the liquid ingress protection.

1.7. Joule [J]
A unit of energy expressed as one watt (a unit of power) multiplied by the time (in seconds).

1.8. Laser
An acronym for Light Amplification by Stimulated Emission of Radiation.

1.9. Power cable
The electrical cable connecting the system to the electricity, also called a "power cord".

1.10. Proximal end
The end side of the device nearest to the point of attachment or origin.

1.11. Repetition rate
The rate at which the laser delivers pulses, usually expressed as pulses per second.

2. Warnings, Responsibility, Intended Purpose and Indications for Use

IMPORTANT

Read the Operator Manual thoroughly before operating the Auryon Atherectomy System. Please pay attention to the NOTES, CAUTIONS, WARNINGS and DANGERS throughout this manual to ensure safe operating conditions at all times.
Also refer to the Instructions for Use which accompany the catheters.

Intended purpose:
For Infra Inguinal Atherectomy, use with the Auryon Laser System.

Indications for Use:
The Auryon Atherectomy System used together with Auryon Atherectomy Catheters with aspiration are indicated for use as atherectomy devices for arterial stenoses and occlusions, including in-stent restenosis (ISR), and to aspirate thrombus adjacent to stenoses in native and stented infra-inguinal arteries.

The Auryon Atherectomy System used together with Auryon Atherectomy Catheters without aspiration are indicated for use as atherectomy devices for arterial stenoses and occlusions, including in-stent restenosis (ISR), in native and stented infra-inguinal arteries.

DANGER
Possible explosion hazard if the laser is used in the presence of flammable anesthetics or other solutions and gases. The laser beam may ignite solvents of adhesives and flammable solutions. Allow flammable materials to evaporate before the laser is used.

WARNING
The Auryon Atherectomy System is a Class IIb medical device. It contains a Class IV laser that produces an invisible beam of high-energy ultraviolet radiation. Improper use of the Auryon Atherectomy System could result in serious personal injury. Observe all safety precautions for use of Class IV laser equipment.

WARNING
The Auryon Atherectomy System contains potentially lethal high voltages. To avoid electrical shock, do not open the Auryon Atherectomy System cover. Internal maintenance of the system must be performed only by authorized representatives of AngioDynamics.

WARNING

The system is not intended to be used during a defibrillation event.

WARNING

Eye and skin exposure to laser radiation should be avoided.

WARNING

Only catheters approved by AngioDynamics may be used in the Auryon Atherectomy System. The Auryon Catheters are supplied sterile. Sterility is guaranteed only if the package is unopened, undamaged and used before the expiry date.

WARNING

Pay attention when handling the Auryon Catheter to ensure that the fibers at the distal and proximal ends are not damaged.

WARNING

When moving the Auryon Atherectomy System, be careful to avoid crashes and sudden impacts. Before moving the system, unlock the wheels, disconnect the footswitch pedal cable from its connector in the laser system, and place the footswitch pedal in the rear storage compartment. After the system is positioned for use, lock the wheels, take out the footswitch pedal from the rear storage compartment, connect the footswitch pedal cable to the laser system, and place the footswitch pedal on the floor.

WARNING

Some sources of electromagnetic disturbance, such as diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors may possibly interfere with the Auryon system. Keep these sources out of the area where the Auryon system is being used.

CAUTION

Do not block air intake/exhaust openings located in the front and back sides of the laser system.

CAUTION

Ensure the system is connected to the proper voltage. The voltage rating is marked on the back panel of the laser system. Operating the system at the incorrect voltage may result in damage to the system units.

CAUTION

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

CAUTION

The Auryon Atherectomy System is not intended to work in an environment with the possible presence of flammable gases.

NOTICE

The Auryon Atherectomy System is intended for use only by licensed physicians. All persons who operate and service this equipment must be properly trained by AngioDynamics Inc.

WARNING

The Auryon atherectomy system is MR unsafe.

WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

The equipment is manufactured with substances that are considered hazardous to the environment and cannot be disposed of directly. In the event that the customer wishes to remove the equipment from service, the system must be sent to AngioDynamics, Inc.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

3. Specification

The Auryon Atherectomy System is a pulsed laser system with the following nominal specifications:

Active medium	Nd:YAG
Wavelength	355 nm ±1 nm
Catheter output fluence*	50-60 mJ/mm^2
Catheter Output Fluence Accuracy Level	±20%
Pulse repetition rate	40 Hz
Energy at the catheter tip at 60 mJ/mm^2	30.6 mJ/Pulse
Averaged Power at the catheter tip at 60 mJ/mm^2	1.2 Watt
Beam divergence (at the catheter tip – full angle)	25.4 Deg
Pulse width (duration)	10-25ns, FWHM
Weight	90 kg / 198.45 lbs
Main body volume:	
Length	74 cm / 29.13 in
Height	95 cm / 37.4 in
Width	34 cm / 13.38 in
Blocking volume:	
Length	91.2 cm / 35.9 in
Height	128.7 cm / 50.66 in
Width	50.5 cm / 19.88 in
Control touch panel	10.1in diagonal
Aspiration (Vacuum) level	70-100 Torr

The system footswitch is IP68 rated and the control touch panel is IP65 rated
Power Requirements: EU: 200-240 VAC, 50/60 Hz, 10A, Single Phase

The system complies with IEC60601-1, IEC60601-2-22, IEC60825-1 and IEC60601-1-2 standards.

Environmental specifications:

- Operating temperature: 15 °C to 30 °C (59 °F to 86 °F)
- Storage temperature: 5 °C to 50 °C (41 °F to 122 °F)
- Transportation temperature: -40 °C to 70 °C (-38 °F to 158 °F)
- Operating humidity: 10 to 75% relative humidity, non-condensing
- Storage humidity: 10 to 90% relative humidity, non-condensing
- Transportation humidity: 10 to 90% relative humidity, non-condensing
- Atmospheric pressure range for operation: 70 kPa to 106 kPa
- Atmospheric pressure range for storage and transportation: 50 kPa to 106 kPa

* See the Directions for Use documentation supplied with each Auryon catheter regarding the appropriate energy level (fluence) setting information.

Auryon Atherectomy Catheters

The following catheters are available for use with the Auryon Atherectomy System. To obtain more specific information refer to the Directions for Use of the specific catheter.

Part Number	Description
EXM-4E01-0000	Auryon Catheter 1.5mm
EXM-4E02-0000	Auryon Catheter 0.9mm
EXM-4E03-0000	Auryon Catheter 2.0mm
EXM-4E04-0000	Auryon Catheter 2.35mm
EXM-4E01-H000	Auryon Catheter 1.5mm, with Hydrophilic Coating
EXM-4E02-H000	Auryon Catheter 0.9mm, with Hydrophilic Coating
EXM-4E03-H000	Auryon Catheter 2.0mm, with Hydrophilic Coating
EXM-4E04-H000	Auryon Catheter 2.35mm, with Hydrophilic Coating

Components supplied with the system:

- Power cord
- Foot switch pedal
- Safety goggles
- Canister

Description of devices required **for Auryon procedure**:

The following commercially available devices are required for an atherectomy procedure with the Auryon Atherectomy System:

- 0.014 in (0.36 mm) guidewire with a minimum length of 300 cm
- Sterile suction tube, with length of 2-3m, maximal diameter of 6mm and funnel connectors
- Vascular access sheath of sufficient diameter for the catheter size
- 1 liter disposable liner with overfill protection mechanism

4. Safety Precautions

1. The Auryon Atherectomy System must be operated only by personnel who have been trained by AngioDynamics, Inc.
2. Ensure that all entrances to the procedure room are equipped with appropriate laser warning signs.
3. All persons in the laser operating area including doctors, nurses, observers, and the patient must wear the appropriate laser safety goggles. Laser safety goggles of 5 OD or greater at 355 nm must be worn before the laser is activated. The laser safety goggles must state the OD rating and wavelength on the lens or on the side shields. **Wear only the safety goggles supplied by AngioDynamics, Inc.**
4. Never look directly into the laser beam.
5. Avoid reflections of the laser beam.
6. Skin exposure to laser radiation should be avoided.
7. If exposed optical fibers have been identified along the catheter outer cover, replace the catheter.
8. When the laser system is not in use, remove the key switch and keep it in a safe place.
9. Do not open the laser system.
10. Do not bypass electrical connections.
11. **In the event of an internal fault in the laser system, turn off the laser system and contact an AngioDynamics representative for further instructions.**

5. Nominal Ocular Hazard Distance (NOHD)

The nominal ocular hazard distance (NOHD) is defined by the American National Standard (ANSI®) Z136.1 – 2007 as the distance along the axis of the unobstructed beam from the laser (catheter output) to the human eye beyond which the irradiance or radiant exposure during operations is not expected to exceed the applicable maximum permissible exposure (MPE) limits.

The laser energy produced by the Auryon Atherectomy System is enclosed within the system and no laser energy is emitted out of the system when operated according to this operator manual. The optical fiber catheter is within the patient`s body during the clinical procedure so there is no case in which the user should be aware of the NOHD.

6. EMC Precautions

Special precautions are required regarding the Electromagnetic Compatibility (EMC) of the Auryon Atherectomy System. The system must always be installed according to the EMC information provided in this manual.

No device functions are considered essential to the safety of the user or patient.

Pay attention to the warnings and the instructions below:

WARNING
Use of the Auryon Atherectomy System adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The Auryon Atherectomy System must be used only with power cables and equipment provided by AngioDynamics, Inc.

WARNING
Use of equipment, transducers and cables other than those specified or provided by AngioDynamics, Inc. (the manufacturer/distributor of this equipment) could result in increased electromagnetic emissions or decreased electromagnetic immunity of the system and result in improper operation.

WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Auryon Atherectomy System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the system could result.

Note: The emissions characteristics of the Auryon Atherectomy System 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.

Essential performance: The essential performance of the Auryon Atherectomy System consists of the normal operation of the vacuum pump with energy level maintained within the range of ±20% of the preset value. Follow the guidance of this clause to maintain the essential performance of the system.

RFID system: The frequency of reception and transmission of the RFID system is 125kHz. The modulation type is Amplitude Shift Key (ASK). The effective Radiated Power (ERP) is 70 dB (uV/m) @ 3m

The Auryon Atherectomy System should be used in the electromagnetic environment specified in all the tables below.

It is the user's responsibility to verify that the Auryon Atherectomy System is used in the environment specified below:

Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1 Class A	The Auryon Atherectomy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The Auryon Atherectomy System is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Auryon Atherectomy System or shielding the location.
Voltage fluctuations and flicker IEC 61000-3-3:2013	Complies	

Declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15 kV air	8 kV contact 2, 4, 8, 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 for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV signal input/output to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycles	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Auryon Atherectomy System requires continued operation during power mains interruptions, it is recommended that the Auryon Atherectomy System be powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

Declaration – electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V, 6 V	3 Vrms, 6 V	Portable and mobile RF communications equipment should be used no closer to any part of the Auryon Atherectomy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	$d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
	3 V from 0.15 to 80M Hz; 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz	3 V from 0.15 to 80 MHz; 6 V from 0.15 to 80 MHz and 80% AM at 1 kHz	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 V/m from 80 MHz to 2.7 GHz	10 V/m from 80 MHz to 2.7GHz	

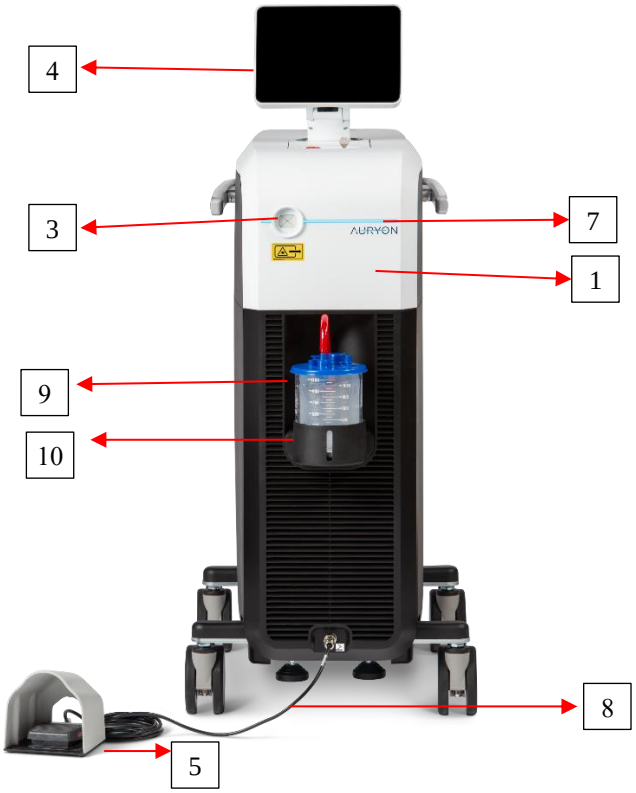
Recommended separation distances between portable and mobile RF communications equipment and the Auryon Atherectomy System				
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 –390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9	9
5500							
5785							
NOTE: If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.							

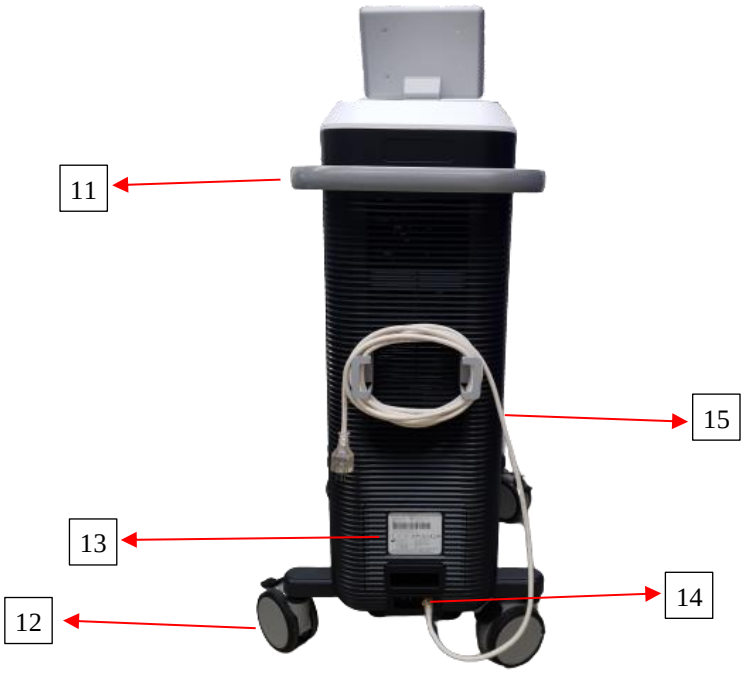
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation 2.1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7.5

7. Auryon Atherectomy System Components' Description

1. Laser system – The "Laser System" is a console that incorporates the laser head and its optics, a controller, an electrical unit, and a dedicated vacuum pump supplied with the system. In addition, the console is composed of the following components.
2. Key switch – For main system "On" and "Off" control
3. System's aperture (connector housing)
4. Control touch panel – The interface for the laser operator
5. Footswitch pedal – To be pressed and released by the treating physician to activate and deactivate the laser energy
6. EMO (Emergency Machine Off) – A button to be pushed in case of an immediate need to shut off the laser system.
7. LED indicator panel – indicates different levels of laser status: stand by, ready, and active
8. Footswitch pedal cable
9. Reusable Canister (including disposable liner inside).
10. Canister base – to hold the canister for aspiration
11. System's handle
12. Wheels
13. Rear storage compartment to store the footswitch pedal
14. Power cord connector
15. Power cord



Front side of the laser system



Back side of the laser system

Note: Not shown is the Sterile catheter and the aspiration Tube that is connected on one side to the catheter handle and the other end to the Disposable Liner's cap (the blue cap shown in item 9 of the image).

8. Laser System Labeling

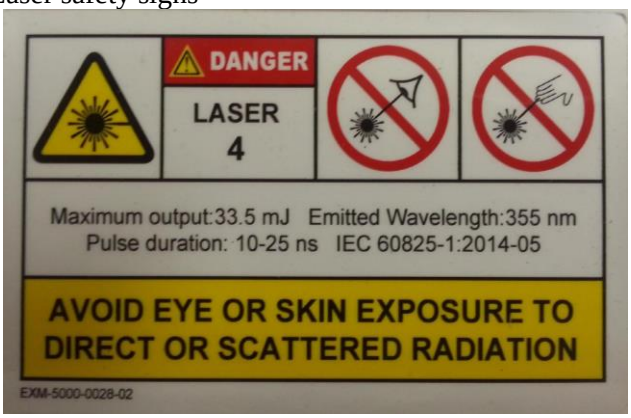
8.1. On the back of the laser system

The following label is located on the rear storage compartment:
Laser system identifying label

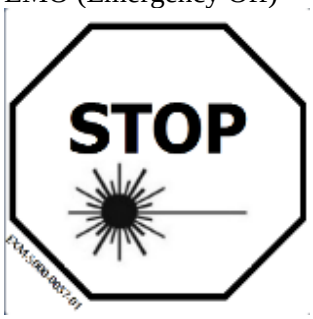
The equipotentiality label is located at the back panel next to the equipotential plug

8.2. On the top of the laser system

Laser safety signs



EMO (Emergency Off)



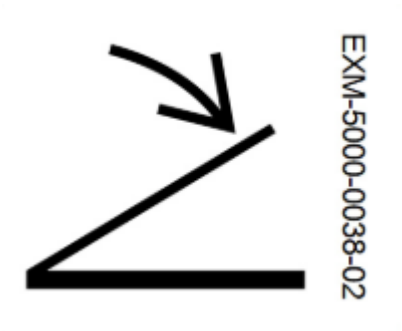
This label is located on top of the EMO.

8.3. On the front of the laser system

Laser aperture sign

This label is located next to the system's aperture (connector housing).

Footswitch pedal connector



8.4. On the laser system package

Laser system identifying label regarding the laser system package

See Appendix A for pictures of the labels' locations.

9. System Controls

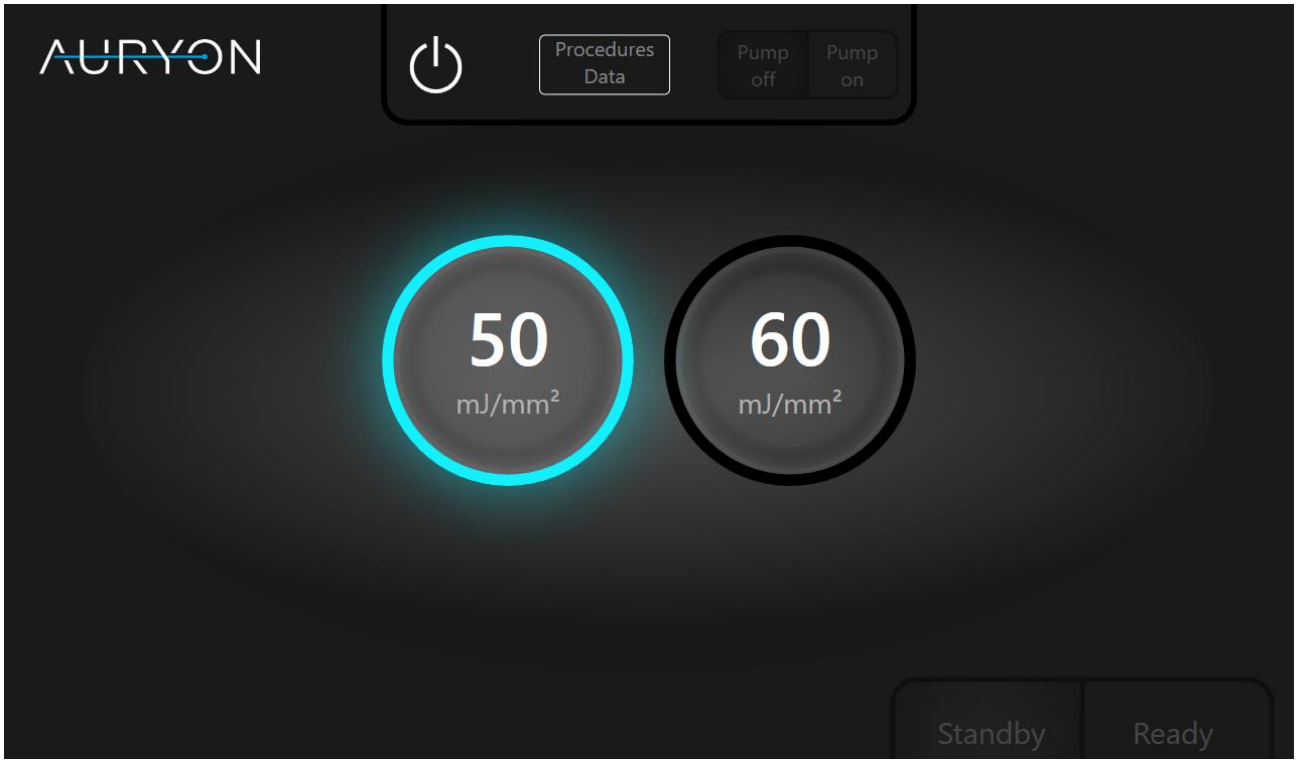
9.1. Control touch panel screens

This section describes the different screens that will be used by the operator during the procedure. This section does not describe the steps to prepare the system for operation, nor does it describe the steps to operate the system during the procedure. Both procedures are described in section 10.

Available screens during procedure flow

After the laser system has been activated by turning the key switch clockwise, a “please wait” message followed by countdown timer will be presented:

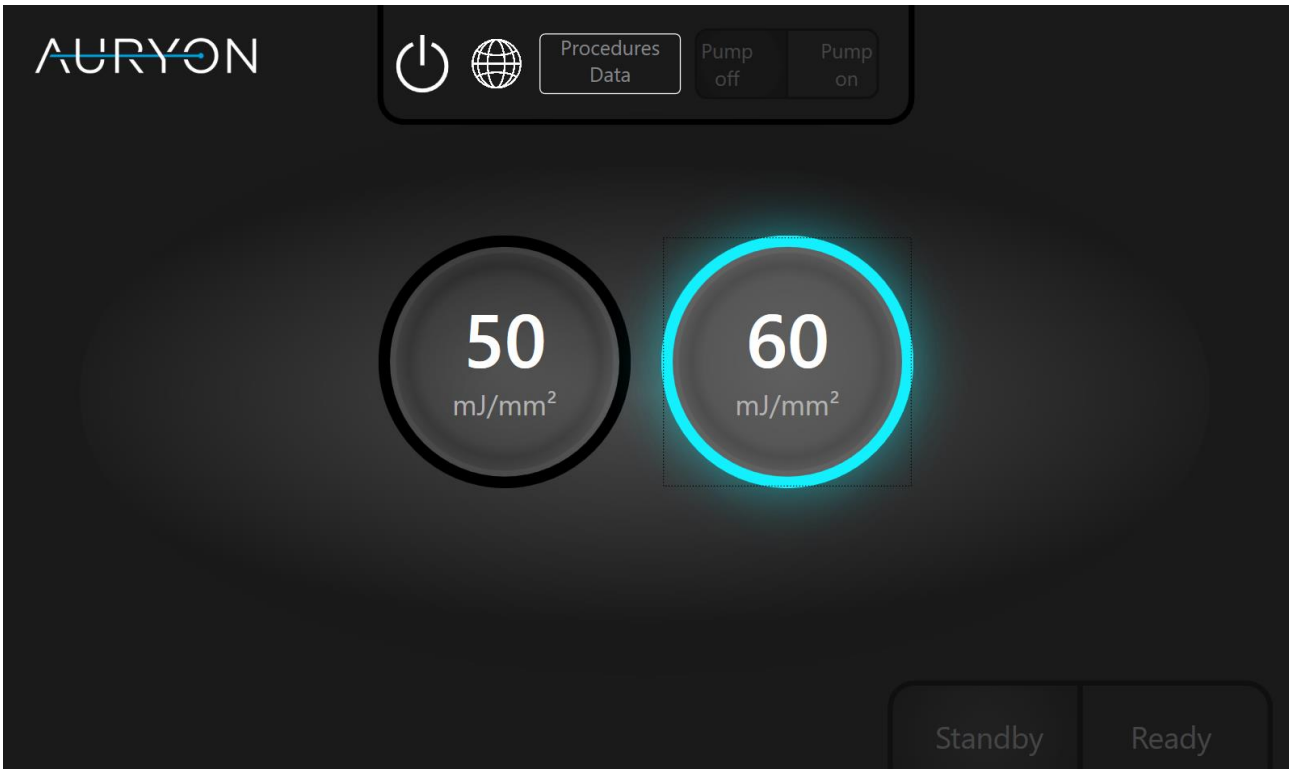
Once the countdown is complete, the system is ready for use and the following screen will appear on the control touch panel:



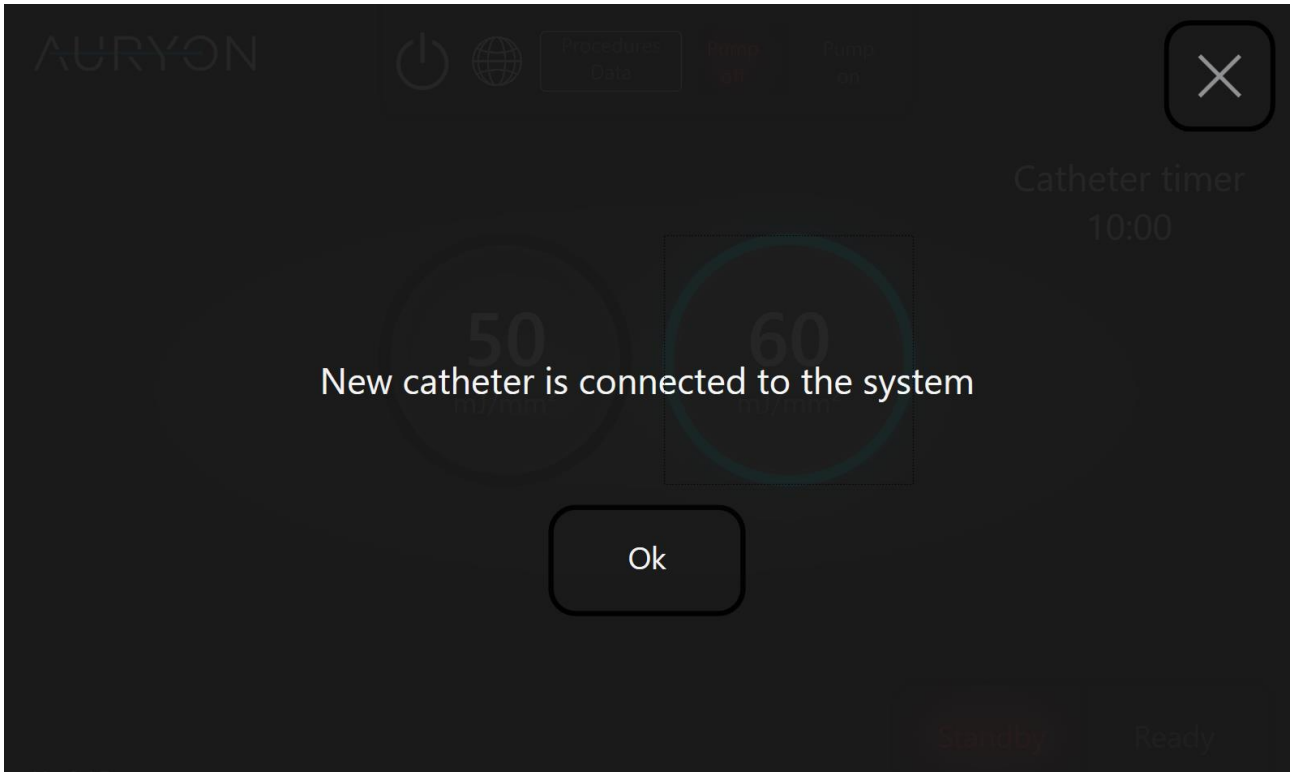
The default energy level 50 mJ/mm² is selected and has an illuminated blue circle around it. In this default mode both “Standby” and “Ready” are in gray and disabled.

To increase the energy level, select 60 mJ/mm².

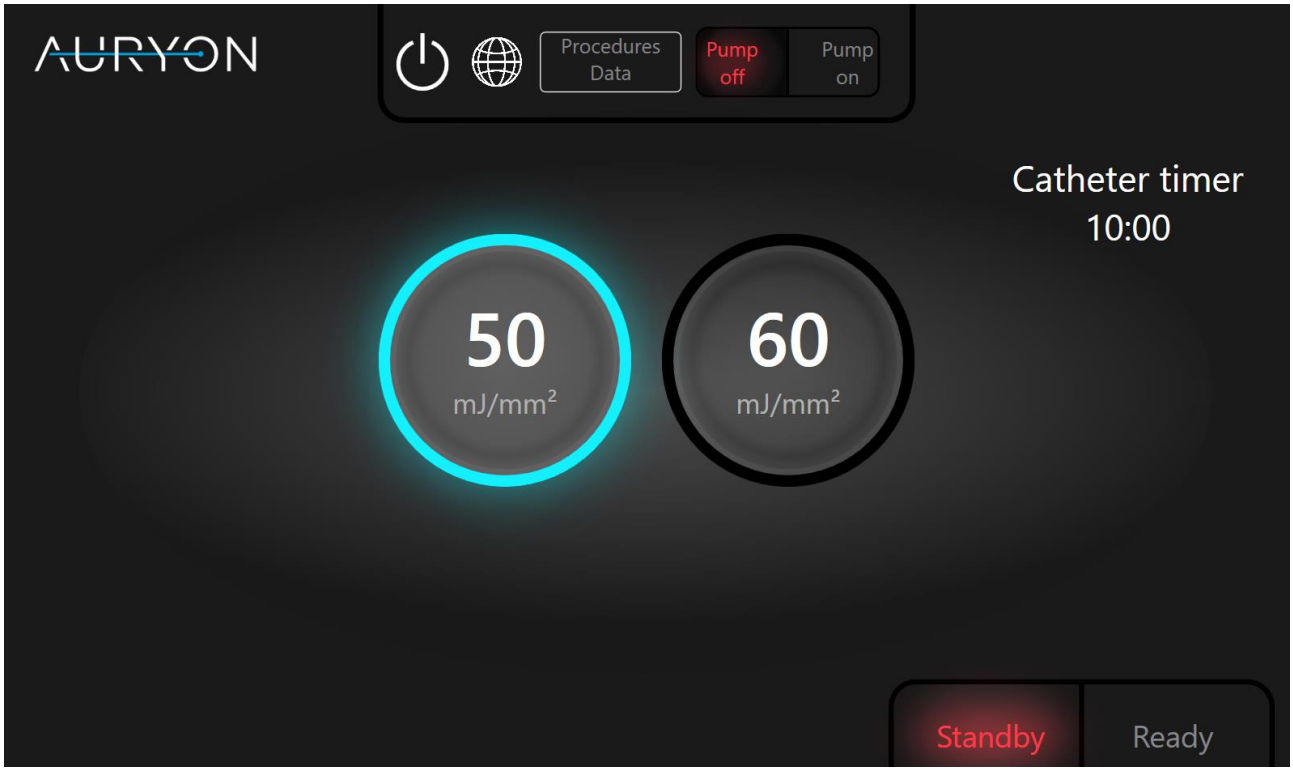
The image below shows an example of the 60 mJ/mm² energy level selected:



After connecting a catheter to the system, the catheter's RFID tag will be recognized by the RFID reader inside the connector house, and a notification will appear:

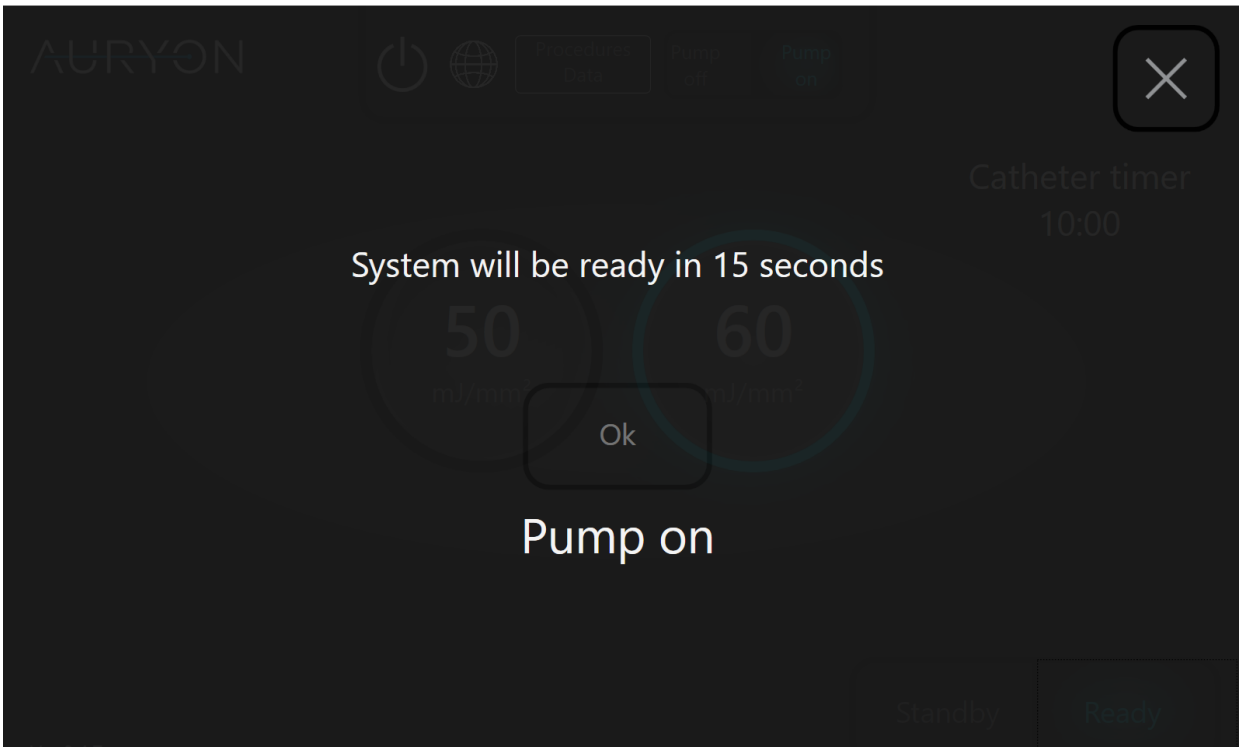


Once the "OK" button is pressed the following screen with the system activation mode ("Standby" and "Ready"), and the catheter counter time (all catheters can work no more than 10 minutes) will appear:



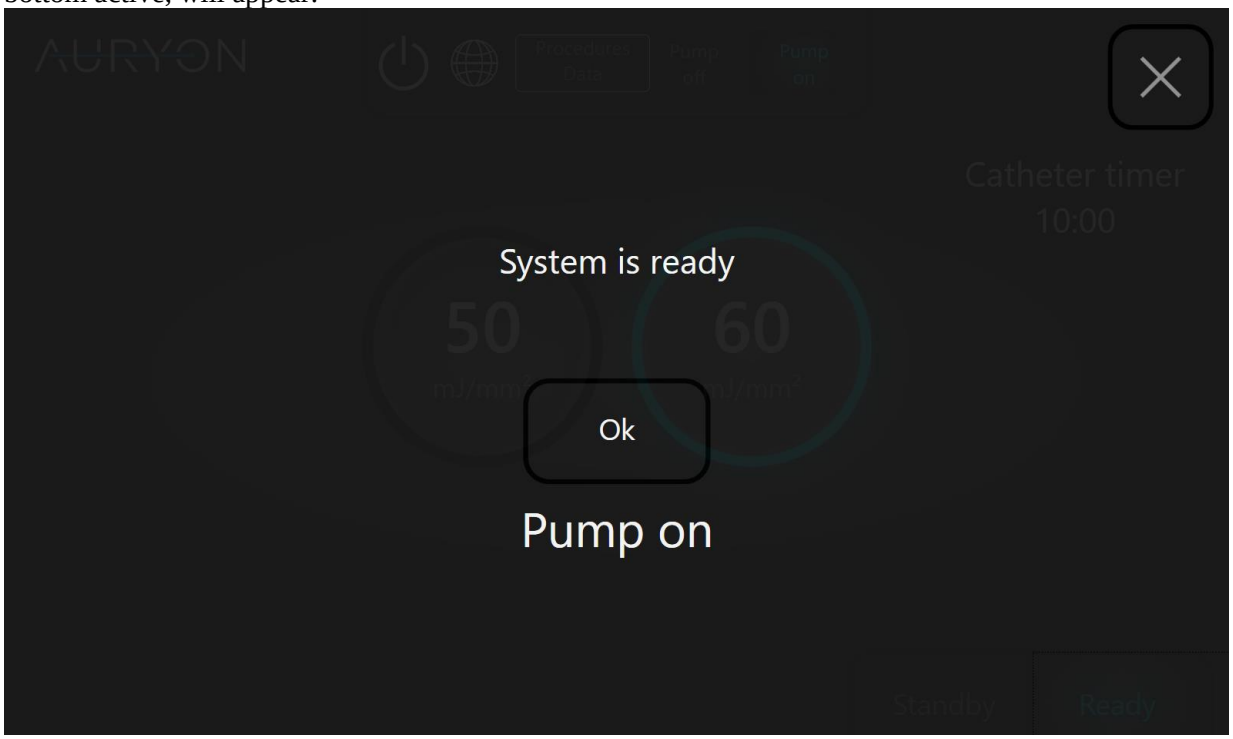
The pump toggle will be enabled (means that both icons of "Pump off" and "Pump on" are accessible) only if 2.0mm or 2.35mm catheters are connected to the system, as shown above.
In Standby mode, the pump is off by default, and the "Pump off" icon will be illuminated in red.

To continue, press the "Ready" icon. This will activate the pump (in the 2 and 2.35mm catheters) and at the same time the system will start a 15-second countdown while stating that the pump is on. After the countdown ends, the system will be in “Ready” mode. The countdown screen is shown below:



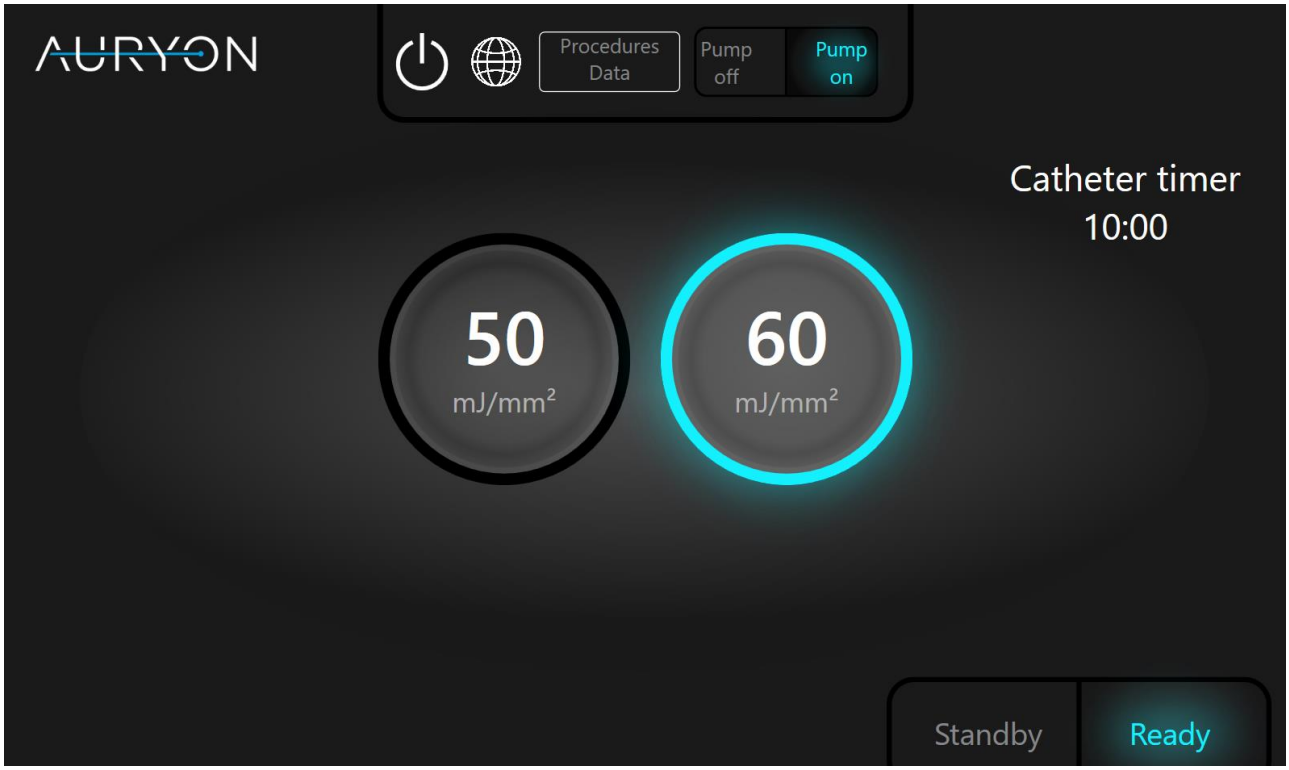
Note: In case that there is a momentary fault, the system may restart the countdown. In this case, a message will be presented to the user: "Countdown restarted". To return to the “Standby” mode during the countdown, press the "X" icon at the top right of the screen. The system will return to "Standby" mode and the screen with the energy level selection icons will be shown.

The system will be ready after the 15 seconds countdown is complete, and the following screen, with “OK” bottom active, will appear:



If the "X" icon (located on the top right of the screen) is selected, the system returns to "Standby" position and the screen shown above with the energy level selection icons will appear again.
Press "OK" to continue.

In the next screen, all toggles are highlighted in blue, showing that the pump is on, the status is on “Ready” mode, the energy that was chosen (keep in mind that the default is 50mJ/mm2), and the counter that starts with the maximum 10 minutes.



The energy selection screen will appear with the "Ready" icon illuminated in blue, as shown below. The system is now in “Ready” mode. The energy level can also be changed in “Ready” mode before the laser is activated.

Note: *Pump activation and deactivation are also available when the system is in "Ready" mode by pressing the "Pump off" icon for deactivation or "Pump on" for activation. When the physician resumes pressing the footswitch, while the system is in “Ready” mode, the pump will automatically turn on again.*
Note: *The pump is always on when the laser is active.*

To start emission of laser radiation from the Auryon catheter (connected to the laser system), the physician should press the footswitch pedal only when the system is in “Ready” mode and the catheter tip has been placed just proximally to the target lesion. Once footswitch pedal is pressed, the following screen will be shown:

The "LASER ON" label on the screen indicates that laser radiation is being emitted from the system and as soon as laser emission begins, the timer on the screen is activated. The timer in the middle of the screen indicates the operating time of the laser in each laser activation cycle in **Minutes:Seconds.** In this example, 11 seconds of lasing elapsed, so 9 minutes and 49 seconds remain for catheter activation.
The timer is activated only when the footswitch pedal is pressed.

Note: *In the background of the screen, the selected energy level (50mJ/mm^2) can be seen in fade status, with a blue circle illuminated around it.*

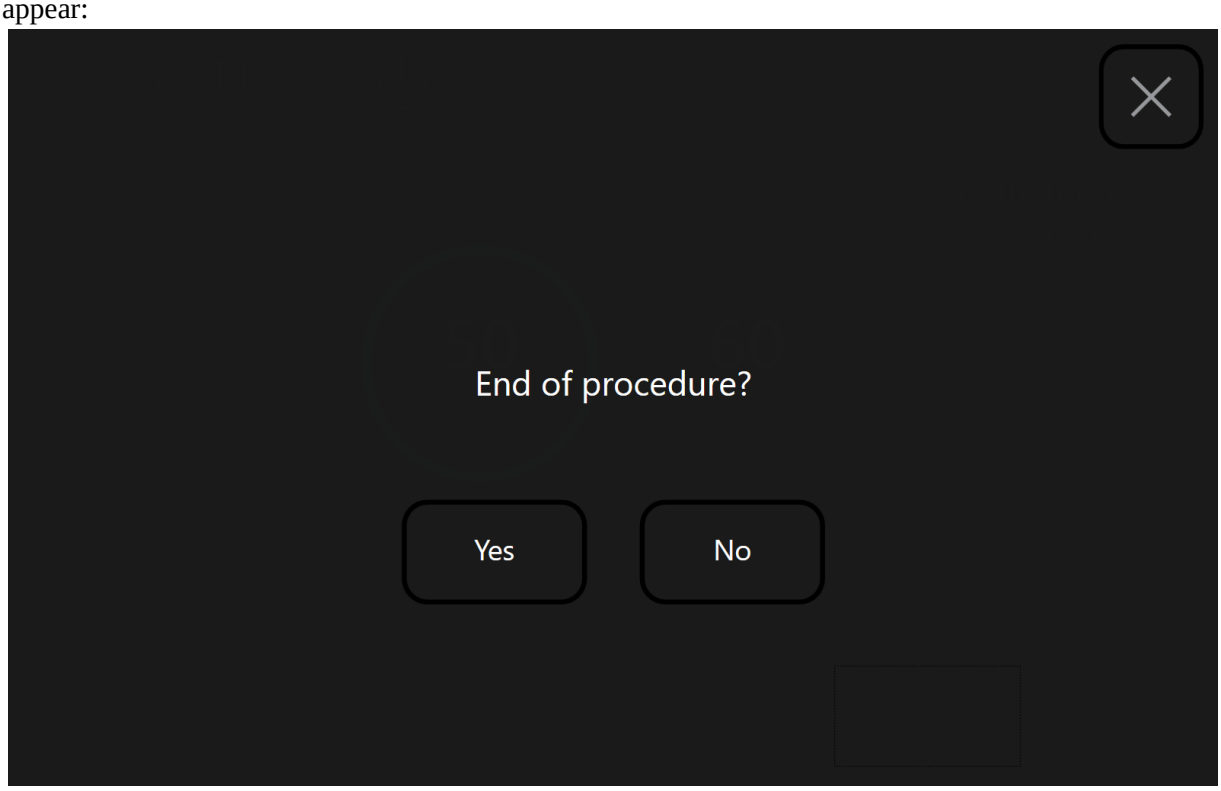
NOTE: *50mJ/mm^2 is the default energy level that should be used. 60mJ/mm^2 should be used only when the physician feels high resistance in advancement.*

NOTE*: Pressurized saline (preferably heparinized) should be continuously fed through the introducer sheath or the guiding catheter that is positioned as close as possible to the Auryon catheter distal tip at a rate of 100ml/min. Saline should be fed throughout the entire duration of the atherectomy procedure while inside the body.*

To stop the emission of the laser, the physician should release the footswitch pedal. The system will stay in “Ready” mode and the energy selection screen will appear again.

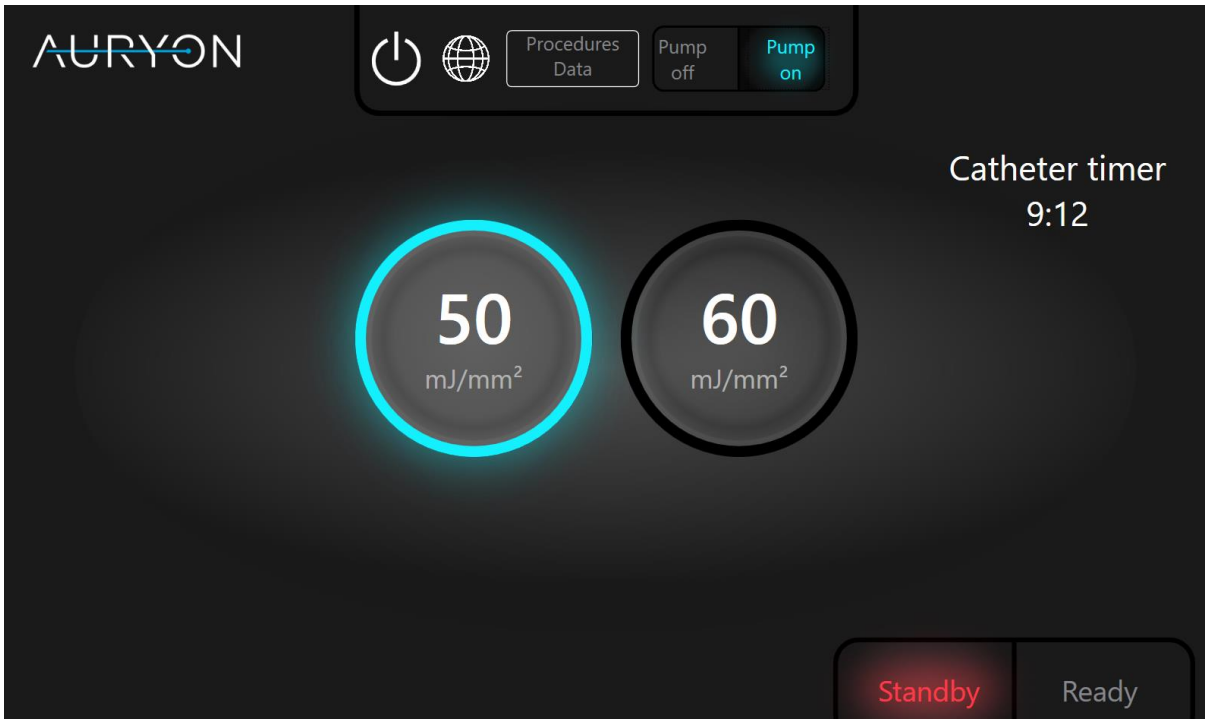
The physician can reactivate and deactivate the laser only by once again pressing and releasing the footswitch pedal.

Per physician request, moving from “Ready” mode to “Standby” mode should take place by pressing the “Standby” icon, and the system will ask the operator if the procedure ended. The following screen will appear:

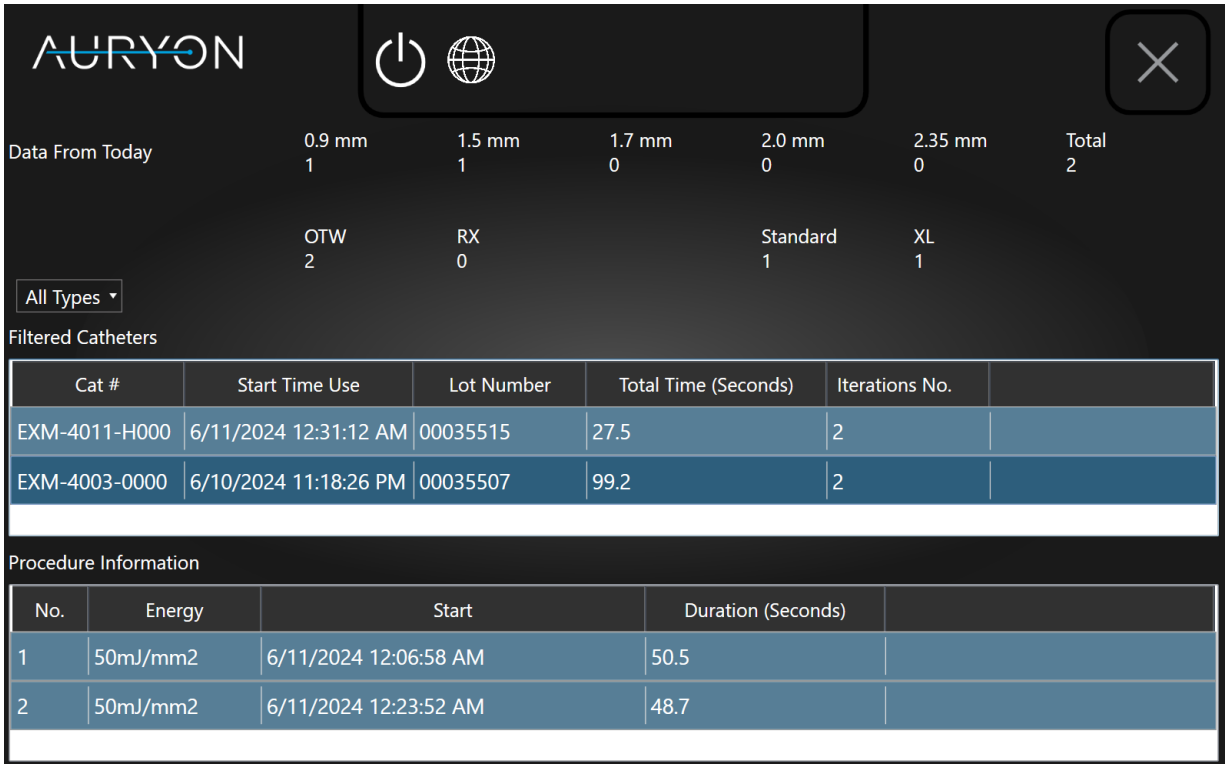


If the procedure has ended, press “Yes”. If additional laser activation is needed, press “No”.

To activate the pump **when the system is in "Standby" mode (e,g, per physician request while the catheter is still in the arteries)**, press the "Pump on" icon. It will then be illuminated in blue with “Standby” in red as the current status as shown in the screen below:



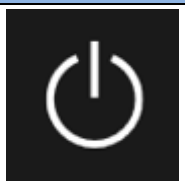
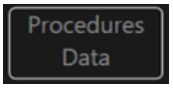
In order to get a summary of all the procedures done in the same day, press the “procedure data” button. This will open following screen:



This screen indicates the number of procedures done that day with counters according to catheter size, type (OTW/RX) and length (standard/XL). It also presents a list of all catheters used with the date and time of usage. Upon pressing on a catheter in the list, the user can access the procedure information, including energy level used, date, time and duration.

See Section 10.1 for further operation instructions.

9.2. Icons' descriptions

Icon	Description	Icon image
PC and Screen Off	Pressing this icon will turn off the PC and control touch panel.	
50 mJ/mm²	Pressing this icon will adjust the output energy of the laser system so that the catheter output fluence (at the distal tip) will be 50 mJ/mm².	
60 mJ/mm²	Pressing this icon will adjust the output energy of the laser system so that the catheter output fluence (at the distal tip) will be 60 mJ/mm².	
Stand-by	The system is placed in **Standby** mode and is not emitting laser radiation.	
Ready	The system is placed in **Ready** mode and is ready to emit laser radiation. To release laser energy from the system, the system should be in **Ready** mode and the user must press the footswitch pedal.	
Pump off	When the system is in "Standby" mode, this is the default pump mode.	
Pump on	When the system is in "Ready" mode this is the default pump mode for the 2.0 and 2.35mm catheters.	
Procedures data	By pressing this icon, a screen with the procedures data will be presented to the user.	
Language icon	By pressing this icon, a list with all the available languages will be opened. Once new language is selected, the system restarts and uploaded with the new language.	

9.3. Safety controls

Key switch: The **key switch** is the power control for the Auryon Atherectomy System and is located on the top of the laser system. In order to activate the laser system, turn the **key switch** from the OFF (◯) position to the ON (|) position.

The laser equipment should be protected against unauthorized use, by removal of the key from the key switch when not in use.

EMO (Emergency Off Button): In case of an emergency that requires sudden shutdown of the Auryon Atherectomy System, press the **EMO** to immediately stop laser activation. Caution should be taken not to activate the **EMO** accidentally. To reactivate the system, rotate the **EMO** clockwise.

LED indicator panel: The **LED indicator panel** is located on the front side of the Auryon Atherectomy System, on the left and right of the system's aperture (see Section 7).

When the laser system is turned on, the **LED indicator panel** will be illuminated by a constant blue LED on the left of the system's aperture only (see below left image).

When the "Ready" icon is pressed, the **LED indicator panel** will remain illuminated a constant blue on the left of the system's aperture during the 15-second countdown, while to the right of the system's aperture there will be a blinking blue light.

After the 15-second countdown has ended and the system is still in "Ready" mode, the **LED indicator panel** will illuminate a constant blue to the left and right of the system's aperture (see below middle image).

Then, when the footswitch pedal is pressed, a blinking yellow light from the **LED indicator panel** will be seen to the left and right of the system's aperture (see below right image).

		
Laser system in "Standby" mode. Constant blue light to the left of the aperture	Laser system in "Ready" mode. Footswitch pedal is not pressed. Constant blue light.	Laser system is active. Footswitch pedal is pressed. Blinking yellow light.

Footswitch pedal:

The purpose of the **footswitch pedal** is to cause the Auryon Atherectomy System to emit the desired laser radiation out of the operating catheter distal end during the clinical treatment, when the laser should be activated according to the IFU.

The **footswitch pedal** is used by the treating physician to control the laser emission out of the Auryon Atherectomy System safely and easily, without the risk that laser energy will be emitted accidentally or the need to be occupied with the control touch panel during treatment.

The **footswitch pedal** can be activated by pressing it when the system is in "Ready" mode after the 15-second countdown.

When the **footswitch pedal** is released, the system stops emitting laser radiation. The system status will remain in "Ready" mode with the previously selected energy level and pump status.

Caution should be taken not to activate the **footswitch pedal** accidentally.

10. Operating the System

10.1. Setting up System

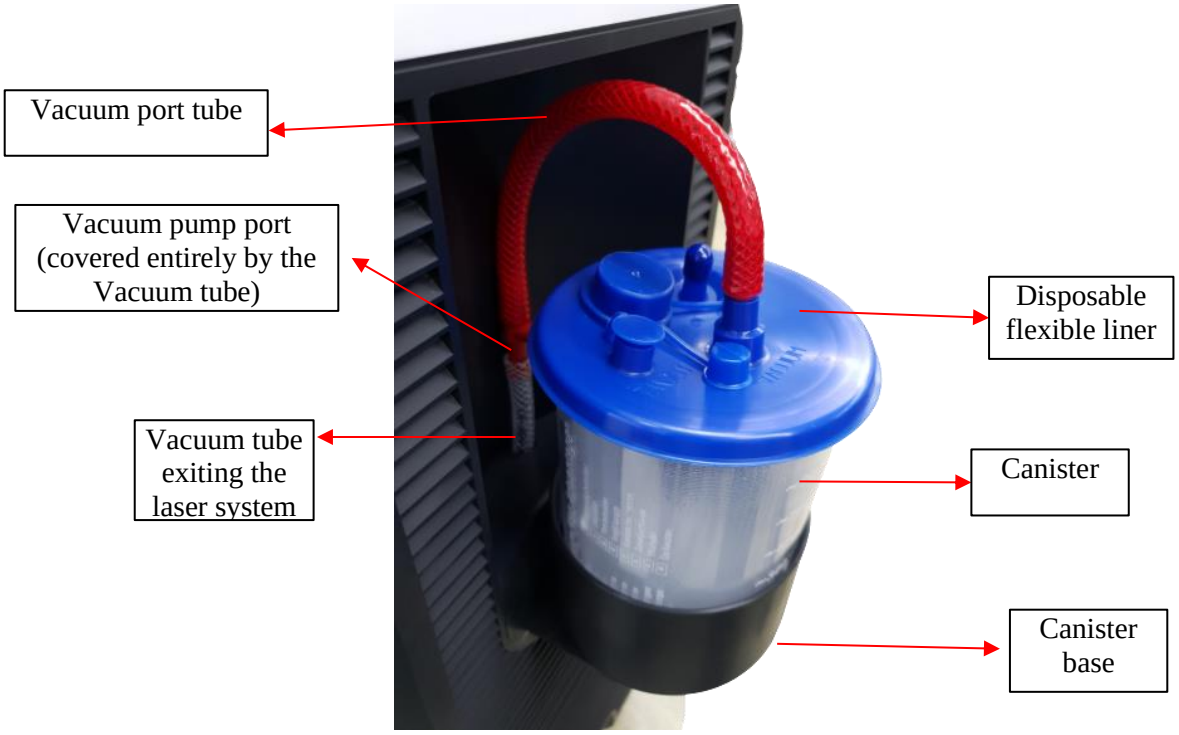
Note: Only personnel trained by AngioDynamics should activate the system.

10.1.1. Prior clinical procedure:

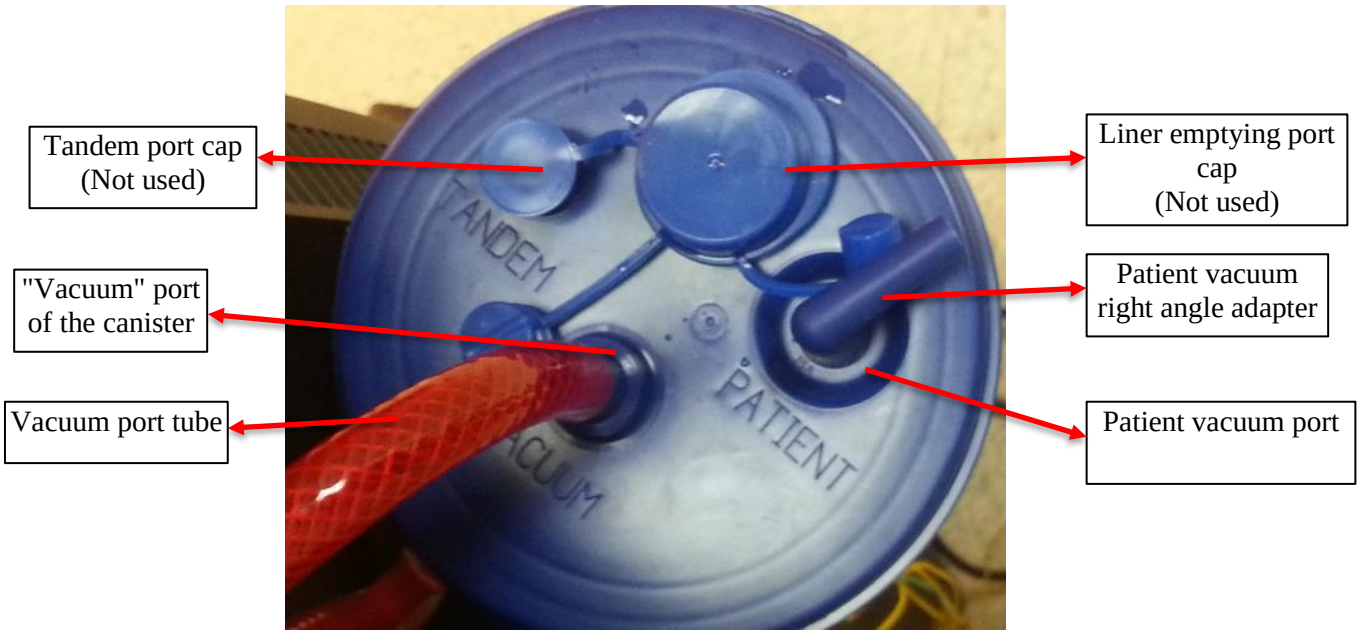
1. Connect the appropriate end of the power cable to the power cable receptacle located on the lower back of the laser system (see section 7). Ensure the power cable sits properly and entirely in the power cable receptacle. Insert the other end of the power cable into an electrical outlet with proper voltage and grounding.

   Make sure that the power cable is on the floor to prevent a tripping hazard in the treatment room.
2. Ensure that the electrical switch of the system located on the back of the laser system (to the right of the power cord connector) is in the ON position (I).
3. Take the footswitch pedal out from the rear storage compartment and connect the footswitch pedal cable to the footswitch pedal cable connector located at the bottom front of the laser system (see Section 7).
4. Close the rear storage compartment and position the footswitch pedal so that it can easily be accessed.
5. Rotate the control touch panel such that all the messages and icons are visible and accessible.
6. Make sure that all persons in the treatment room have the appropriate laser safety goggles supplied by AngioDynamics, ready to wear.
7. Insert the key into the key switch socket located on the top of the laser system (see Section 7). Turn the key switch clockwise to activate the system. Make sure that the "beep" sound is heard, and the LED indicator panel is illuminated as constant blue on the left to the system's aperture.
8. Ensure that the energy selection screen appears in the control touch panel with no system fault messages (see Section 9.1).

9. If a catheter with aspiration was chosen, prepare the vacuum pump of the system as follows:
   - Ensure that the canister (which is reusable and does not have to be replaced unless not functioning properly) is located properly in the canister base and that the transparent vacuum tube exiting the system is entirely covering the vacuum pump port. Insert a disposable flexible liner into the canister. Refer to the figure below (side view):



   - Ensure that the top (blue) side of the disposable flexible liner is set as in the following figure (top view).
     Note: Only the patient and vacuum ports are in use. The other two ports (emptying and tandem) should be closed with their caps.



Verify that:

- The vacuum port tube entirely covers the vacuum port of the canister.
- The red vacuum tube is inserted into the vacuum port of the canister.
- The patient vacuum right angle adapter (if used) sits tightly on the patient vacuum port.
- The liner emptying port cap and the tandem port cap must be in place covering their ports. Make sure that these ports are tightly covered by their caps.
- Set the canister in its base such that the canister side with the scale is visible.
- Ensure that the disposable flexible liner top (blue) side covers the top edge of the canister tightly and entirely.

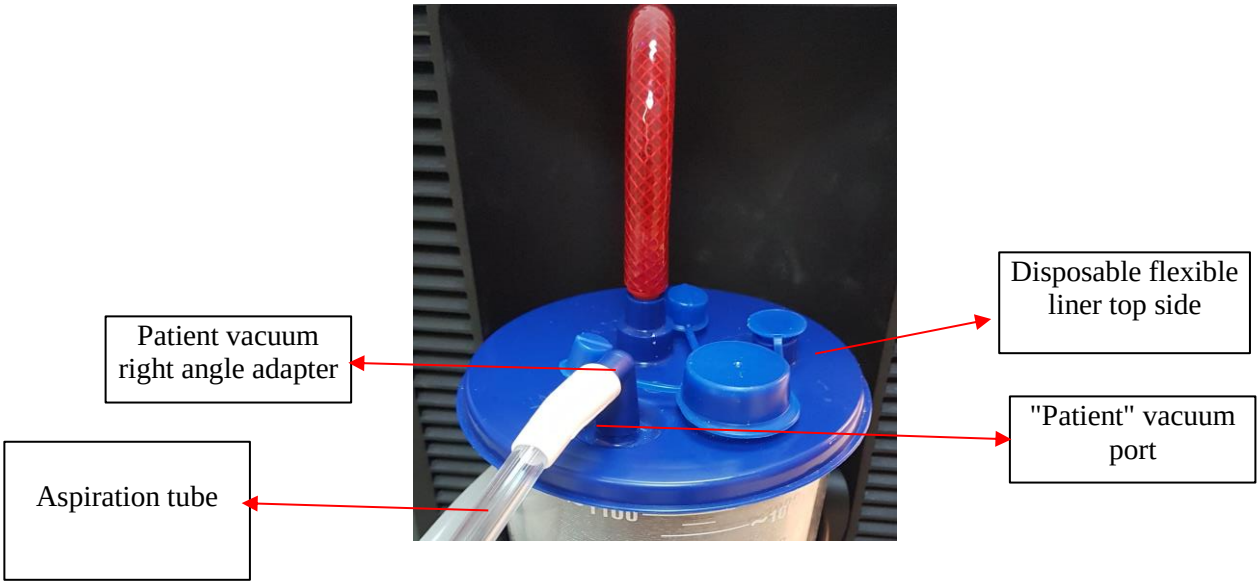
10.1.2. Direction for use (for clinical procedure):

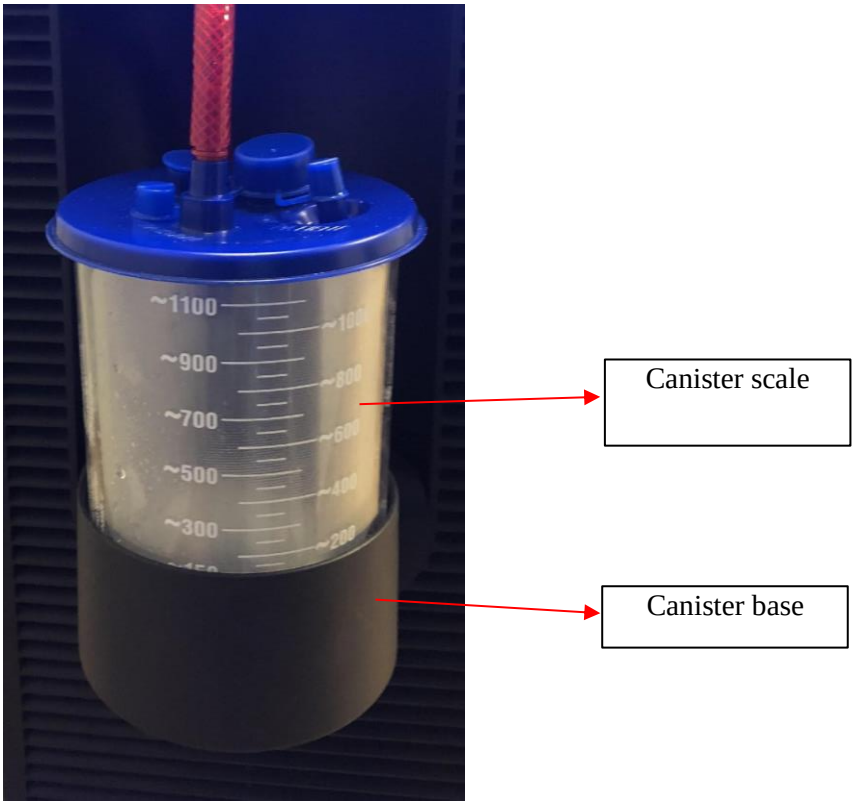
1. Position the cart as far away as possible from the treatment room bed but close enough to allow the connection of the catheter.
2. Verify that the relevant items of steps 1-9 from the above Section 10.1.1 were done correctly.
3. Position the footswitch pedal to be accessible for the treating physician to perform the clinical treatment.
4. The treating physician will indicate which catheter size will be used.
5. When the clinical procedure comes to the stage of using the laser catheter (GW has crossed the lesion and is in the lumen) insert the Auryon catheter's proximal end (connector) into the system's aperture and make sure that a "click" sound is heard. **Be careful to touch only the connector of the catheter after receiving it from the sterile staff member to avoid breaching the sterility of the catheter. Verify that the catheter identified by the system is the one that was chosen and inserted into the system`s aperture.**

   Note: Check the integrity of the catheter before use.

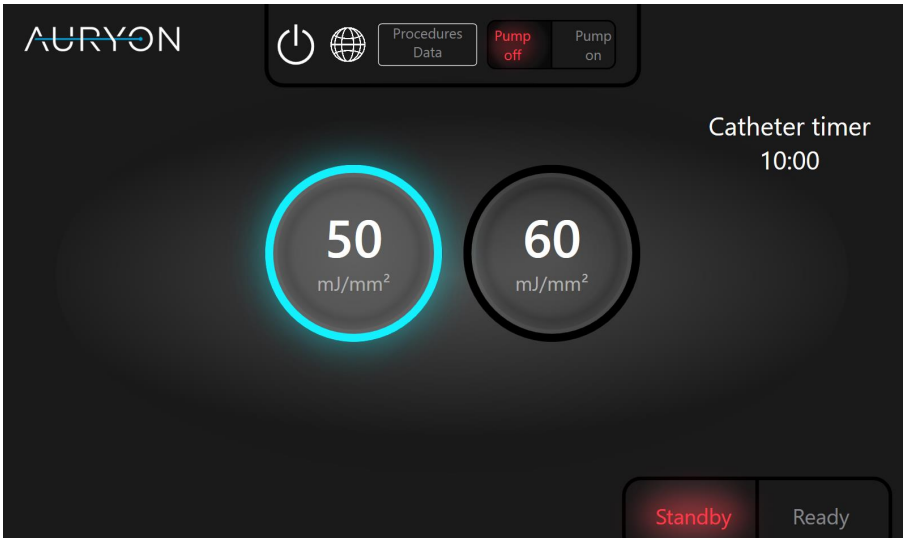
   Note: Do not sharply bend the catheter. Not following these recommendations may lead to damage to the catheter and/or harm to the patient or laser operator.

6. When using the 2.0 mm and 2.35 mm Auryon catheters, receive one end of the sterile aspiration tube after its other end has been connected to the Auryon catheter handle. Connect the aspiration tube to the patient vacuum right angle adapter (if applicable), or directly as shown below (front view):





7. Select the appropriate energy level (fluence) according to the information received from the treating physician, by pressing the appropriate icon in the energy level selection screen to be 50 mJ/mm² or 60 mJ/mm² (the default is 50 mJ/mm²). Ensure that a blue circle is illuminated around the text, as shown below:



8. Set the Laser system to **"Ready"** mode following the request from the treating physician once the catheter is inserted over the wire and located proximal to the lesion. Press the "Ready" icon on the bottom right of the energy level selection screen. At this point the system will perform a 15-second countdown. During this time a blue horizontal light on the console will blink. At the end of 15 seconds the light will stop blinking. This countdown takes place whether or not the aspiration pump is used. As soon as the "System is ready" message appears, press on the "OK" icon (see Section 9.1).

   Note: *When the system is in "Ready" mode, the energy level can be increased or decreased if the treating physician requests. The pump is operated automatically as soon as the system moves into "Ready" mode. (only in the 2mm and 2.35mm catheters).*

   Note: *If the treating physician requests to stop the pump operation, you may do so by pressing the "Pump off" icon when the footswitch pedal is not pressed. When the physician presses the footswitch pedal, the pump will resume activation automatically.*

   Note: *Be careful not to touch the screen again until the end of the clinical procedure (so that the system settings will not be accidently changed) unless you receive a specific request from the treating physician.*

9. After pressing OK, the operator should notify the treating physician that the countdown of 15 seconds has ended and that the laser system is in "Ready" mode. At that point, the physician must press the footswitch pedal to emit laser radiation from the Auryon catheter distal end.

   While the footswitch is pressed, the "LASER ON" label to indicate that laser radiation is being emitted from the system and the timer that indicates the laser activation time and lasing counter will both appear on the screen:

   During this time, a yellow color horizontal LED on the console will be blinking and a beep sound will be played to notify that the laser is active. Laser activation will stop as soon the footswitch pedal is released. The energy level selection screen with the laser system is still in "Ready" mode and the pump operating mode will then appear again.

   Note: *To change the energy level during the clinical procedure, the treating physician must release the footswitch pedal to do so. There is no need to remove the catheter from the treated area.*

   Note: *If the patient`s bed is moved during the procedure, pay attention to ensure that the proximal side of the catheter, connected to the system, is not stretched. If needed, move the system together with the patient`s bed.*

10. Make sure that beeping is audible when the footswitch is depressed, the laser is activated and that the LED indicator light is blinking yellow (see Section 9.2.)

    Note: *If the control touch panel does not respond, power down the system using the key switch and contact an AngioDynamics representative for further instructions.*

    Note: *When laser radiation is emitted from the Auryon catheter, the laser system will automatically self-test the output energy and the aspiration integrity constantly to verify that the system is valid. If the system detects a change in the energy level or if the vacuum or the laser is stopped, a notification will be displayed on the system screen.*

    Note: *If the 2.0mm or 2.35mm catheters are used, after 3 minutes pass from pump activation, the system will provide a notification accompanied by a "beep" to check the level of aspirated volume in the disposable liner. These beep notifications will continue until the operator closes it by pressing the "X" button on the left of the notification. The notification will appear every three minutes until the "end of the procedure" is chosen.*

    Note: *After 5 minutes (in total) of laser activation during a procedure with the same catheter, the operator will receive a notification: "More than 5 minutes of laser activation".*

    After a further 5 minutes (10 minutes in total) of laser activation (during a procedure), the laser will stop and the operator will receive a message: "More than 10 minutes of laser activation". After 10 minutes of laser activation, the laser cannot be used anymore with the same catheter. The catheter countdown activation time will be shown on the screen at all times so the operator can easily notify the physician on the time left for a certain catheter. If additional catheter (e,g. additional size) must be used before the 10-minute limit, you may use the new catheter as needed, and still revert to the already used catheter in the same procedure, if needed.

Note: *The 60mJ/mm2 is limited to 5 minutes of use. After 5 minutes of use at 60mJ/mm2, this energy level will be disabled, and usage at the 50mJ/mm2 energy level for the end of the fiber lifetime will be allowed.*

Note: *If liquids or solids have been drawn into the vacuum pump, contact AngioDynamics for servicing the system.*

Caution: Ensure that the area around the system's aperture and the control touch panel is clean, dry, and free of contaminants.

Caution: The personnel operating the Auryon Atherectomy System should be trained by AngioDynamics, Inc.

Caution: Carefully read the Operator Manual and Catheter Instructions for Use before using the system.

Caution: In case of emergency, press the EMO in order to stop laser emission.

Caution: Never extract the catheter proximal end from the system's aperture before the system mode has been set to "Standby".

11. Once the procedure is finished, set the laser system to "Standby" mode, and when “End of procedure?” appears on the screen, press “Yes”, extract the catheter connector from the system aperture and remove the catheter from the patient`s artery.

    Note: *Avoid crushes, hits, and impacts to the Auryon Atherectomy System during procedures and when waiting between procedures.*

    Note: *If the system is in “Ready” mode for more than 5 minutes, it will automatically move to “Standby” mode.*

    Note: *The detailed instructions for Auryon catheter operation are present in the IFU (Document IFU0100). Users should carefully read the Catheter IFU before using the system to ensure proper, safe operation.*

10.2. Power Down of the System

The Auryon Atherectomy System must be powered down at the end of the day after the clinical procedures have ended.

Follow the following steps to power down the system:

1. Check that the system mode in the control touch panel is **"Standby"** and that the pump mode in the control touch panel is **"Pump off"**.
2. Shut down the computer by pressing the “Shut Down” icon on the screen.
3. Turn the key switch located on the top of the laser system to the OFF (◯) position.
4. Disconnect the power cable from the power source (electrical socket).
5. Disconnect the footswitch pedal cable from its connector and store the footswitch pedal in the rear storage compartment.
6. When not in use, the Auryon Atherectomy System should be protected from unqualified use by removing the key switch.
7. Store the Auryon Atherectomy System in a safe place and cover it.

11. Warnings and Errors

Errors and accompanying error messages on the control touch panel screen are described in the following table:

Error	**Message**
Fault in the laser head/controller	“Laser error state”+ the error code
EMO is pressed	“Please release emergency button”
Pedal is pressed, not in “Ready” mode	“Please release pedal”
Laser is disconnected from PC	“No connection to laser”
Energy sensor is disconnected from PC	“No connection to laser sensor”
Vacuum sensor is disconnected from PC	“No connection to vacuum sensor”
Energy is lower than the preset value	“Sensor tolerance error - low”
Energy is higher than the preset value	“Sensor tolerance error - high”
Pump is disconnected or vacuum is too low	“Please check the connection to the pump”
RFID reader is not connected	“No connection to RFID reader"

If any of the above errors appear, refer to the Troubleshooting Section of this manual (Section 13).

12. Maintenance

12.1. Storage, transportation and movement

The Auryon Atherectomy System should be stored in a secure place, protected from freezing or extremely high temperatures, and draped with a protective cover when not in use. Never store the laser system in areas that may be below 5 °C (41 °F) or above 50 °C (122 °F).

Never transport the laser system in areas that may be below -40 °C (-38 °F) or above 70 °C (158 °F).

Relative humidity regarding the storage and the transportation of the system should be between 10% and 90% non-condensing.

The atmospheric pressure range for storage and transportation of the system is 50 kPa to 106 kPa.

Note: *Always use the handle to push or pull it to a new position*

When moving the Auryon Atherectomy System, avoid traversing steps, bumps, and rough surfaces.

Clean the external surfaces of the Auryon Atherectomy System with a damp, soft cloth (and a mild detergent, if necessary) after each use. Do not use running water. Any cleaning must take place with the laser in "power off" mode.

12.2. Auryon Atherectomy System Inspection

It is required to power ON the system every four weeks for one hour in order to circulate the coolant through the system. This will prevent the growth of biological contaminants in the coolant system and maintain coolant properties.

Prior to use, the operator should check the system as follows:

1. Visually inspect the power cord to ensure that the connections on both ends are free of damage.
2. Visually inspect externally the Auryon Atherectomy System cover, control touch panel, and footswitch pedal and verify that no signs of damage appear.
3. If needed, clean the control touch panel screen very gently with a soft cloth.

If any signs of damage appear following the visual inspection listed above, contact an AngioDynamics representative, prior to operating the system.

Note: a System Calibration and Preventative Maintenance Service by AngioDynamics or its Authorized Service Representative is recommended to be performed every 18 months.

When lamp needs to be replaced, the system will give a notification "Lamp replacement is needed. Please call a technician."

12.3. Auryon Atherectomy System End of Life

The Auryon Atherectomy System should be disposed of in accordance with local regulations/hospital procedures for disposal of electronic devices or return the System to AngioDynamics for safe disposal.

For information regarding disposal of the catheters, see the Instructions for Use regarding disposal of each single-use device (Auryon catheter).

Warning

During maintenance activities avoid possible exposure to hazardous laser radiation.

Caution

Use of controls or adjustments or performance of procedures other than those specified herein may result in HAZARDOUS radiation exposure

13. Troubleshooting

13.1. Diagnostic Problems

Problem	Possible Cause	Solution/Suggestion
No system power (The system does not turn ON)	Power cord is not connected	Make sure that the power cord is plugged into the outlet in one end and ensure the connection to the system at the other end of the cable
	Electrical switch is OFF	Verify that the electrical switch of the system (located on the bottom of the back of the system) is ON by pressing the switch toward the ON “I” position
	Key switch is OFF	Verify the key switch is in the ON position by turning the key switch located on the top of the laser system to the ON “I” position
	System fuses	Call AngioDynamics Inc. for assistance.
Key switch and electrical switch are in the ON position and the power cord is connected properly, but the laser system still does not power ON	Emergency button is not released. (A message: “release emergency button” should appear on the screen)	Release the emergency button located next to the key switch by turning it in a clockwise direction
No laser output	The footswitch pedal cable is not connected properly to its connector in the front of the system	Make sure that the footswitch pedal cable is connected properly to its connector and that it does not disconnect when slightly pulled
	The footswitch pedal cable is connected properly into its connector but the footswitch pedal cannot be pressed properly	Verify that no object is preventing the footswitch pedal from being pressed
	An internal cable is disconnected, laser fault ("Laser error state" message appears)	Power down the system and call AngioDynamics representative for assistance
"Sensor tolerance error-low" message appears during laser activation	System didn`t warm up or system spent too much time in ready mode	Move the system to standby mode and then move to ready once again.
	Laser not stable or misalignment of elements inside the system	Contact an AngioDynamics representative for assistance

The aspiration of the system is not functioning properly and the "Please check the connection to the pump" message appears	The disposable flexible liner is faulted	Replace the disposable flexible liner
	The tubes are not connected properly to the disposable flexible liner or the caps	Check all the connections of the tubes and the caps of the disposable flexible liner top side
	The disposable flexible does not cover the top edge of the canister effectively, causing vacuum leaks.	Ensure that the disposable flexible liner top (blue) side covers the top edge of the canister tightly and entirely
	Vacuum leaks before the canister	Ensure that the transparent vacuum tube exiting the system is entirely covering the vacuum pump port (the entry of the vacuum from the pump to the canister
	The vacuum pump is not working	Contact an AngioDynamics representative for assistance

14. Clinical Data

EX-PAD-01

ClinicalTrials.gov Identifier: NCT02556255

The EX-PAD-01 clinical study was a prospective, single-arm, multi-center, international, open-label, non-randomized clinical study to assess safety, performance and efficacy of the Auryon Atherectomy Catheter in subjects with Peripheral Artery Disease (PAD) in lower extremity arteries. Fifty (50) subjects with 53 lesions were enrolled from October 2015 until July 2017 in two European investigational sites. The primary safety endpoints were perioperative (until discharge) freedom from clinically significant device related adverse events requiring intervention (perforation, dissection, distal embolization or pseudo-aneurysm) and freedom from Major Adverse Events (MAE) at 30 days, defined as target lesion revascularization, unplanned target limb amputation above the ankle, and cardiovascular deaths. The primary efficacy endpoint was technical success, defined as the ability of the Auryon catheter to cross the target lesion stenosis over the guide wire (in true lumen) while the Minimal Lumen Diameter (MLD) is smaller than the Auryon catheter diameter. Technical success was achieved in 98.0% (52/53) of the treated lesions (in one lesion, laser crossing was discontinued due to angiographic evidence of sub-intimal guidewire passage). The perioperative freedom from clinically significant device related adverse events was 100%. Freedom from MAE at 30-days was 100% (50/50), freedom from MAE at 6 months was 100.0% (50/50), and freedom from MAE at 12 months in 46 subjects that completed the follow up was 95.7% (44/46). Moreover, the primary patency rate (PSVR<2.5) was 95.7% (22 out of 23) and 81.8% (18 out of 22) at 6 months and 12 months respectively, in those patients for which duplex ultrasound data is available. Two angiographic cases from the EX-PAD-01 study were presented in an article published by Herzog et al.[1]

[1] Herzog et.al. Atherectomy using a solid-state laser at 355 nm wavelength. J Biophotonics. 2017 Oct;10(10):1271-1278. doi: 10.1002/jbio.201600209. Epub 2017 Jan 20.

Summary Table of safety and efficacy results in EX-PAD-01 study[1]

PATIENTS	**N=50**
Male	38 (76%)
Age (years)	63.82 ± 8.5
Diabetes Mellitus	9 (18%)
Baseline ABI	0.57 ± 0.14
Baseline Rutherford	2.90 ± 0.54
Baseline WIQ	34.58 ±8.62
LESIONS	**N=53**
Femoropopliteal arteries	51 (96.2%)
Tibial arteries	2 (3.8%)
Moderate-Severe Calcification	31 (60.8%)
ISR	3 (5.7%)
Lesion length (cm)	7.4 ± 5.5
PROCEDURAL OUTCOMES	**N=53**
Baseline stenosis, %	95.3 ± 10.3
Post-Auryon laser stenosis, %	61.3 ± 25.5
Final residual stenosis, %	14.0 ± 14.0
Number of catheters used	1.2 ± 0.5
Technical success[2]	52 (98%)
SAFETY	**N=50**
30 days Major Adverse events and perioperative until discharge clinically significant device related adverse events requiring intervention[3,4,5]	0 (0.0%)
6 months Major Adverse events	0 (0.0%)
12 months Major Adverse events (N=46)	2 (4.3%)
30 DAYS OUTCOMES	**N=50**
ABI	0.94 ± 0.14
Rutherford	0.66 ± 0.77
WIQ	71.02 ±20.28
6 MONTHS OUTCOMES	**N=50**
ABI	0.84 ± 0.2
Rutherford	0.90 ± 1.04
WIQ	67.84 ±22.05
Lesion Patency (< 2.5 PSVR, N=23)	22 (95.7%)
12 MONTHS OUTCOMES	**N=46**
ABI	0.79 ± 0.16
Rutherford	1.02 ± 1.09
WIQ	58.42 ±20.48
Lesion Patency (< 2.5 PSVR, N=22)	18 (81.8%)

[1] Data presented as (mean ± SD) and n (%), if not mentioned otherwise. [2] Defined as the ability of the Auryon catheter to cross the target lesion stenosis over the guide wire while the stenotic flow diameter is smaller than the Auryon catheter diameter. In one lesion, laser crossing was discontinued due to angiographic evidence of sub-intimal guidewire passage. [3] Major Adverse Events were defined as cardiovascular death, TLR, unplanned amputation above the ankle or emergent surgical revascularization of the target limb. Clinically significant device related adverse events requiring intervention are perforation, dissection, distal embolization or pseudo-aneurysm.[4] There were 2 post procedure access site hematomas unrelated to the device, which required limited local surgical treatment that led to prolongation of hospitalization (non-device related SAE) and were resolved by discharge.[5] No dissections/perforations revealed after catheter pass. In 3 cases, as expected, dissections were noted only post balloon inflation, and which were treated with stent or did not require treatment, and all 3 cases were considered unrelated to the Auryon System.

EX-PAD-01 Step-by-step subset

In addition to the 50 subjects presented above, 8 subjects were enrolled in the EX-PAD-01 study, who underwent study procedures using this specific SBS technique with the 355 nm laser Auryon catheter. This subset included only cases where the Auryon was initially advanced in a step-by-step technique (without a guidewire) to penetrate with the laser an initial channel in the total occlusion plaque tissue (some with heavy calcification). Once Auryon has crossed the occlusion, a guidewire was placed in the channel formed by the laser, another advancement was done with the catheter but now over the wire, to complete the atherectomy procedure.

The primary efficacy endpoint for this subset was technical success, defined as the ability of the Auryon to cross the target occlusion using the step-by-step approach, not over the wire.

From the eight patients treated with Auryon with this SBS approach, technical success of crossing the occlusions was achieved in 7 (87.5%), while in one (12.5%) case, the Auryon catheter was removed prematurely, not due to its inability to cross, but due to the guidewire that was assessed to be sub-intimal (was inserted mistakenly inside the vessel wall), so it was decided not to continue crossing with the Auryon. In terms of safety profile, also with these 8 subjects, although are considered more complicated and challenging, it remained as high as with the other 50 cases that were treated routinely with the laser catheter over the wire, without having any procedural complications (specifically no vessel perforations, dissections or emboli) nor any major adverse events in the long term.

In an article published by Alperovich et al[2], it was shown that the 355nm wavelength of the Auryon solid-state laser and its selectivity feature (penetrating faster the plaque tissue of the occlusion/lesion than the vessel's wall), when is used with an SBS approach to make a first channel in challenging (to cross) total occlusions and severe calcification, reduced the risk of vessel perforations.
NOTE: *The step-by-step technique is not included in the approved indications for use and therefore is prohibited to be used with the Auryon catheter.*

EX-PAD-03

ClinicalTrials.gov Identifier: NCT03157531

The EX-PAD-03 clinical study was a pivotal, prospective, single-arm, multi-center, international, open-label clinical study to assess safety and efficacy of the Auryon Atherectomy catheter in subjects with infra-inguinal Peripheral Artery Disease (PAD). Ninety-seven (97) subjects were enrolled from September 2017 until March 2018 in eight (8) US investigational sites and three (3) European investigational sites. The primary safety endpoint was freedom from Major Adverse Events (MAE) through a 30-day follow-up period, as adjudicated by the Clinical Event Committee (CEC), defined as clinically driven target lesion revascularization (CDTLR), unplanned target limb amputation above the ankle, and cardiovascular deaths. This endpoint is considered to be met if the rate is greater than 85%. The primary efficacy endpoint was acute technical success, defined as reduction from baseline in residual diameter stenosis (measured in percent), prior to any adjunctive therapy, achieved by the Auryon Atherectomy catheter, as assessed quantitatively by the core laboratory based upon the procedure angiograms. This endpoint is considered to be met if the mean reduction in residual diameter stenosis is greater than 20%, prior to any adjunctive therapy. Freedom from MAE at 30-days was 98.9% (92/93). The reduction from baseline in residual diameter stenosis (measured in percent), achieved by the Auryon Atherectomy catheter, as assessed quantitatively by the core laboratory based upon the procedure angiograms was 33.6% (± 14.2%).[3,4]

[2]Alperovich et al. Tissue post-classification using the measured acoustic signals during 355 nm laser atherectomy procedures, J Biophotonics. 2021 Mar;14(3):e202000185. doi: 10.1002/jbio.202000185. Epub 2020 Dec 27.
[3]Shammas N. W. et al. Acute and 30-Day Safety and Effectiveness Evaluation of Eximo Medical's B-Laser™, a Novel Atherectomy Device, in Subjects Affected With Infrainguinal Peripheral Arterial Disease: Results of the EX-PAD-03 Trial. Cardiovasc Revasc Med. 2020 Jan;21(1):86-92. doi: 10.1016/j.carrev.2018.11.022. Epub 2018 Nov 29.
[4]Rundback et al. Novel laser-based catheter for peripheral atherectomy: 6-month results from the Eximo Medical B-Laser™ IDE study Catheter Cardiovasc Interv. 2019 Dec 1;94(7):1010-1017. doi: 10.1002/ccd.28435. Epub 2019 Aug 13.

Summary Table of safety and efficacy results in EX-PAD-03 study

PATIENTS	**N=97**
Age, yrs.	70.5 [46, 86]
BMI	27.6 [15.4, 42.4]
Male	51 (52.6%)
Hypertension	89 (91.8%)
Dyslipidemia	83 (85.6%)
Diabetes Mellitus	41 (42.3%)
Active or prior smoking	78 (80.4%)
Coronary Artery disease	53 (54.6%)
Statins	60 (61.9%)
Antiplatelet	80 (82.5%)
Baseline ABI	0.71±0.19 (N=88)
Baseline WIQ	0.23 ± 0.22 (N=93)
Baseline Rutherford	2.77±0.6 (N=97)
Rutherford 2	31 (32.0%)
Rutherford 3	57 (58.8%)
Rutherford 4	9 (9.3%)
ABI< 0.9 (N=88) [1]	73 (83.0%)
WIQ <39 (N=93)	76 (81.7%)
LESIONS	**N=107**
Length, cm	5.4 ± 4.3
RVD – proximal (mm)	4.5 ±1.1
Baseline stenosis (%)	85.7 ± 12.2
Moderate – severe calcification	41 (38.3%)
Chronic Total Occlusion	23 (21.5%)
Restenosis/ISR	22 (20.6%)
Location	
Femoral	79 (73.8%)
Popliteal	9 (8.4%)
Tibial	19 (17.8%)
Adjunctive inflow treatment	18 (16.8%)
PROCEDURAL OUTCOMES	**N=107**
Baseline stenosis (%)	85.7 ± 12.2
Stenosis post Auryon (%)	52.1 ± 14.6
Reduction of stenosis post Auryon (%)	33.6 ± 14.2
Final stenosis after PTA (%)	17.7 ± 11.0
Stenosis post Auryon in moderate-severe calcification (%)	54.3 ± 12.6
Embolization	0 (0%)
Perforation	0 (0%)
Pseudoaneurysm	0 (0%)
Grade A/B dissection[2]	16 (14.9%)
Grade C-E dissection[3]	0 (0%)
Bail-out stenting	1 (0.9%)
Spasm (transient)	1 (0.9%)
Staining	1 (0.9%)
30 DAYS OUTCOMES	
ABI at 30-day visit post-procedure, n=88	0.95 ± 0.15
ABI difference (post-procedure - baseline), n=82	0.24 ± 0.18
Rutherford Category at 30-day post procedure, n=94	0.98 ± 1.01
Rutherford category difference (post-procedure - baseline), n=94	-1.79 ± 1.22
WIQ at 30-day visit post-procedure, n=84	0.50 ± 0.32
WIQ difference (post-procedure - baseline), n=81	0.26 ± 0.28
Freedom from MAE through a 30-day follow-up[4,5]	92/93 (98.9%)

Lesion Patency (< 2.5 PSVR, by Duplex core-lab)	90/93 (96.8%)
6 MONTH OUTCOMES	
CD-TLR	
Per subject (N=91)	3 (3.3%)
Per lesion (N=101)	3 (2.9%)
Rutherford class (N=88)	
R0	44 (50%)
R1	31 (35%)
R2	9 (10%)
R3	2 (2%)
R4	1 (1%)
R5/6	1 (1%)
ABI<0.9 (N=85)	38 (45 %)
WIQ<39 (N=83)	34 (41.0%)
Lesion Patency (< 2.5 PSVR, by Duplex core-lab)	90 (85.6%)

[1] There were only 88 ABI measured as baseline, since in few patients, baseline ABI was attempted but was unobtainable due to non-compressible arteries. The presence of poorly compressible arteries (PCA) in the lower extremities has been found to be highly specific for calcification of the medial layer in these arteries. [2] Sixteen A/B dissections were reported post Auryon, 11 dissections grade A and 5 dissections grade B. [3] No >C dissections were reported post Auryon alone; 14 dissections grade C and 2 dissections grade D were noted only post balloon inflation. [4] Major adverse events were defined as: Unplanned target limb amputation above the ankle, Clinically Driven Target Lesion Revascularization (CDTLR), Cardiovascular related deaths. [5] Per CEC, there was 1 MAE up to 30 days (non-device related cardiovascular death).

PATHFINDER (EX-PAD-05)

ClinicalTrials.gov Identifier: NCT04229563

The PATHFINDER study was a prospective, single-arm, US based multicenter, open-label registry to evaluate the safety and efficacy of the 355 nm laser Atherectomy System in a real-world setting for the treatment of infrainguinal lesions in patients with peripheral artery disease (PAD). The study included 102 patients (44.6% CLI), with 107 lesions that were angiographically analyzed by core laboratory: average length 13.6 (0.51-52.0 cm), 22.3% ISR, 44.4% CTOs, 47.3% Tibial lesions and 36.5% moderate-severely calcified. 56 (43.5%) aspiration catheters were used. Outcomes were reported till 12-months post procedure[5]. Stenosis percentage was 87.1%, 60.7% and 24.4% at baseline, post-laser and post-procedure (after final adjunctive therapy of balloon/stent), respectively. The mean residual stenosis at the end of the procedure was 24.4 ± 15.5 with 69 lesions (69.0%) achieving technical procedural success (less than 30% stenosis); similar rates were observed for subjects with in-stent restenosis (ISR) (25.5± 14.9), chronic total occlusion (CTO) (28.1± 17.0) and severe calcification (36.5± 21.6) lesions. There were no procedural perforations, amputations, or deaths. Four (3.9%) bail out stenting post balloon (not laser related), 2 (2.0%) from dissection grade C, and 1 (1.0%) clinically significant distal embolization events occurred that resolved intra-procedurally without sequelae. Freedom from MAEs was 97.0% at 30-days (N=99, 1 (1.0%) amputation, 1 (1.0%) CD-TLR and 1 (1.0%) TVR), 90.7% at 6-months (N=97, 5 (5.2%) CD-TLRs, 2 (2.1%) amputation, 2 (2.1%) TVR), 88.8% at 12-months (N=89, 6 (6.7%) CD-TLRs, 2 (2.2%) amputation, 2 (2.2%) TVR) and 81.4% at 24-months (N=70, 7 (10.0%) CD-TLRs, 2 (2.9%) amputation, 3 (4.3%) TVR), 1 (1.4%) CV death. Rutherford, ABI, and WIQ (n=47,51,48) were improved at 24 months compared to baseline (3.64 vs. 1.11; 0.73 vs. 0.89; and 22.77 vs. 37.19, respectively). 24-months Rutherford class was improved from baseline in 93.5% of the patients. Initial post market data on real-world cases with Auryon in a variety of complex infrainguinal lesions demonstrates excellent safety and efficacy outcomes, including in severe/medial calcification[6]. Low CD-TLR rates with improved clinical presentation were consistent with prior data (CE study and IDE) and were maintained out to 24 months.

[5]Das et al. Solid state, pulsed-wave 355 nm UV laser atherectomy debulking in the treatment of infrainguinal peripheral arterial disease: The Pathfinder Registry. Catheter Cardiovasc Interv. 2024;1–14.

[6]Rundback et al. Treatment effect of medial arterial calcification in below-knee after Auryon laser atherectomy using micro-CT and histologic evaluation. Cardiovasc Revasc Med. 2023 Jun 28;S1553-8389(23)00674-7.

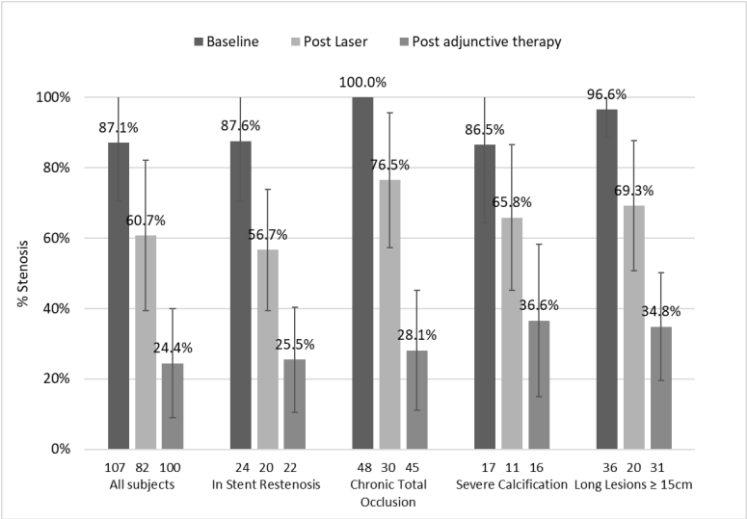
Summary Table of safety and efficacy results in Pathfinder study.

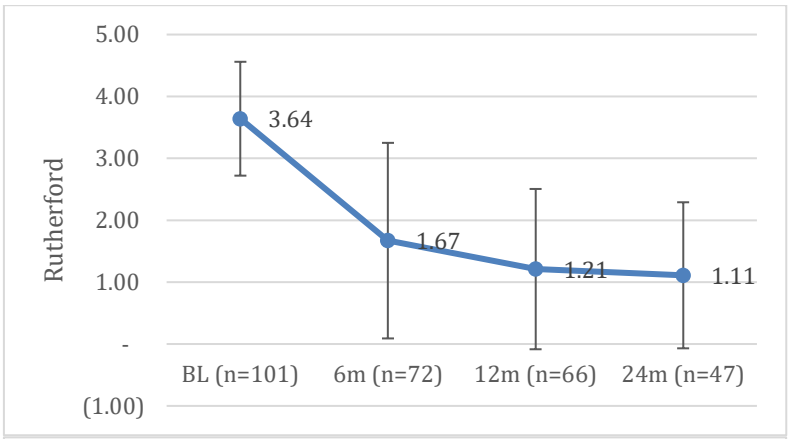
PATIENTS	**N=102**
Male	63 (61.8%)
Age, years	68.4 ± 10.2
Smoker, current/former	68 (66.6%)
Diabetes Mellitus	54 (52.9%)
BMI	28.8 ± 5.4
Hypertension	89 (87.3%)
Hyperlipidemia	77 (75.5%)
Coronary artery disease	45 (44.1%)
Critical limb ischemia[1]	45 (44.6%)
Previous PAD intervention	60 (58.8%)
Time from last intervention (years)	2.3 ± 3.3
LESIONS	**N=107[2]**
Tibial	51 (47.3%)
Lesion length, cm	13.6 ± 11.5
CTO	48 (44.4%)
Moderate - severe calcification	39 (36.5%)
ISR[3]	27 (22.3%)
Baseline stenosis	87.1 ± 16.58
Stenosis post Auryon	60.7 ± 21.37
Final stenosis after PTA	24.4 ± 15.48
ADJUNCTIVE THERAPIES[3]	**N=121**
EPD[4]	1 (1.0%)
DCB	30 (24.8%)
BMS	19 (15.7%)
DES	9 (7.4%)
PROCEDURAL COMPLICATIONS	**N=102**
Clinically significant Embolization[5]	1 (1.0%)
Perforation	0 (0%)
Dissection, major (C)	2 (2.0%)
Bail-out stenting[6]	4 (3.9%)
Amputation	0 (0.0%)
Death	0 (0.0%)

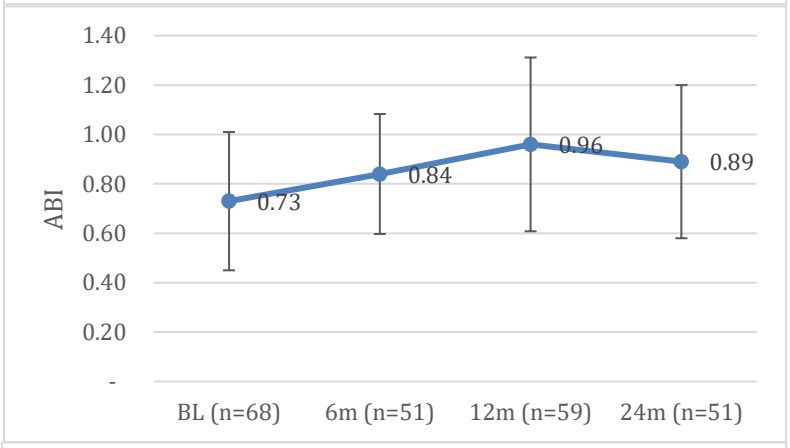
[1] Rutherford 4-6 (N=101); only one patient was R6.[2] Only 107 lesions out of the 121 were qualified for analysis by corelab. [3] Site reported (N=121 lesions). More than one entry is possible. [4] Per subject (N=102). [5] Resolved intraop without complications. Another non-clinically significant embolization event occurred. [6] Due to ≥C flow limiting dissection / >30% RDS, occurred post balloon (not post laser).

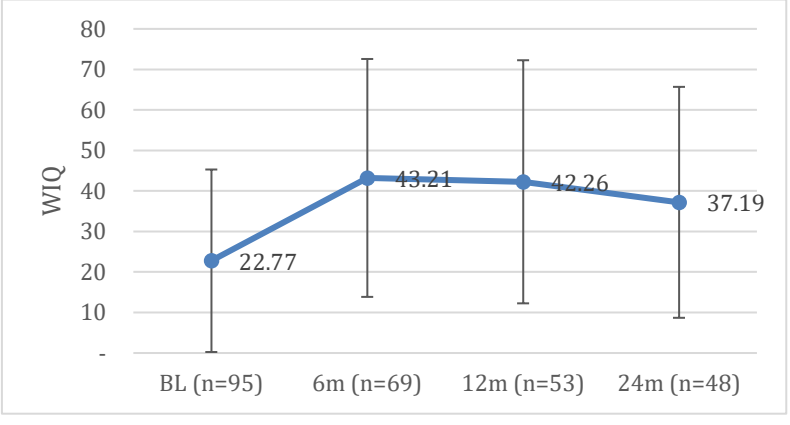
MAJOR ADVERSE EVENTS[7]	**30 DAYS N=99**	**6 MONTHS N=97**	**12 MONTHS N=89**	**24 MONTHS N=70**
No MAEs	96 (97.0%)	88 (90.7%)	79 (88.8%)	57 (81.4%)
Amputation	1 (1.0%)	2 (2.1%)	2 (2.2%)	2 (2.9%)
CD-TLR	1 (1.0%)	5 (5.2%)	6 (6.7%)	7 (10.0%)
TVR	1 (1.0%)	2 (2.1%)	2 (2.2%)	3 (4.3%)
Cardiovascular Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)

[7] Data are cumulative, reporting MAEs from days 0-37 (30d), from days 0-213 (6m), from days 0-395 (12m) and from days 0-study termination (24m) from the index procedure. Seven (6.86%) all cause deaths, unrelated to PAD.


Baseline
Post Laser
Post adjunctive therapy
% Stenosis
100%
80%
60%
40%
20%
0%
87.1%
60.7%
24.4%
87.6%
56.7%
25.5%
100.0%
76.5%
28.1%
86.5%
65.8%
36.6%
96.6%
69.3%
34.8%
107 82 100
All subjects
24 20 22
In Stent Restenosis
48 30 45
Chronic Total Occlusion
17 11 16
Severe Calcification
36 20 31
Long Lesions ≥ 15cm


Rutherford
5.00
4.00
3.00
2.00
1.00
-
(1.00)
3.64
1.67
1.21
1.11
BL (n=101)
6m (n=72)
12m (n=66)
24m (n=47)


ABI
1.40
1.20
1.00
0.80
0.60
0.40
0.20
-
0.73
0.84
0.96
0.89
BL (n=68)
6m (n=51)
12m (n=59)
24m (n=51)


WIQ
80
70
60
50
40
30
20
10
-
22.77
43.21
42.26
37.19
BL (n=95)
6m (n=69)
12m (n=53)
24m (n=48)

Auryon iDissection study

An article[7] presenting IIT (investigator-initiated trial) results from a US-based center, showed an IVUS assessment and correlation with angiographic findings of arterial dissections post Auryon and balloon.

Summary Table of safety and efficacy results in Auryon iDissection study.

PATIENTS	**N=29**
Age (years)	69.3±12.1
BMI	27.6±6.2
ABI (n=12)	0.7±0.3
Male	22 (75.9%)
Coronary artery disease	17 (58.6%)
History of major amputation	1 (3.4%)
Hypertension	25 (86.2%)
Hyperlipidaemia	26 (89.7%)
Current / prior smoker	25 (86.2%)
Diabetes mellitus	14 (48.3%)
Chronic limb-threatening ischemia	11 (37.9%)
LESIONS	**N=29**
Runoff vessels (n=28)	1.6±1.0
Lesion Type	
Denovo	16 (55.2%)
Restenotic	13 (44.8)
Lesion Location	
Above the knee	26 (89.7%)
Above and below the knee[1]	3 (10.3%)
Lesion length (mm)	140.2±114.7
Treated length (mm)	169.3±110.9
Vessel diameter by angio, mm	6.5±1.5
Vessel diameter by IVUS, mm	6.7±1.5
Total stented segment, mm (n=26)	37.1±17.4
Stenosis (%)	
Baseline	82.0±14.5
Post Laser (n=25)	40.0±10.2
Post–adjunctive	17.5±11.1
Filter used with the laser (n=28)	22 (78.6%)
No Debris	15 (53.6%)
Macro < 2 mm debris	2 (7.1%)
Microdebris	5 (17.9%)
Macrodebris ≥2 mm	0 (0.0%)
Distal embolization	0 (0.0%)
Angiographic thrombus	1 (3.4%)
Total occlusion	7 (24.1%)
IVUS arc of calcium	
180°–270°	5 (17.2%)
>270° (severe)	5 (17.2%)
Drug-coated balloons	22 (75.9%)
IN-HOSPITAL AND PROCEDURAL ADVERSE EVENTS	**N=29**
New type C dissection by IVUS (iDissection classification) (n=28)[2]	3 (10.7%)
Dissections by angiogram by NHLBI (n=28)[3]	6 (21.4%)
Stenting[4]	7 (24.1%)
Bailout stenting (n=28)[5]	6 (21.4%)
Distal embolization requiring treatment	0 (0.0%)
Unplanned major or minor amputation in-hospital	0 (0.0%)
In-hospital mortality	0 (0.0%)
Nonfatal myocardial infarction	0 (0.0%)
Major bleeding	0 (0.0)

[1]Femoropopliteal, TP, and PT or CFA and profunda femoris. [2]Change in dissection grade from baseline to post laser: 2 None to A, 1 None to B, 1 A to C; Change from laser to post PTA: 1 A to C. [3] NHLBI classification A = 0, B = 1, C = 5, D–F = 0. [4] One (3.4%) was primary stenting. [5] due to residual >30% or ≥ C dissection (NHLBI).

[7]Shammas et al. Intravascular Ultrasound Assessment and Correlation with Angiographic Findings of Arterial Dissections Following Auryon Laser Atherectomy and Adjunctive Balloon Angioplasty: Results of the iDissection Auryon Laser Study. J Endovasc Ther. 2022 Feb;29(1):23-31.

Auryon SCE (Single-Center-Experience)

An article presenting IIT results from a single center experience (Auryon-SCE), US-based, showed the safety profile was replicated in the Auryon-SCE study, where only one type C dissection (1.4%) was recorded post-Auryon in the treatment of 70 lesions. The Auryon-SCE study further reinforces the safety profile of the device, as the average lesion's length was 117.1mm compared to 54mm in the EX-PAD-03 study, indicating that the Auryon laser is safe and effective in longer, more complex lesions. Freedom from TLR in this study was reported as 95.6% and 83.7% at 6 months and one –year, respectively.[8,9]

Summary Table of safety and efficacy results in Auryon SCE study.

PATIENTS	**N=56**
Age (years)	70.9 ± 10.0
BMI	28.1 ± 5.8
Ankle Brachial Index (n=31)	0.7 ± 0.3
Male	37 (66.1%)
Coronary artery disease (CAD)	28 (50.0%)
Chronic Kidney Disease	26 (46.4%)
History of major amputation	2 (3.6%)
Hypertension	50 (89.3%)
Hyperlipidemia	53 (94.6%)
Current / prior smoker	50 (89.3%)
Diabetes Mellitus	27 (48.2%)
CLI per Rutherford Becker Classification 4-6	14 (25.0%)
LESIONS	**N=71**
Lesion length (mm) (n=61)	117.1 ± 101.2
Treated length (mm) (n=64)	174.0 ± 116.0
Vessel diameter by angiography (mm) (n=68)	5.7 ± 1.3
Total stented segment (mm) (n=20)	84.9 ± 49.1
Stenosis (%)	
Baseline (n=70)	91.3 ± 9.7
Post Laser (n=40)	56.0 ± 17.3
Post–adjunctive (n=66)	11.4 ± 11.2
Number of Runoffs (N=65)[1]	
0 Runoffs	5 (7.7%)
1 Runoff	25 (38.5%)
2 Runoffs	15 (23.1%)
3 Runoffs	15 (23.1%)
Lesion Type (n=70)	
Denovo	34 (48.6%)
Restenosis	15 (21.1%)
ISR	6 (8.5%)
Restenosis + ISR	10 (14.1%)
Restenosis + denovo	1 (1.4%)
Denovo, Restenosis, and ISR	1 (1.4%)
Denovo and ISR	3 (4.2%)
Filter used with the laser (n=65 procedures)	26 (40.0%)
Moderate- Severe Calcium (n=70)[2]	28 (40.0%)
Drug coated balloons (n=70)	53 (75.6%)
Below the knee Lesions (n=70)[3]	7 (10.0%)
PROCEDURAL COMPLICATIONS	**N=71**
Dissection ≥C post laser	1 (1.4%)
Dissections ≥C post balloon angioplasty	5 (7.1%)

[8]Shammas et al. Auryon Laser in Peripheral Arterial Interventions: A Single-Center Experience (Auryon-SCE) J Invasive Cardiol. 2022 Jun;34(6):E428-E432. Epub 2022 May 11.

[9]Shammas et al. Auryon Laser in Treating Symptomatic Infrainguinal Arterial Disease: 1-Year Outcome, Vol. 34 Epub 2022 June 17

Stenting (n=70)	24 (34.3%)
Bailout stenting (n=70)[4]	11 (15.7%)
Distal embolization requiring treatment (n=65)[5]	1 (1.5%)
IN-HOSPITAL ADVERSE EVENTS	**N=56**
Death (secondary to myocardial infarction. Not procedure related)	1 (1.8%)
Major bleeding	0 (0.0%)
Unplanned major amputation	0 (0.0%)
Non-fatal myocardial infarction	0 (0.0%)
6-MONTH FOLLOW UP	**N=56**
Death	2 (3.6%)
Major amputation (per procedure)	1 (1.6%)
Freedom from target lesion revascularization	95.6%
12-MONTH FOLLOW UP	**N=56**
Death	3 (5.4%)
Major amputation	2 (3.1%)
Freedom from target lesion revascularization	83.7%

[1] Five were not recorded [2] If reported by and judged by operator, number of lesions; [3] ATA, TP and Peroneal [4] four due to flow-limiting dissection [5] Mechanical aspiration.

Auryon Case Series (EX-PAD-07)

An article presenting IIT results from a single center case series, discusses trends in clinical outcomes associated with the use of Auryon atherectomy system in a real-world setting. This publication reports that in 55 consecutive patients treated with the Auryon laser, zero patients had procedure-related complications prior to discharge.[10]

Summary Table of safety and efficacy results in Auryon Case Series study.

PATIENTS	**N=55**
Age (years)	73.7 ± 9.3
Male	35 (63.6 %)
Smoking history	41 (71.5 %)
Diabetes mellitus	37 (67.3 %)
Hypertension	41 (74.5 %)
Dyslipidemia	37 (67.3 %)
Coronary artery disease	17 (30.9 %)
Myocardial infarction	10 (18.2 %)
Chronic obstruction lung disease	9 (16.4 %)
History of stroke	13 (23.6 %)
End-stage renal disease	5 (9.1 %)
Intermittent claudication	31 (56.4 %)
Critical limb threatening ischemia	29 (52.7 %)
Chronic total occlusion	24 (43.6 %)
In-stent restenosis	1 (1.8 %)
Rutherford classification	3.9 ± 1.0
2	1 (1.8 %)
3	25 (45.5 %)
4	7 (12.7 %)
5	22 (40.0 %)
LESIONS	**N=55**
Lesions treated per patient	2.1 ± 1.0
Lesion location	
Above the knee	9 (16.4 %)
Below the knee	2 (3.6 %)
Both	44 (80.0 %)
Lesions length	
<5 cm	6 (10.9 %)
5–10 cm	12 (21.8 %)
10–15 cm	7 (12.7 %)

[10]Kovaleski A. Trends in outcomes associated with the use of Auryon atherectomy system in a real-world setting. Cardiovascular Revascularization Medicine. Available online 24 June 2023. https://doi.org/10.1016/j.carrev.2023.06.020

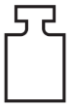
15–20 cm	11 (20.0 %)
>20 cm	19 (34.5 %)
Reference vessel diameter (mm)	4.7 ± 1.6
Moderate/Severe Calcification	24 (43.6 %)
Target limb run-off	1.7 ± 1.0
Angioplasty balloon	
Cutting or scoring	0 (0.0%)
Non-drug coated balloon	55 (100.0%)
Drug coated balloon	0 (0 %)
Stent placed	3 (5.5 %)
Procedural success[1]	47 (85.5 %)
Procedure-related complications	0 (0.0%)
30-DAYS SAFETY	**N=55**
cardiovascular death	0 (0.0%)
TLR	0 (0.0%)
Amputation above the ankle	0 (0.0%)
POST 30-DAYS SAFETY	
TLR due to Stenosis/re-occlusion	14 (25.5%)
Time to TLR, days	218.3 ± 92.4
Death[2]	1 (1.8%)

[1]defined as <30 % residual stenosis without any complications. [2]Unrelated to the procedure

15. Symbols

Symbol	Ref	Title of Symbol	Meaning of Symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer. [a]
	5.1.2	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union. [a]
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured. [a]
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified. [a]
	5.1.7	Serial number	Indicates the manufacturer's serial number so that the medical device can be identified. [a]
	5.1.8	Importer	Indicates the entity importing the medical device into the locale. [a]
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process. [a]
	5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully. [a]
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources. [a]
	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture. [a]
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed. [a]
	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed. [a]
	5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed. [a]
	5.7.7	Medical device	Indicates the items is a medical device. [a]
	5.7.10	Unique device identifier	Indicates a carrier that contains unique device Identifier information. [a]

Symbol	Ref	Title of Symbol	Meaning of Symbol
	101	Emergency Laser Stop	Emergency Laser Stop.[l]
	0623	This way up	This is the correct upright position of the distribution packages for transport and/or storage.[hj]
	2402	Do not stack	Stacking of the distribution packages is not allowed and no load shall be placed on the distribution packages.[hj]
	5114	Foot switch	To identify a foot switch or the connection for a foot switch.[f]
	5140	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.[f]
	NA	Follow instructions for Use ifu.angiodynamics.com	Refer to instruction manual.[e]
	NA	General warning sign	General warning sign. [e]
	NA	FCC Declaration of Conformity	Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.[i]
	NA	Type CF applied part	Type CF applied part.[e]
	NA	Wheelie bin	Separate collection for Waste Electrical and Electronic Equipment (do not place in trash).[g]

Symbol	Ref	Title of Symbol	Meaning of Symbol
CE 2797	NA	CE Mark	Manufacturer's declaration of conformity to the Medical Device Regulation EU 2017/745. [c]
℞ ONLY	NA	Rx only	Caution: (US) Federal law restricts this device to sale by or on the order of a licensed practitioner. [b]
	NA	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.[d]
	NA	Equipotentiality	Equipotentiality.[e]
	NA	Mass	Mass[h]
	NA	"OFF"	"OFF" (power).[e]
	NA	"ON"	"ON" (power).[e]
	NA	Laser aperture	Laser aperture.[k]

Appendix A: Pictures of the label locations on the system (see Section 8)

Label locations on the top of the laser system:

Label locations at the back of the laser system:

Label locations at the front of the laser system:

Limited Warranty

Warranty Summary

- The Auryon Atherectomy System and Auryon Atherectomy Catheters ("Products") are warranted free from defects in material or workmanship for 1 year from the date of delivery to the purchaser.
- Warranty repairs can be obtained by calling AngioDynamics' customer service department at +1 800-772-6446.
- All returned products must be prepaid and have a return materials authorization (RMA) number.
- Certain hardware and software updates or upgrades may be provided at no charge during the Warranty Period when Products are returned to AngioDynamics.
- Unauthorized repairs, misuse, or abuse of the Products will void the warranty.
- For all service or maintenance support, please contact your local distributor or AngioDynamics directly: USA Telephone: 1-866-883-8820 Fax: 1-518-932-0660 Email: service@angiodynamics.com

AngioDynamics warrants to the initial purchaser that the Products will be free from defects in material or workmanship, under normal, proper, and intended usage, for a period of one (1) year from the date of initial shipment to purchaser ("Warranty Period"). Excluded from this warranty are expendable components and supply items such as, but not limited to, power cords, footswitches, and cables. AngioDynamics' obligations under this warranty are to repair or replace any Products (or part thereof) that AngioDynamics reasonably determines to be covered by this warranty and to be defective in workmanship or materials, provided that the purchaser has given notice of such warranty claim within the Warranty Period and the Product is returned to AngioDynamics with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, purchaser should contact AngioDynamics directly (see contact information on the back cover of this manual). AngioDynamics will authorize purchaser to return the Product (or part thereof) to AngioDynamics. AngioDynamics shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become AngioDynamics' property. In the course of warranty service, AngioDynamics may, but shall not be required to, make engineering improvements to the Product or part thereof. If AngioDynamics reasonably determines that a repair or replacement is covered by the warranty, AngioDynamics shall bear the costs of shipping the repaired or replacement Product to purchaser. All other shipping costs shall be paid by purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If purchaser ships a Product to AngioDynamics in unsuitable packaging, any physical damage present in the Product on receipt by AngioDynamics (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of purchaser.

This warranty does not extend to any Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Product, including but not limited to failure of or faulty electrical power; that have been used in violation of AngioDynamics' instructions; that have been affixed to any nonstandard equipment attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than AngioDynamics; or that have been disassembled, serviced, or reassembled by anyone other than AngioDynamics, unless authorized by AngioDynamics. AngioDynamics shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. AngioDynamics makes no warranty (a) with respect to any products that are not Products; (b) with respect to any products purchased from a person other than AngioDynamics or an AngioDynamics-authorized distributor; or (c) with respect to any product sold under a brand name other than AngioDynamics.

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