AngioDynamics®

VenaCure® 1470

DIODE LASER OPERATOR MANUAL

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Manufactured in the United Kingdom by AngioDynamics UK Limited

SECTION 1 WELCOME

Thank you for purchasing an AngioDynamics **VenaCure 1470** laser. This is a high quality medical instrument that will give many years of service if used and cared for according to the instructions in this operator manual.

Before going any further it is important that the Product Information on page 4 is completed at installation for future reference. The Warranty Form in the accompanying Warranty Booklet must also be filled in and the form returned to AngioDynamics to complete the registration process.

INTRODUCTION

This manual describes the operation of the **VenaCure 1470** laser. This product is to be used only by experienced, trained operators familiar with laser procedures.

Before using this instrument for the first time, read the Safety & Warnings (section 2) and the Operating Instructions (section 3).

The operator must become familiar with all the controls before commencing any therapy.

The **VenaCure 1470** laser is a diode laser capable of delivering up to 12W of continuous wave or pulsed radiation via an optical fiber coupled to the laser aperture.

The **VenaCure 1470** laser incorporates a Class 4 (IV) InP (Indium Phosphide) diode laser with a wavelength of 1470nm (±20nm).

The **VenaCure 1470** laser incorporates a visible Class 3R (IIIa) diode laser aiming beam with a wavelength of 635-660nm and a maximum power output of 5mW.

DESCRIPTION OF THE VENACURE 1470 LASER

The **VenaCure 1470nm** laser has been designed for use with the AngioDynamics range of VenaCure EVLT® procedure kits for Endovenous Laser Treatment.

The **VenaCure 1470** laser system consists of three main components:

- The main enclosure houses the laser module containing the optics, heatsink, microprocessor-based control electronics and power supplies
- The footswitch to activate the laser output when in READY mode
- The fiber for delivering the laser radiation (sold separately)

Key features of the **VenaCure 1470** laser include:

- 12W power output
- Compact & portable
- Intuitive user interface
- Automatic fiber recognition for use with the AngioDynamics Endovascular Laser procedure kits
- Minimal maintenance & service
- Memory card slot for transfer of data between the **VenaCure 1470** laser and a PC

ABOUT THIS MANUAL

This manual is broken down into five sections as described below.

1	Welcome	
2	Safety & Warnings	Explains the general warnings and precautions that must be followed to ensure that the **VenaCure 1470** laser is used in a safe manner.
3	Operating Instructions	Provides detailed instructions on how to install and operate the **VenaCure 1470** laser.
4	Technical Information	Explains all the maintenance procedures that can be performed by the user.
5	Warranty	Contains the AngioDynamics warranty policy.

PRODUCT INFORMATION

Laser Serial Number

Software Version .....
(Note: This is shown on the screen displayed at start-up.)

Date Installed .....

Installed by.....

Signed .....

Print Name .....

Organization .....

For service, parts or repair, contact your local AngioDynamics representative:

CONTENTS

SECTION 2 SAFETY & WARNINGS

SYMBOLS USED IN THIS MANUAL

	This symbol indicates caution should be taken, as there may be a potentially hazardous situation that could result in injury to personnel or damage to the equipment.
	This symbol indicates the possibility of a non-radiation hazard that may result in severe injury to personnel within the vicinity of the equipment.
	This symbol indicates the possibility of an electrical hazard that could cause injury to personnel within the vicinity of the equipment or damage to the equipment.
	This symbol indicates the possibility of exposure to hazardous laser radiation that could cause injury to personnel within the vicinity of the equipment.
	This symbol indicates personnel within the vicinity of the equipment should wear appropriate eye protection.
	This symbol indicates an important point to be noted.

SYMBOLS USED ON ANGIODYNAMICS PRODUCTS

The following symbols are used on the **VenaCure 1470** laser and on accessories provided by AngioDynamics.

	Consult instructions for use
	Caution, consult accompanying documents
	Power Off
	Power Off (only for a part of equipment)
	Power On
	Type B applied part
	Intentional radiator
	Follow Electrostatic Discharge (ESD) precautions
	The component or accessory is non-sterile
	Do not re-use
	Do not use if packaging is damaged
	Expiration date
	Batch number
	Product re-order code
	Sterile by Ethylene Oxide

WARNINGS

	US Federal Law restricts the use of this device to sale by or on the order of a physician. Intended for use only by trained physicians/surgeons familiar with laser procedures.
	Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	This product must be stored at temperatures between 0°C (32°F) and 55°C (130°F). If stored at temperatures outside these limits for a period of time, the laser requires up to 12 hours acclimating prior to operation. Failure to observe this could result in invalidation of the warranty.
	If the product has been stored at a temperature above 30°C (86°F), the laser's cooling system may take a few minutes to stabilize after it has been switched on. A message will be displayed on the screen to indicate this.
	The laser is not designed to operate at temperatures below 10°C (50°F).
	This product contains a lithium battery, which should only be replaced by authorized service personnel. Replace the battery only with the same or equivalent type. Dispose of used batteries according to the manufacturer's instructions and local disposal requirements.

EMC WARNING

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

The **VenaCure 1470** laser may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Portable and mobile RF communications equipment can affect medical electrical equipment.

The **VenaCure 1470** laser should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the **VenaCure 1470** laser should be observed to verify normal operation in the configuration in which it will be used.

If electromagnetic interference is experienced, relocate or re-orientate the **VenaCure 1470** laser or the other equipment.

Accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the **VenaCure 1470** laser as replacement parts for internal components, may result in increased emissions or decreased immunity of the **VenaCure 1470** laser. 'Immunity' is the ability of a device to function normally when operated in the presence of electromagnetic radiation.

The following cables are compatible with the **VenaCure 1470** laser**:**

- Foot Switch Assembly (supplied with laser):
  AngioDynamics part number: AS1/A0/0002.

- Remote Interlock Lead (if required):
  Lemo connector (supplied with laser): AngioDynamics part number: CON/51/0003
  Ferrite sleeve (Farnell part number: 898-454).
  Screened twisted pair cable 7/0.2 (Farnell part number: 140-457), maximum length 4m (13ft).

  Note: The ferrite sleeve should be fitted to the remote interlock cable, at a maximum of 75mm (3 inches) from the Lemo connector.

- Remote Interlock Bypass (supplied with laser):
  AngioDynamics part number: AS1/A3/0024.

- IEC Power Lead (supplied with laser):
  AngioDynamics part number: CBL/02/0040.

SAFETY CLASSIFICATIONS, HAZARDS AND PRECAUTIONS

The **VenaCure 1470** laser is classified as a Class 4 (IV) laser product in compliance with FDA 21 CFR 1040.10 and 1040.11, UL 60601-1, EN 60601-1, EN 60601-1-2, EN 60601-2-22 and EN 60825-1.

The **VenaCure 1470** laser conforms to the requirements of Council Directive 93/42/EEC of the Council of European Communities (Medical Devices Directive). Affixing the 'CE Mark' to the instrument indicates conformity to this directive.

CE
0086

The local Laser Safety Officer should review all procedures for safety prior to system use.

A Class 4 (IV) laser is hazardous to the eye from the direct beam and diffuse reflections. It also presents significant skin and fire hazard.

Avoid eye or skin exposure to direct or scattered radiation. Take all necessary protective measures, as explained in the rest of this section, in areas where the laser is being used.

All personnel must wear approved protective glasses appropriate to the wavelength of the **VenaCure 1470** laser to reduce the risk of eye damage.

The aiming beam is a Class 3R (IIIa) laser and an unprotected eye may view the beam scattered from a non-reflective surface. Do not stare into the aiming beam or view it directly with optical instruments.

Avoid directing the laser beam anywhere other than the treatment area or calibration ports.

Before using a fiber, check it carefully for any signs of damage during storage or transit. Protective caps should be in place over SMA connectors. Do not use if there is any sign of damage.

The **VenaCure 1470** laser is a portable laser weighing up to 12kg (26lb). All standard safety procedures for lifting should be applied when moving the instrument.

There are no user serviceable parts in the **VenaCure 1470** laser. The exterior cover should only be removed by a trained and authorized laser service technician**.**

Pins of connectors identified with the Electrostatic Discharge (ESD) warning symbol should not be touched. Connections should not be made to these connectors unless the ESD precautionary procedures detailed on page 22 are followed.

It is recommended that all staff receive an explanation of the ESD warning symbol and made aware of the ESD precautionary procedures described at the end of this section.

EYE INJURY

Extreme caution should be taken when operating the VenaCure 1470 laser near the eyes.

All personnel must wear approved protective glasses to reduce the risk of eye damage. The patient should wear protective glasses.

The local Laser Safety Officer should review all procedures for safety prior to system use.

All protective glasses should be designed for protection from continuous wave laser radiation in the wavelength range 1440 – 1500nm.

The degree of optical filtration (Optical Density or OD) depends on the application and should be assessed and approved by the appointed Laser Safety Officer for the establishment.

The recommendations of European Standards EN 60825-1 or EN 207 are appropriate to assessing laser eye risk. Note that the standards assume a viewing distance from the source of light of more than 100mm (4 inches).

AngioDynamics supplies laser safety glasses marked in accordance with EN 207 as L3 or greater. Contact your local AngioDynamics representative if these are required.

The ‘Nominal Ocular Hazard Distance’ is 0.31m (1 foot).

Use of optical accessories and viewing aids, which may increase the eye exposure beyond a safe limit, should be subject to the approval of the Laser Safety Officer.

Never look directly into the laser aperture even if wearing safety glasses. Serious eye injury could result.

BURNS

Irradiation of any substance or material other than the target treatment of varicose veins and varicosities may result in a laser burn.

REFLECTION WARNING

Avoid placing reflective materials such as glass, metals and polished plastic in the beam.

EXPLOSION HAZARD WARNING

Avoid using flammable or explosive anesthetic gases that may be ignited by the laser. Avoid using other flammable or fume-emitting substances (e.g. ether, iodine solution, collodion, and alcohol) in the operative field.

VAPOR PLUME

AngioDynamics recommends that a smoke evacuator or in-line filter be used when lasing.

CLINICAL INDICATIONS & CONTRAINDICATIONS

Indications

The VenaCure 1470 laser is intended for use in delivering up to 12 Watts of continuous wave or pulsed radiation with AngioDynamics EVLT Procedure Kits in endovascular coagulation of the Greater Saphenous Vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

Recommended power range is between 5W and 7W. A specific level is not recommended, but is left to user preference and best medical judgement.

Contraindications

The **VenaCure 1470** laser is contraindicated for:

- Patients with thrombus in the vein segment to be treated
- Patients with an aneurysmal section in the vein segment to be treated
- Patients with peripheral artery disease as determined by an Ankle-Brachial Index < 0.9

Potential Complication

The potential for complications exists, including:

- Vessel Perforation
- Thrombosis
- Pulmonary Embolism
- Phlebitis
- Hematoma
- Infection
- Skin Pigmentation Alteration
- Neovascularization
- Paresthesia due to thermal damage of adjacent sensory nerves
- Anesthetic Tumescence
- Non-Target Irradiation
- Hemorrhage
- Necrosis
- DEHP Exposure
- Skin Burns and Pain

(This is not an exhaustive list.)

CLINICAL WARNINGS

As with any conventional surgical operations, adverse reactions may occur following treatment.

Use cautiously with patients who have had difficulty with previous laser procedures.

CLINICAL PRECAUTIONS

General Precautions

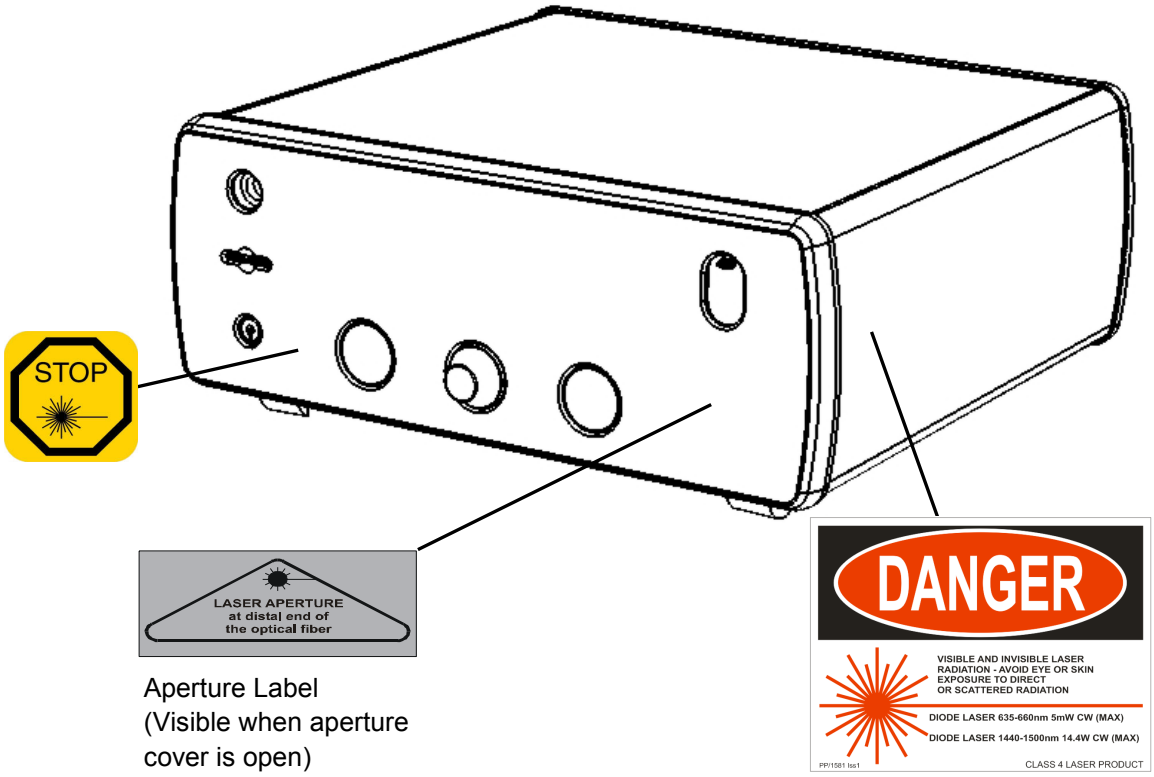
Only operators who have been trained in the use of lasers and are thoroughly familiar with this Operator Manual should use the **VenaCure 1470** laser. The information provided in this section is not intended to be all-inclusive and it is not intended to replace operator training or experience. Please contact your AngioDynamics representative for training materials available on the use of this equipment.

Specific parameters are not recommended, but are left to operator preference and best medical judgment.

SAFETY LABELING

Location of Safety Labeling

Safety labels for the **VenaCure 1470** laser are positioned as indicated below.

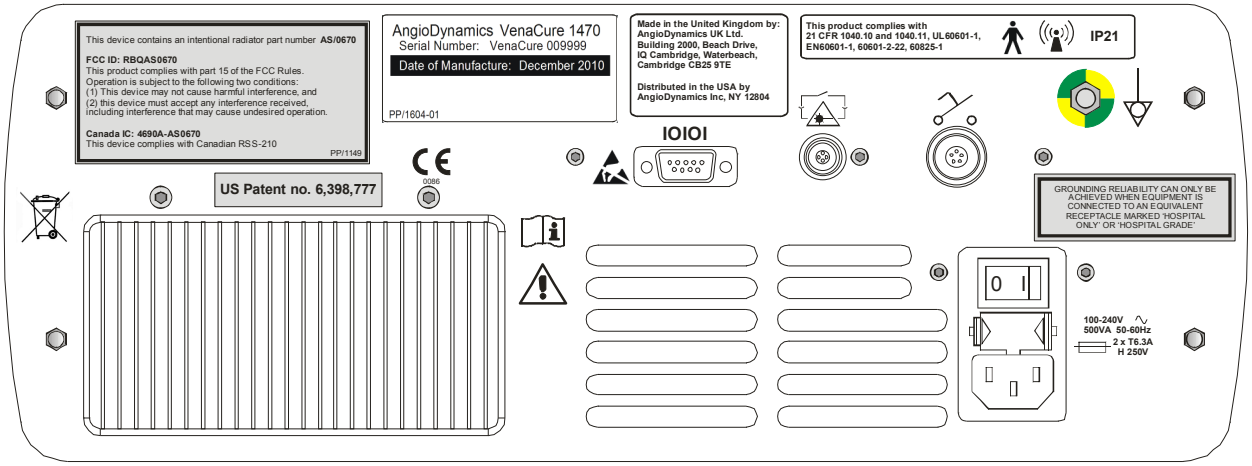


Aperture Label
(Visible when aperture cover is open)

Safety Label

Product Identification Labeling

Product identification labeling is located on the rear of the **VenaCure 1470** laser.



SAFETY FEATURES

The **VenaCure 1470** laser includes a number of safety features, which are provided in accordance with the requirements of the appropriate standards.

- protective housing
- remote interlock bypass
- key switch
- laser radiation emission indicator, visible and audible
- **READY** and **STANDBY** modes
- manual reset mechanism
- shutter (not mechanical)
- emergency switch
- location of controls
- safety labels (see diagram)
- identification and compliance label (see diagram)
- aiming beam

The **VenaCure 1470** laser is equipped with the following additional safety features:

- self-test
- laser condition monitoring
- pulse duration monitoring
- power diodes watch-dog
- microprocessor watch-dog
- mains power fail protection
- power supply monitor
- temperature monitors

EMC DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The **VenaCure 1470** laser is intended for use in the electromagnetic environment specified below. The customer or user of the **VenaCure 1470** laser should ensure it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic emissions – guidance**
RF emissions CISPR 11	Group 1	The **VenaCure 1470** laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **VenaCure 1470** laser is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The **VenaCure 1470** laser is intended for use in an electromagnetic environment specified below. The customer or the user of the **VenaCure 1470** laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV 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	+/- 2kV for power supply lines +/- 1kV for input/output lines	+/- 2kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV differential mode +/- 2kV common mode	+/- 1kV differential mode +/- 2kV common mode	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	<5% U_T (>90% dip in U_T) for 0,5 cycle 40% U_T (90% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>90% dip in U_T) for 0,5 cycle 40% U_T (90% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **VenaCure 1470** laser requires continued operation during mains interruptions, it is recommended that the **VenaCure 1470** laser be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **VenaCure 1470** laser is intended for use in an electromagnetic environment specified below. The customer or the user of the **VenaCure 1470** laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the **VenaCure 1470** laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance.**
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	d = 1.2 √P
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	d = 1.2 √P 80MHz to 800MHz d = 2.3 √P 800MHz to 2,5GHz 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 electronic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **VenaCure 1470** laser is used exceeds the applicable RF compliance level above, the **VenaCure 1470** laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **VenaCure 1470** laser.

[b] Over the frequency range 150kHz to 800MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications and the VenaCure 1470 laser.

The **VenaCure 1470** laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **VenaCure 1470** laser can help prevent electromagnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the **VenaCure 1470** laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter m**		
W	**150kHz to 80MHz** $d = 1.2\ \sqrt{P}$	**80MHz to 800MHz** $d = 1.2\ \sqrt{P}$	**800MHz to 2,5GHz** $d = 2.3\ \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ESD PRECAUTIONARY PROCEDURES

ESD (Electrostatic Discharge) occurs in air, causing a spark, when the potential difference between two bodies exceeds the dielectric strength of the air.

The **VenaCure 1470** laser has built-in protection from damage due to ESD, but no protection is 100% effective and precautions should be taken to protect the **VenaCure 1470** laser and any device connected to it.

When connecting the **VenaCure 1470** laser with another device, it is very important for the **VenaCure 1470** laser, the device, and the user to be at or close to the potential of the earth.

(1) First, momentarily touch a grounded object to remove any existing static charge
(2) Connect one end of the 9-way interface lead to the **VenaCure 1470** laser, taking care not to touch the pins of the connector
(3) Connect the other end of the 9-way interface lead to the device, taking care not to touch the male pins of the associated connector

ESSENTIAL PERFORMANCE

By risk analysis of the hazards posed by electromagnetic interference, the following performance factors of the **VenaCure 1470** laser have been determined to be Essential Performance:

- The laser output power must be within +/-20% of the indicated power
- The display and front panel indicators must function correctly

Also, note that the RFID system must not fail to read the fiber's tag. This will ensure that the correct product is used in combination with the **VenaCure 1470** laser. Failure to read the fiber's tag will not allow the laser to be fired.

FCC DECLARATION

This product 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.

This equipment generates uses and can radiate radiofrequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at their expense.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

SECTION 3 OPERATING INSTRUCTIONS

INTRODUCTION

The **VenaCure 1470** laser is capable of working with the AngioDynamics range of VenaCure EVLT procedure kits for endovenous laser treatment. The FRS system fitted as standard allows it to identify that the correct VenaCure EVLT fiber is connected. This enables the laser to automatically display the preset parameters for the endovascular coagulation procedure.

The following instructions focus on the most common situations, when the **VenaCure 1470** laser is being used with an AngioDynamics VenaCure EVLT procedure kit, fitted with the FRS system.

CONVENTIONS

The following naming conventions are used throughout these Operating Instructions:

Controls on the front panel are expressed in bold capitals.	**SCROLL**, **STANDBY**
Functional modes of the **VenaCure 1470** laser are expressed in capitals.	STANDBY, READY
Menu items are expressed in bold mixed case.	**Main Menu**, **Language**

SUMMARY

1. Place the **VenaCure 1470** laser in a convenient position on an instrument table no farther than 1.8m (6 feet) from the patient. Ensure that all controls are within easy reach of the operator. The viewing angle of the front panel may be altered by raising or lowering the folding foot located under the **VenaCure 1470** laser.

2. Ensure that the ventilation holes in the base and rear of the **VenaCure 1470** laser are not obstructed.

3. Connect the electrical power cord to the main power outlet.

4. Connect the footswitch and place in a convenient position for the operator.

5. Insert either a remote interlock bypass or, if required, connect the door interlock cable to the remote interlock socket on the rear of the **VenaCure 1470** laser.

6. Check that approved safety glasses are available and laser-warning signs are provided at entrances to the treatment room. All personnel present must wear approved safety glasses.

7. Connect the optical fiber to the laser aperture, ensuring that the connector is screwed 'finger tight'.

8. Turn on the rear power switch and key switch to activate the **VenaCure 1470** laser. While the self-test is running, check that the front panel indicators light up and the audible indicator sounds momentarily.

9. After the self-test, use the **SCROLL/CONFIRM** control to select the mode.

THE FRS SYSTEM ENSURES BEST PERFORMANCE AND EFFICACY BY ALWAYS USING ANGIODYNAMICS FIBERS.

THE DISPLAYED POWER IS THE POWER LEVEL AT THE LASER APERTURE. IT SHOULD BE ASSUMED THAT THE POWER LEVEL AT THE FIBER TIP IS 10-15% LOWER.

10. The system will automatically go to the STANDBY mode, with a set of default operating parameters. If required, adjust these parameters now using the **SCROLL/CONFIRM** control. The **VenaCure 1470** laser is now ready to begin the treatment.

11. To start treatment and delivery of laser energy, press **STANDBY/READY**, wait for the **VenaCure 1470** laser to enter READY mode and depress the footswitch. During laser radiation the laser emission indicator will light and an audible warning will be heard.

12. To pause treatment, release the footswitch. To continue treatment, press the footswitch. To end treatment, release the footswitch and return the unit to STANDBY.

13. A summary of laser energy delivered during the current or previous session may be reviewed if required by selecting **Statistics** from the **Main Menu**.

14. To turn the **VenaCure 1470** laser OFF turn the key switch and remove the key, then switch off the rear power switch.

If an error message is displayed, refer to section 4 - Technical Information.

INSTALLATION AND SET-UP

Installation of the **VenaCure 1470** laser can be carried out by the end-user.

Inspection

Inspect the **VenaCure 1470** laser and accessories for signs of damage. If the unit is damaged **DO NOT USE** - contact AngioDynamics or your local AngioDynamics representative. If there are no signs of damage and all components are present, assemble the **VenaCure 1470** laser.

Check that the following components are included in the packaging:

- **VenaCure 1470** laser unit
- Footswitch
- IEC power cable
- Operator Manual
- Laser warning sign
- Test fiber
- Emergency override reset device

Inside the Operator Manual there is a sleeve containing the following accessories:

- 2 x Keys
- 2 x Remote Interlock bypass connectors
- 4 x spare fuses

Automatic Software Upgrades

From time to time, AngioDynamics will release software upgrades for the **VenaCure 1470** laser. These may be provided on a special memory card, for installation by the user. Insert the memory card into the slot on the front panel and then switch on the **VenaCure 1470** laser. If the card contains the correct software upgrades for the laser they will be detected after the self-test and installed automatically. Follow the instructions on the screen, but do not switch off until 'Upgrade complete' is displayed.

If you have any difficulty with this process, please contact your local AngioDynamics representative.

Further details on how to install software upgrades manually are provided on page 43.

The **VenaCure 1470** laser will operate at voltages between 100V and 240V AC without adjustment.

1. Connect the footswitch to the footswitch socket (line up red dots and insert).
2. Connect a remote interlock bypass connector to the remote interlock socket (line up red dots and insert).
3. Connect the optical fiber to the laser aperture as described in the section below.
4. Insert the IEC power cord into the power inlet socket and connect to the main power supply.
5. Switch the power switch to ON (|).
6. Insert a key into the key switch on the front of the unit.
7. The **VenaCure 1470** laser is now installed and ready for use.

Connecting to the Laser Aperture

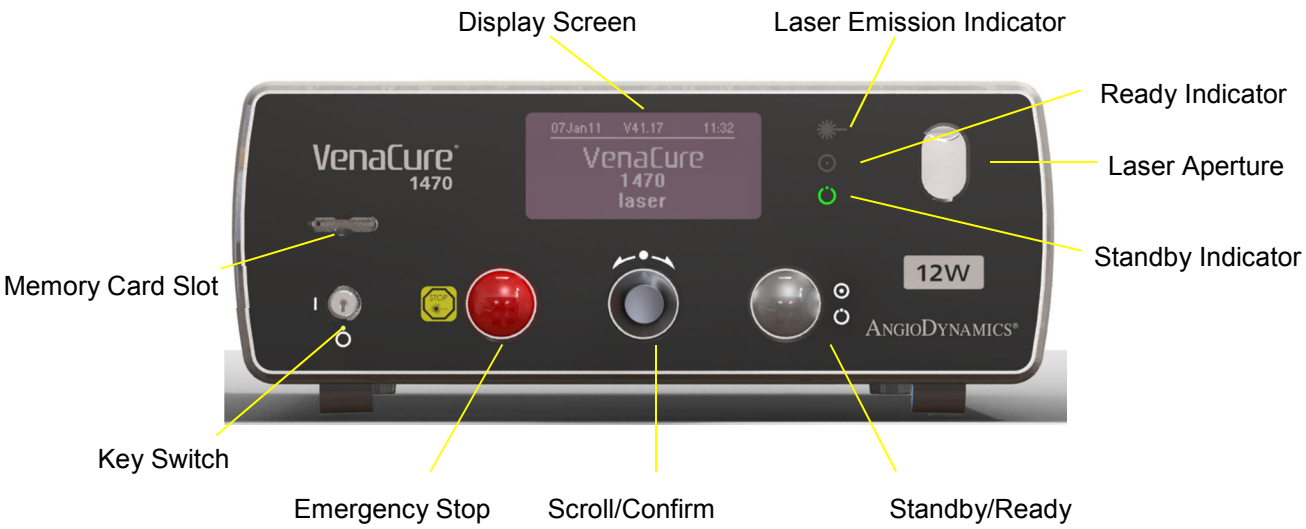
Laser energy is delivered to the optical fiber via the laser aperture located on the front panel of the **VenaCure 1470** laser. The fiber is connected by means of an SMA-905 type optical fiber connector.

To insert the optical fiber connector, first remove the protective cap from the end of the fiber. Then press down on the tab of the spring-loaded cover on the front panel to reveal the laser aperture. Insert the optical fiber connector into the laser aperture and turn the gripper clockwise until secured in place (light finger tight only).

It is essential that the exposed end of the optical fiber be kept clean to prevent damage to the VenaCure 1470 laser and optical fiber.

To remove the optical fiber connector, turn the gripper counter-clockwise until fully unscrewed and disconnect from the laser aperture. Dispose of the optical fiber according to institution policy.

FRONT PANEL CONTROLS



The main operating controls for the **VenaCure 1470** laser are located on the lower section of the front panel. The display and other indicators are located in the top section of the panel, as illustrated in the figure above.

Key Switch

The key switch is used to start the **VenaCure 1470** laser and is the main control for the device. The key is removable only in the OFF position and the laser is not operable when the key is removed.

AngioDynamics recommends that the keys are assigned to one or two key-holders, who should keep the keys in a secure place and make them available for scheduled procedures only, thus preventing unauthorized use of the system.

AngioDynamics also recommends that the key is not mixed with other keys on the same ring.

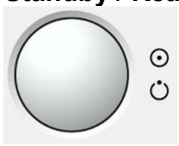
Display Screen

This displays all menu options and information.

Scroll / Confirm

To enable selection of Menu commands, turn the knob left or right to move between commands and press the knob to confirm the selection.

Standby / Ready



To select STANDBY or READY mode. Laser energy delivery is possible only in the READY mode. When the READY request is made, the READY light flashes for two seconds before the system enters READY mode. Pressing the button a second time will return the system to STANDBY mode.
If the footswitch is pressed when the READY request is made, the message 'Footswitch pressed' is displayed and the footswitch should be released before the operation can continue. The message will disappear when the footswitch is released.

Standby Indicator

This light will be on when the laser is in STANDBY mode.

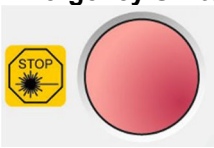
Ready Indicator

This light will be on when the laser is in READY mode.

Laser Emission Indicator

When laser energy is being delivered to the output port, this light will be on.

Emergency Switch



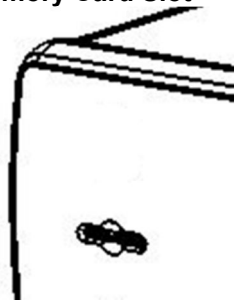
To shut down the laser immediately in case of emergency, press the red button located on the front panel of the main enclosure. After activation of the emergency switch, the power switch on the rear panel must be used to restart the system.

Laser Aperture

Laser energy is delivered to the optical fiber via the laser aperture located on the front panel. The aperture is protected from the ingress of dust etc. by a sliding cover. To gain access to the aperture, slide the cover down using the tab. When the aperture is open, the window beneath shows the Laser Aperture warning.

Use only AngioDynamics optical fibers. Damage caused by use of unapproved fibers will not be covered by warranty.

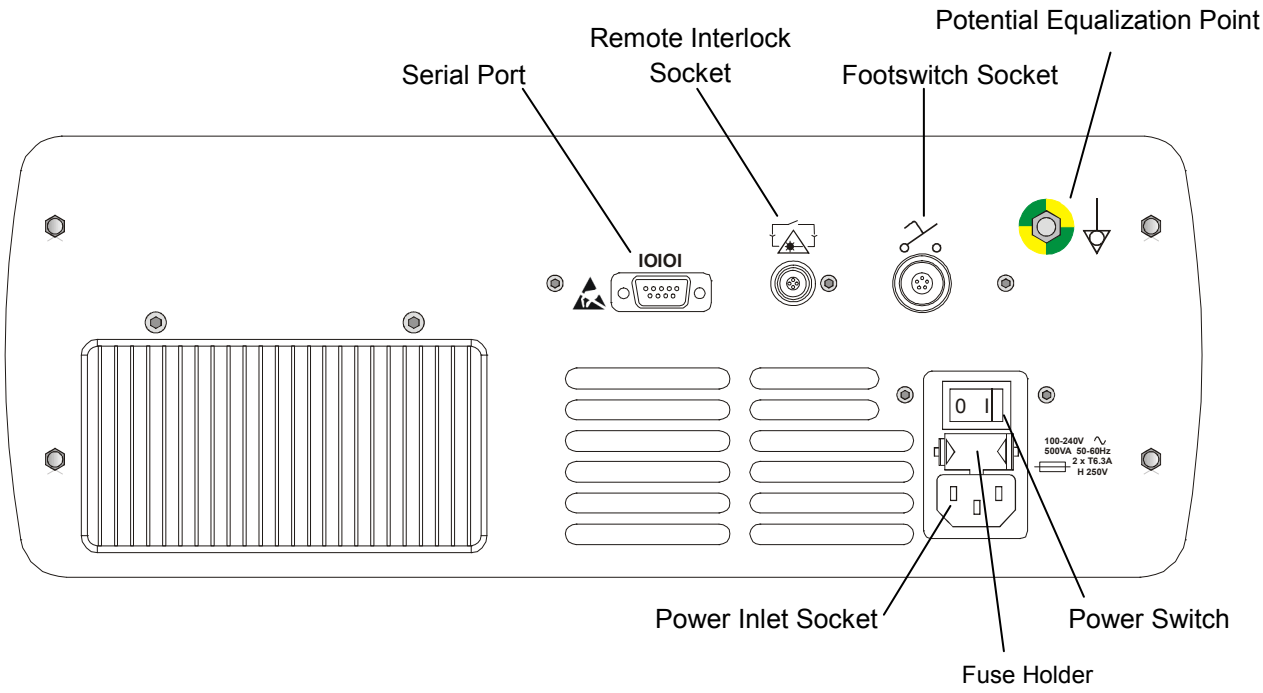
Memory Card Slot



The **VenaCure 1470** laser is compatible with both Multi Media Card (MMC) and Secure Digital (SD) memory cards. To ensure reliable performance only use cards with the AngioDynamics label. An AngioDynamics memory card is available as an accessory.

The memory card may be used to transfer data between the **VenaCure 1470** laser and a PC equipped with a suitable memory card reader interface.

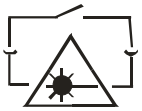
REAR PANEL CONTROLS



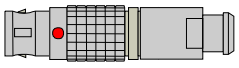
Power Inlet Socket To connect an IEC power cord.

Power Switch To switch the main power to the system on or off.

Remote Interlock Socket To connect the remote interlock cable connector. This will automatically switch the system to STANDBY mode in the event of the door being opened during the procedure.



If the remote interlock is connected to a door switch, then the cable used should be shielded and the shield connected to the plug body. An EMC sleeve (ferrite tube) should also be fitted over the cable adjacent to the connector. AngioDynamics can supply these, on request. These precautions will ensure that the possibility of electromagnetic emissions is minimized.



AngioDynamics supplies two remote interlock bypasses for facilities without or not wishing to use the door switch option. The **VenaCure 1470** laser will not operate without either a remote interlock or remote interlock bypass inserted into the remote interlock socket on the rear of the laser.

Footswitch Socket To connect the footswitch to the **VenaCure 1470** laser.

Serial Port
IOIOI

This connection is normally only used for diagnostic purposes by authorized AngioDynamics personnel.

Potential Equalization Point

To connect a potential equalization line, for common grounding between equipment, if needed.

Fuse holder

2 x T6.3A H 250V

Use of controls or adjustments, and or performance of procedures other than those specified herein may result in hazardous radiation exposure.

FIBER RECOGNITION SYSTEM

What is the Fiber Recognition System (FRS)?

All **VenaCure 1470** lasers are equipped with the AngioDynamics Fiber Recognition System (FRS). This system provides a means of identifying the fiber that is connected to a **VenaCure 1470** laser. AngioDynamics fibers are normally supplied in a kit of components for the endovascular coagulation procedure. The **VenaCure 1470** laser can automatically select preset parameters for the procedure. Compared to setting the parameters manually, this process is much quicker and far less prone to user error.

AngioDynamics does not recommend the use of third party fibers as their quality and efficacy cannot be guaranteed. Any damage caused to your VenaCure 1470 laser by using a fiber not supplied by AngioDynamics will not be covered under the AngioDynamics warranty. Please consult AngioDynamics Customer Support before using any unapproved fiber.

How does FRS work?

A miniature Radio Frequency Identification (RFID) device is located inside the gripper at the end of the fiber connected to the laser. This is read by a receiver inside the **VenaCure 1470** laser whenever it is switched on and a fiber connected to it. The RFID device contains a memory chip that holds the following information:

The type of fiber	This tells the system what type of fiber or accessory has been connected.[1]
The date when the sterility of the fiber expires	If the current date in the internal clock of the **VenaCure 1470** laser is later than the sterility expiration date, then the fiber is invalid and cannot be used.
Has the fiber already been used?	This function allows the laser to determine if the single use disposable fiber has already been used. If it has then the fiber is invalid and cannot be reused.
Compatibility of the fiber with the laser	Some fibers are designed to be compatible only with certain types of AngioDynamics laser.

What are the benefits of FRS?

- Operation of the **VenaCure 1470** laser is simplified because the FRS is able to automatically recognize the attached fiber and load preset parameters that are suitable for the procedure. A specific level is not recommended, but is left to user preference and best medical judgement.
- Single-use fibers cannot be re-used, as sterility and optical performance cannot be assured.
- Fibers that have passed their sterility expiration date cannot be used, minimizing the risk of patient infection.

[1] The system will read the fiber's data if the power is on and a FRS fiber is connected or if the **VenaCure 1470** laser is powered up with a FRS fiber already connected.

OPERATING INSTRUCTIONS

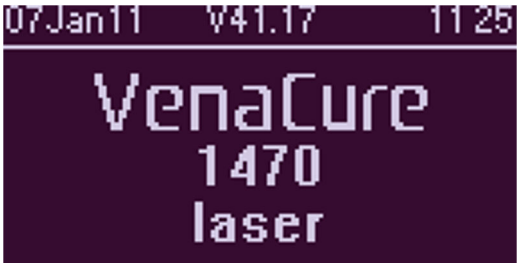
Once the **VenaCure 1470** laser has been correctly installed and switched on, it is operated using just two controls:

SCROLL / CONFIRM Turn the knob in either direction to **SCROLL** through the available options highlighted on the screen.
Press the knob to **CONFIRM** the selection.

STANDBY / READY Once the **VenaCure 1470** laser is set up and ready for the procedure, press this button to switch between the STANDBY ○ and READY ⊙ modes. Laser energy delivery is possible only in the READY mode.

Switching On

Ensure that the **VenaCure 1470** laser has been set up correctly, as described above and that the remote interlock footswitch and fiber connectors are all in place. Switch on the rear panel power switch. The display will show a screen similar to the one on the right.



Turn the key switch clockwise to activate the system. It will now perform a self-test function for a few seconds. While this is running, ensure that the indicators for Laser Emission, Standby and Ready are all illuminated and that the audible indicator sounds briefly.

Status Indicators

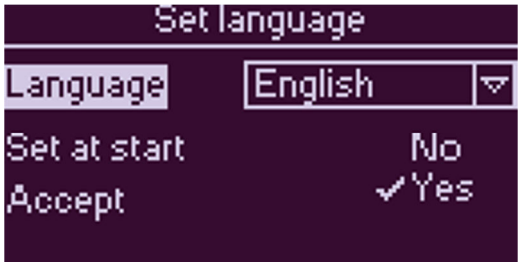
Before the **VenaCure 1470** laser is activated with the key switch, the screen may display various indicators to inform the user of the status of some of the system's functions.

These indicators are for information only and do NOT prevent the **VenaCure 1470** laser from being used. Please contact your AngioDynamics representative for further details.

The **VenaCure 1470** laser should have an annual check of the calibration of the output power of the laser. If either of these checks is due, a 'wrench' symbol will be displayed on the screen at start-up. This symbol will be removed after the checks are completed.

.The **VenaCure 1470** laser has an Emergency Override feature that allows a treatment to be continued in the event of a Session Fault (see page 39). If the override has been used then it must be reset using an Emergency Override Reset Device before it can be used again. The flashing symbol is a reminder that a Reset Device should be obtained from AngioDynamics

Setting the language at switch-on



The system will now prompt for the language to be used by the user interface. If you wish to change it, turn the **SCROLL** knob until **Language** is highlighted and press to **CONFIRM**. You can now use the **SCROLL** knob to select the required language from the drop down list. Press again to **CONFIRM** the selection.

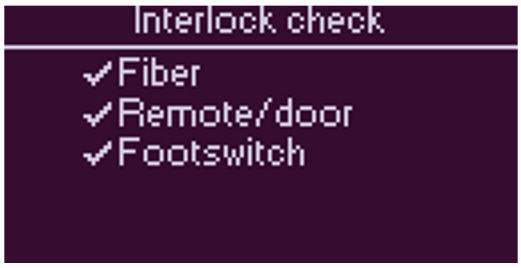
When **Set at start** is set to **Yes**, this screen will occur every time that the **VenaCure 1470** laser is switched on. To prevent this, change the selection to **No** as follows:

- Turn the **SCROLL** knob until **Set at start** is highlighted.
- Press **CONFIRM** to toggle between **Yes** and **No**.
- Turn the **SCROLL** knob to select **Accept**.
- Press **CONFIRM**.

You will still be able to change the language setting from the **Set-up Menu** option on the **Main Menu**.

Interlock Checks

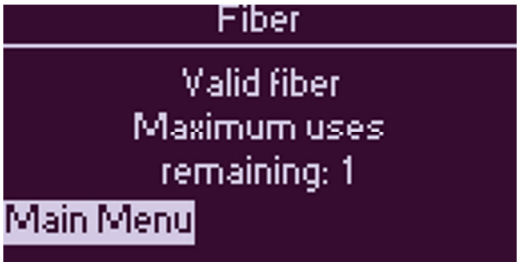
The system will now check that all the safety interlocks are properly in place. If a tick is not shown against one or more of the items in the display, recheck the appropriate connection.



Until all of the safety interlocks are in place, the **Statistics** and **Set-up Menu** options are also available on the display. This allows statistics to be accessed and the laser to be set up even when a fiber, remote interlock or footswitch are not connected. These functions are described in detail later in this manual.

Fiber Identification & Validation

After it has finished checking the interlocks, the **VenaCure 1470** laser system reads the FRS information stored inside the fiber's gripper. It will verify the fiber type, that the fiber has not already been used, and whether it is within its sterility expiration date.



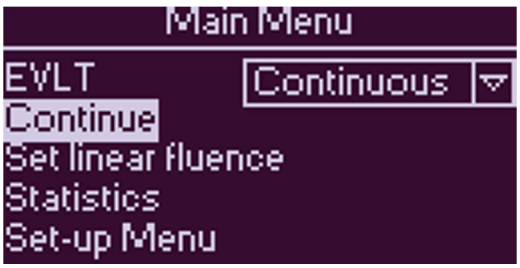
The **VenaCure 1470** laser will only permit a procedure to be carried out if an AngioDynamics FRS fiber is used. An incompatible fiber will be shown on the screen as **Invalid Fiber**.

AngioDynamics does not recommend the use of third party fibers as their quality and efficacy cannot be guaranteed. Any damage caused to your **VenaCure 1470** laser by using a fiber not supplied by AngioDynamics may not be covered under the AngioDynamics warranty.

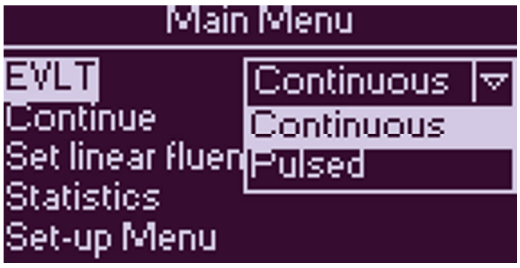
An **Emergency Override** option is included to allow the **VenaCure 1470** laser to be used once only in the event of a session fault, which has prevented the completion of a treatment. See **Session Fault Emergency Override** below for instructions on how to use this option.

AngioDynamics' policy of continual product development and improvement means that fibers and procedure kits may be added to the product range at any time. In order to use these, your **VenaCure 1470** laser will need to be updated with the latest procedure information. Please contact your AngioDynamics representative to obtain the latest product information.

Once the fiber is validated, the **VenaCure 1470** laser is ready to perform the treatment and can set itself up with the appropriate parameters. A screen similar to the following will be displayed.



Mode Selection



When the fiber has been validated by the FRS system, the **VenaCure 1470** laser is able to determine the procedure for selection by the operator. For The **VenaCure 1470** laser the fiber is from an AngioDynamics VenaCure® EVLT procedure kit. The **VenaCure 1470** laser recognizes this fiber and loads a list of available modes, as shown on the display.

The default mode is shown at the top of the menu. To select a different mode turn the **SCROLL** knob until **EVLT** is highlighted and press **CONFIRM**. Select the desired mode with the **SCROLL** knob and press **CONFIRM** again.

When the mode has been selected, highlight **Continue** using the **SCROLL** knob and press **CONFIRM**.

Parameter Adjustment

The **VenaCure 1470** laser will set the default operating parameters. Some situations may require the default parameters to be varied within lower and upper limits. A specific level is not recommended, but is left to user preference and best medical judgement.

The following parameters may be adjusted:

Mode The available modes are:

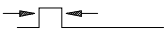
 Continuous

 Pulsed

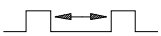
Power (W) Power may be adjusted in all operating modes:

 1W to 12 W in 0.5W increments

Pulse Duration (s) The pulse duration may be adjusted from:

 0.1 to 2.0 seconds in 0.1 second increments

Interval (s) The interval between the pulses may be adjusted from:

 0.1 to 2.0 seconds in 0.1 second increments

The default parameters for each available mode are:

Mode	Power	Pulse Duration	Pulse Interval
Continuous	6 W	Not available	Not available
Pulsed	6 W	1 sec	1 sec

The settings are adjustable depending on the physician's preference.

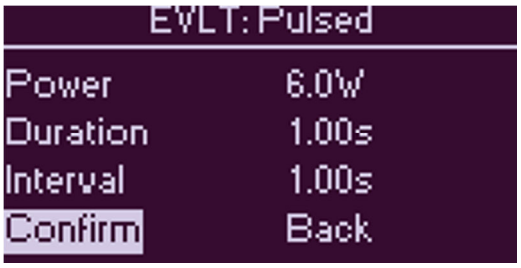
Depending on the mode selected, the next screen will display the parameters that are preset for the VenaCure EVLT procedure.

To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter and press **CONFIRM**. The highlight will now move to the value of the parameter on the right hand side of the display. Turn the **SCROLL** knob to adjust the value and press **CONFIRM** again. The highlight will move back to the left hand side of the display. Repeat this process for the other parameters as required.

VenaCure EVLT Continuous Mode

VenaCure EVLT Pulsed Mode

If the VenaCure EVLT Pulsed mode is selected, the duration and interval of the pulses may also be adjusted.



When the operating parameters of the **VenaCure 1470** laser are set, turn the **SCROLL** knob to move the highlight to **Confirm** and press **CONFIRM**. A message will appear for a few seconds, instructing you to press the **STANDBY/READY** button next.

Alternatively, to return to the main menu select **Back** and press **CONFIRM**.

Run the Procedure

The **VenaCure 1470** laser is now ready to start the procedure. Press **STANDBY/READY** and wait for the **VenaCure 1470** laser to enter the READY mode.

Depress the footswitch. An audible warning will be heard during laser irradiation and the laser emission indicator will be lit.

To pause treatment, release the footswitch. Press the footswitch again to continue. To end treatment, release the footswitch and return the unit to STANDBY.

To turn the **VenaCure 1470** laser off, turn the key switch counter-clockwise, remove the key and switch off at the rear panel.

The settings used for a treatment are retained in the **VenaCure 1470** laser and restored the next time that the procedure is selected. Note that the new values are only stored in the memory of the **VenaCure 1470** laser when the laser is put into the READY mode.

Screen Symbols

When the **VenaCure 1470** laser is in the READY mode the screen may show various symbols. The meanings of which are explained below:

Power output setting

Displayed power is the power launched into the optical fiber

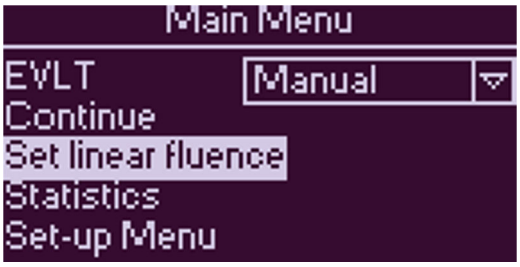
Pulse duration (if set to pulse mode)

Pulse interval (if set to pulse mode)

LINEAR FLUENCE

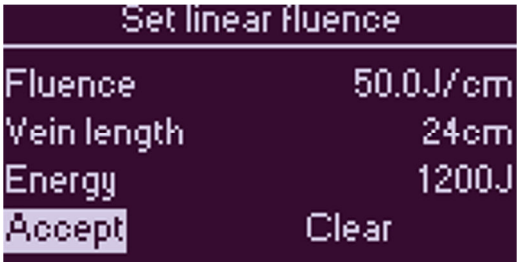
The purpose of the linear fluence function is to provide the operator with relative data on the status of the procedure they are performing. The normal Energy display and Elapsed time features show the total time and energy used. By entering details of the required fluence and the length of the vein to be treated, the display will instead show how much of the procedure is remaining, both as a percentage and the length of vein.

Note that this feature only affects the display on the **VenaCure 1470** laser and does not alter the actual operation of the laser or the way that statistics are recorded.



The linear fluence function requires the operator to enter the required linear fluence and length of vein into the **VenaCure 1470** laser before commencing a procedure. The total energy for the procedure is then automatically calculated.

This function is only available when the **VenaCure 1470** laser is used with compatible procedures.



By default, the linear fluence function is turned off. To enable, turn the **SCROLL** knob to highlight **Set linear fluence** and press **CONFIRM**. Now use the **SCROLL** and **CONFIRM** knob to select and adjust the values of **Fluence** and **Vein length**. As soon as an entry is made in **Vein length**, the total energy required to treat that length of vein is calculated and displayed.

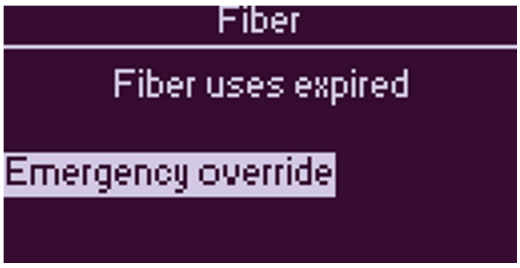
To accept the values, select **Accept** using the **SCROLL** knob and press **CONFIRM**. To cancel the linear fluence function select **Clear** instead.

The screen will now return to the Main Menu. Select **Continue** using the **SCROLL** knob and press **SELECT** to continue. Now follow the procedure as normal to enter the **READY** mode. Instead of the Energy display and Elapsed time indicators, the screen will now show the remaining proportion of the vein to be treated, as a percentage and length of vein. As the laser is fired, the remaining percentage and vein length will decrease. When these figures reach zero, the **VenaCure 1470** laser will continue firing until the footswitch is released.

EMERGENCY OVERRIDE

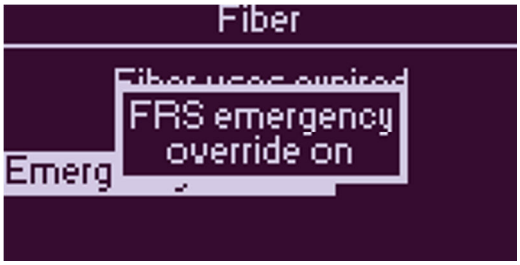
In certain circumstances, such as a technical problem or if the Emergency Stop button is pressed, the fiber in use may become invalid before the completion of the treatment. If this situation should occur, the Emergency Override may be activated to allow treatment to continue. This option is only available immediately after the fault has been cleared and will not work if an attempt is made to use an expired or otherwise invalid fiber at any other time.

With the fiber still connected to the laser, turn the laser off at the key switch and the power switch on the rear panel. After a few seconds turn on again at the power switch then the key switch.



The message 'Fiber uses expired' will appear on the screen and 'Emergency override' will be highlighted at the bottom. Press **CONFIRM** to select the Emergency Override function.

'FRS emergency override on' will momentarily appear on the screen, followed by 'Main Menu'. Press **CONFIRM** to continue. The connected fiber can now be used as normal.



After use of the Emergency Override, the laser must be reset using the supplied reset device, following the instructions below.

If the Emergency Override has already been used, then this option is not available. The Emergency Override is not available following a power cut.

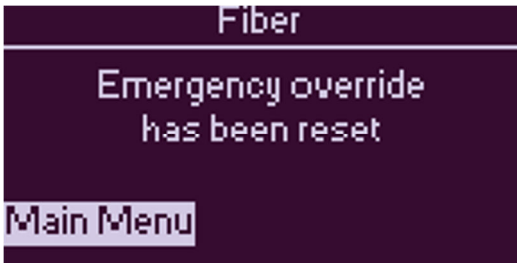
If the Emergency Override has been used and needs to be reset, a flashing symbol, shown right, will be displayed when the **VenaCure 1470** laser is switched on.

This acts as a reminder that a reset device should be obtained from AngioDynamics.

Resetting the Emergency Override

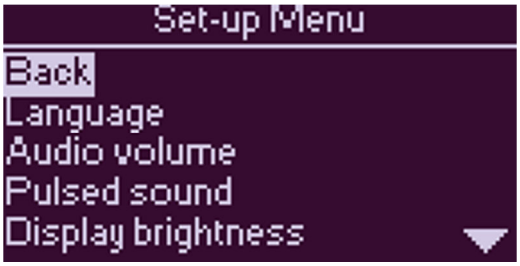
The Emergency Override must be reset by means of a special reset device (AngioDynamics part number AS/598). One of these is supplied with the **VenaCure 1470** laser. Each device can only be used once, after which it is advisable to contact your AngioDynamics representative as soon as possible to obtain a replacement. To reset the Emergency Override:

- Switch on the laser
- Attach the device by screwing it on to the laser aperture port, in the same way as you would attach a fiber
- The **VenaCure 1470** laser will detect the device, reset the Emergency Override and display a message on the screen



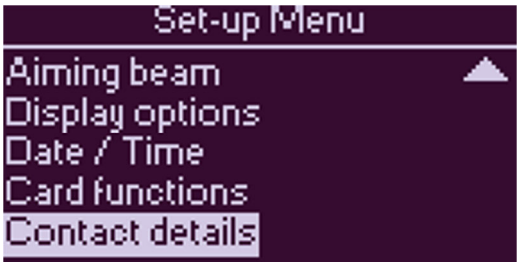
SET-UP MENU

The **Set-up Menu** is available from the **Main Menu**. It allows the operator to customize certain properties of the **VenaCure 1470** laser.



To access any of the functions within the **Set-up Menu** turn the **SCROLL** knob until the function is highlighted and then press **CONFIRM**.

To return to the **Set-up Menu** from any of these functions, highlight **Accept** and press **CONFIRM**.

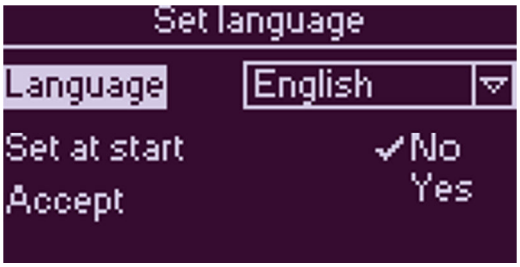


Changes made to the Language, Audio volume, Display brightness and Display options settings will be retained when the **VenaCure 1470** laser is switched off.

Changes to the Pulsed sound and Aiming beam settings will only be retained when a procedure using an AngioDynamics FRS fiber is being performed. In this case the current settings are associated with the selected procedure and will be restored the next time the procedure is used.

Language

To change the language used for the user interface, turn the **SCROLL** knob to highlight **Language** and press **CONFIRM**. Now use the **SCROLL** knob to select the required language from the drop down list and press **CONFIRM**.
When **Set at start** is set to **Yes**, this language selection screen will occur every time that the **VenaCure 1470** laser is switched on. This option can be toggled between **Yes** and **No** by using the **SCROLL** knob to highlight **Set at start** and pressing **CONFIRM**.



Audio Volume

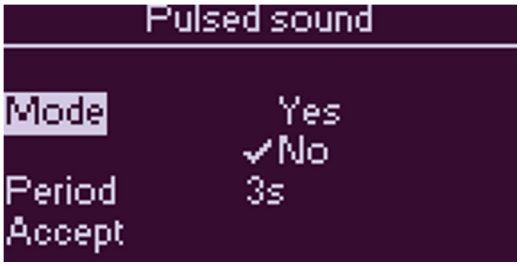
To adjust the volume of the audible indicator heard when the laser is firing, turn the **SCROLL** knob to highlight **Adjust** and press **CONFIRM**. Now use the **SCROLL** knob to select the required volume. Press **CONFIRM** when finished.

If the volume is set to 0% the audible indicator is switched off. In this case the visible laser emission indicator is the sole indication of laser activity.

Pulsed Sound

The audible indicator can also operate in two modes, which can be selected by choosing **Mode** with the **SCROLL** knob:

- **Yes** – the tone of the audible indicator will change momentarily at a frequency set by the value of **Period**. This mode is only available when the laser is firing continuously.
- **No** – the audible indicator sounds continuously when the laser is firing.



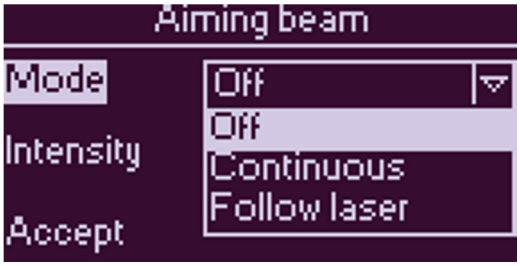
Display Brightness

To adjust the brightness of the display, turn the **SCROLL** knob to highlight **Adjust** and press **CONFIRM**. Now use the **SCROLL** knob to select the required brightness. Press **CONFIRM** when finished.

Aiming Beam

The aiming beam can operate in three modes, which can be selected by choosing **Mode** with the **SCROLL** knob:

- **Off** – the aiming beam is switched off
- **Continuous** – the aiming beam is on continuously when the laser is firing
- **Follow laser** - the aiming beam pulses in time with the laser output (as long as the pulses are long enough to be discernable)

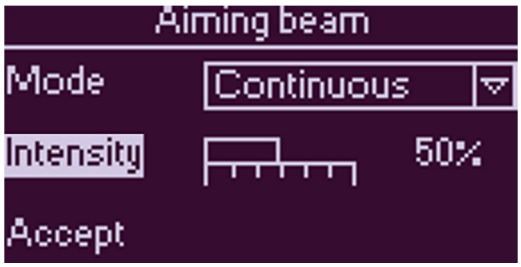


The **Follow laser** mode is a useful aid for the operator as it causes the aiming beam to mimic the characteristics of the procedure. For example, if the laser output is pulsing one second on and one second off then the aiming beam will pulse at the same rate. Similarly, if the intensity of the laser output varies then so will the aiming beam's intensity.
In this mode, the aiming beam's output will always provide a visual indication that the laser is active, even if the output is very low or very short, infrequent pulses.

To observe the different modes of the aiming beam, place the **VenaCure 1470** laser into READY mode by pressing the **STANDBY/READY** button. The aiming beam will be activated if **Continuous** or **Follow Laser** are selected. For safety, it is not possible to fire the laser in READY state at this menu.

Intensity

To adjust the intensity of the aiming beam, turn the **SCROLL** knob to highlight **Intensity** and press **CONFIRM**. Now use the **SCROLL** knob to select the required intensity. Press **CONFIRM** when finished.



The intensity adjustment will be ignored if the aiming mode is **Off**.

To observe the intensity of the aiming beam, place the **VenaCure 1470** laser into READY state by pressing the **STANDBY/READY** key. The aiming beam will be activated. For safety, it is not possible to fire the laser in READY state at this menu.

Display Options

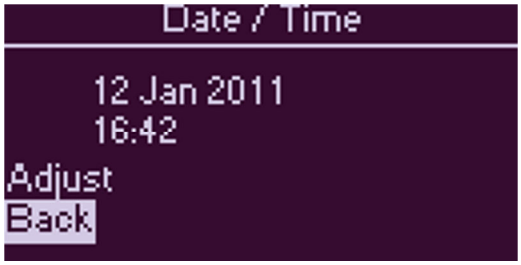
To set up the display of either delivered energy or elapsed time, turn the **SCROLL** knob to highlight the required option and press **CONFIRM** to toggle between **Ye**s and **No.**

When Energy Display is enabled, the delivered energy will be displayed in the bottom left hand corner of the display when the **VenaCure 1470** laser is in READY mode. Similarly the Elapsed Time, when enabled, will be shown in the bottom right hand corner.

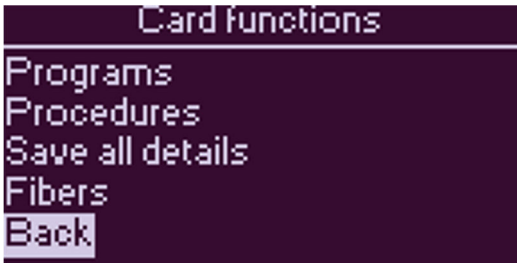
To reset the displays to zero, press **CONFIRM** at any time. The reset function is indicated by the symbol in the bottom center of the display.

Time & Date

To set the internal clock and calendar of the **VenaCure 1470** laser turn the **SCROLL** knob to highlight **Adjust** and press **CONFIRM**. Turn the **SCROLL** knob to change the highlighted value and press **CONFIRM** to accept and move on.
The order of adjustment is day, month, year, hours & minutes.



Card Functions

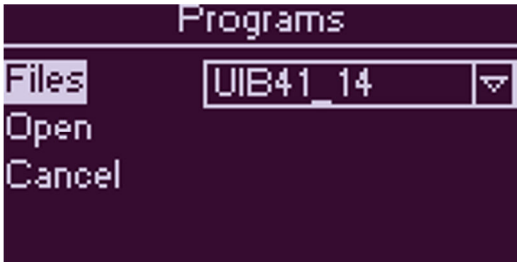


The Card functions are only available when a memory card is present in the slot on the left side of the front panel.

The **Card functions** menu enables the operator to load new software or procedures from a memory card. It also allows configuration details stored in the laser to be saved to the card, for transfer to a computer.

To access this menu turn the **SCROLL** knob until **Card functions** is highlighted in the **Main Menu** and then press **CONFIRM**.

To access any of the functions within the **Card functions** menu turn the **SCROLL** knob until the function is highlighted and then press **CONFIRM**.



The **Programs** option allows new software to be loaded from the memory card into the laser.

This feature is protected by a 'key file' that prevents incorrect or unauthorized software from being installed. You should contact your AngioDynamics representative for advice before using this feature.

Similarly, the **Procedures** option allows new procedures to be loaded from the memory card into the laser.

Unauthorized use of this feature is also protected by a 'key file'. You should contact your AngioDynamics representative for advice before using this feature.
Save all details will save information about the software and procedures which are currently loaded into the **VenaCure 1470** laser**,** to the memory card. The card can then be removed from the **VenaCure 1470** laser, inserted into a reader attached to a PC and the details transferred to the PC.

Contact Details

Selecting this option will display the telephone, e-mail and website contact details for AngioDynamics.

STATISTICS

Treatment Statistics can be defined as a summary of the laser energy delivered and are recorded for the time that the **VenaCure 1470** laser is switched on. Treatment Statistics will be displayed as the amount of joules of energy delivered.

A Treatment is made up of one or more Setups. Each time the power, pulse or interval parameters are changed, a new Setup will be added to the current Treatment. The **VenaCure 1470** laser can display the statistics of the Setups for the current and previous Treatments.

A new Treatment is started when the **VenaCure 1470** laser is switched on, when the fiber is changed or when **New treatment** is selected on the **Statistics** menu.

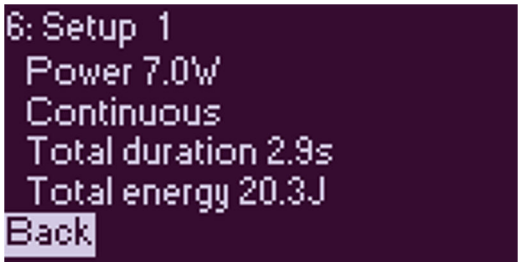
The **VenaCure 1470** laser can store details of approximately 100 Treatments in its internal memory. When this memory is full then the earliest Treatment Statistics will be erased to make room for new details.

To minimize the risk of error, it is advisable to transfer Treatment Statistics from the **VenaCure 1470** laser to a PC immediately after the procedure has been completed.

The **Statistics** menu enables the operator to view the statistics from the current or previous Treatments.
To access this menu turn the **SCROLL** knob until **Statistics** is highlighted in the **Main Menu** and then press **CONFIRM**.

To access any of the functions within the Treatment Statistics menu turn the **SCROLL** knob until the function is highlighted and then press **CONFIRM**.

If **Display current** is selected, the screen will display a summary of laser energy delivered during that Treatment. If there is more than one Setup per Treatment, these can be viewed by turning the **SCROLL** knob.

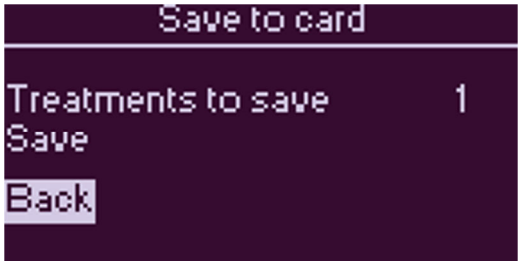


To view the statistics of the previous treatment, select **Display previous**.

Selecting **New treatment** will cause the Treatment reference number to be incremented. The display will return to the Main Menu.

If **Return to previous** is selected, statistics from the previous Treatment will be recalled and resumed, allowing additional Setups to be added to a previous Treatment. This option is only available if the current Treatment is clear of any data.

To save Treatment Statistics to a memory card, select **Save to card** and press **CONFIRM**. The default is to save just the last Treatment. To save several Treatments at one go, turn the **SCROLL** knob until **Treatments to save** is highlighted and press **CONFIRM**. Choose the number of Treatments to save by turning the **SCROLL** knob and highlighted value and press **CONFIRM** to accept and move on.



SECTION 4 TECHNICAL INFORMATION

This section includes technical data and describes the routine maintenance procedures that you can perform on the **VenaCure 1470** laser and its accessories.

The **VenaCure 1470** laser has been designed to operate reliably with minimal maintenance. There are no user-serviceable parts in the **VenaCure 1470** laser. Always disconnect the **VenaCure 1470** laser from the AC supply before performing any cleaning or maintenance procedures.

Any attempts to repair, adjust or modify the laser beyond the procedures allowed in this Operator Manual, by any person not authorized by AngioDynamics, will invalidate the warranty.

SPECIFICATIONS

VenaCure 1470 Laser	
Laser Type	Diode laser, CW
Centre Wavelength	1470nm
Spectral Bandwidth	90% of optical power contained within 1470 ± 20nm
Delivery Fiber	Minimum 400μm diameter, 0.37 Numerical Aperture (NA)
Fiber Connector	Optical SMA-905 to MIL STD
Maximum Power	12W to the laser output port
Minimum Power	1.0W to the laser output port
Set power Accuracy	Better than ± 10% of displayed power
Output power Stability	± 5% maximum
Aiming Beam	Red Class 3R (IIIa) diode laser, ≤ 5mW at port, wavelength 635-660nm
Pulse Duration	100ms – 2000ms
	Continuous Wave (CW)
Pulse Interval	100ms – 2000ms
Fibers	VenaCure EVLT™ kits only
Fiber Recognition System (FRS)	
Operating Frequency	125kHz ± 1kHz
Operating Range	Maximum of 40mm (1.6”) from the laser output port
RFID Modulation Type	A1D
Standards	FCC 47 Part 15c, Canadian RSS-210 EN 300 330-1, EN 300 330-2, EN 301 489-1, EN 301 489-3
Cooling	By ambient air, with fan assistance
Power Supply	100 – 240V AC, 50 – 60Hz, 500VA max.
Dimensions (H x W x D)	150 x 370 x 325mm (± 5mm) (5.9” x 14.6” x 12.8” (± 0.2”))
Weight	12kg max. (26.4 lb)
Operating Temperature	10ºC to 30ºC (50ºF to 104ºF)
Operating Humidity	Up to 75% relative humidity, non-condensing
Operating Pressure	Normal atmospheric pressure
Storage Temperature	0ºC to 55ºC (32ºF to 130ºF)
Storage Humidity	Up to 90% relative humidity, including condensing
Storage Pressure	500hPa to 1014hPa
Safety Standards	UL 60601-1, 21 CFR 1040.10, 1040.11, EN 60601-1, 60601-1-2, 60601-2-22, 60825-1,

CLASSIFICATION

Type of protection from electric shock	Class I
Degree of protection from electric shock	Type B
Degree of protection against ingress of water	IP21

CLEANING

The system enclosure may be wiped down periodically with a cloth dampened with a mild antiseptic solution. Before cleaning always disconnect the **VenaCure 1470** laser from the AC supply. Do not use any other solutions, solvents or abrasives. Take care not to get any liquid inside the enclosure.

CARING FOR FIBERS

Safety Carefully read and follow the package insert instructions for use.

Handling Leave the cap on the SMA connector in place during the uncoiling process and only remove when connecting it to the laser.

To verify the integrity of the fiber, check the fiber for any breaks by overall visual inspection. Ensure the laser is in READY mode, and direct the aiming beam at a flat, white surface positioned 50-70mm away and examine the spot formed. The central spot should be symmetrical and the outer circle uniform in both intensity and shape.

TROUBLESHOOTING

Error Messages

The **VenaCure 1470** laser is continuously monitoring its operation and performance. Should it detect a problem it will display a code and short message on the screen. To clear a message, carry out the instructions on the display. Outlined below are some messages and the appropriate action that the user should take.

If a problem cannot be resolved by following the instructions on the display, contact your local AngioDynamics representative, quoting the error message on the display at the time of the error.

00	**Emergency switch pressed**	The emergency switch has been pressed. Switch the laser off and on at the power inlet. The laser will carry out a self-test and the message will clear automatically.
09	**Card error**	There was an error accessing the memory card. Check that the card is not full.
10	**Serial comms error**	An internal communications problem was encountered. Switch the laser off and on at the power inlet and the message will clear automatically.
17	**Footswitch connection fault**	Check that the footswitch has been connected correctly. If this does not clear the problem, call for support from your AngioDynamics representative.
25	**Heatsink temperature out of range**	The laser is overheating. Switch it off at the power inlet and allow it to cool.
26	**Diode temperature out of range**	The laser diode is too hot. The temperature should stabilize if the laser is left on but not firing. Alternatively switch it off at the power inlet and allow it to cool.
27	**Case temperature out of range**	The laser is being operated outside of its specified ambient temperature range. Switch it off at the power inlet and allow it to stabilize at room temperature.
52	**Clock not set**	Press the rotary control to continue. If the message occurs again it is possible that the internal battery needs to be replaced. Call for support from your AngioDynamics representative.
54	**Memory access error**	A problem was encountered when trying to access memory. If a memory card is in use, check that it is not full.
58	**Serious checksum error**	If either of these message appear, switch the laser OFF at the power inlet and then ON. If the message does not disappear, call for support from your AngioDynamics representative.
	or	
59	**Checksum error**	
64	**Fiber energy limit exceeded**	The energy limit for the fiber has been exceeded. Replace the fiber.
72	**Fiber connector temperature out of range**	The fiber connector is getting too hot. This is usually caused by a dirty or faulty fiber. Check that the fiber is clean and undamaged.

FRS Error Messages

The following error messages are associated with the Fiber Recognition System.

Fiber uses expired	Replace the fiber with a fiber that has not already been used.
Fiber sterility expired	AngioDynamics fibers are programmed at manufacture with a sterility expiration date. This message is displayed when the expiry date is before the date in the laser's internal clock. Replace the fiber with one having a valid sterility expiration date.
Invalid fiber	The fiber attached to the **VenaCure 1470** laser is either not recognized or not equipped with the FRS system. Replace with an appropriate fiber or, if a **Session Fault** is indicated, use the **Emergency Override** option.

FRS Troubleshooting

The AngioDynamics FRS system has been extensively tested. In the unlikely event of a problem being experienced please perform the following checks before contacting your local AngioDynamics representative for further advice.

"Invalid Fiber" is displayed even with a new unused FRS system fiber	(1) Disconnect and then reconnect the fiber to the **VenaCure 1470** laser. This will cause the unit to try and read the fiber's data again. (2) Switch the **VenaCure 1470** laser off and on at the power inlet. (3) Ensure that the **VenaCure 1470** laser is at least 2 meters away from any other electrical or electronic equipment that might interfere with the FRS system, such as computers or other electronic or medical equipment.
The Emergency Override option is not available	After it has been used once, the Emergency Override option must be reset before it can be used again, as described in 'Resetting the Emergency Override' above. Contact your AngioDynamics representative to obtain a spare reset device.
The fiber is still within its sterility date but the laser shows it as expired	Check that the date of the internal clock in the **VenaCure 1470** laser is set correctly. The procedure for setting the clock is described in Section 3 - Operator Instructions.

ACCESSORIES

Optical Fibers

The **VenaCure 1470** laser has an output connector for optical fibers with standard SMA-905 connector. Only AngioDynamics labeled fibers should be used. A list of fibers available for use with the **VenaCure 1470** laser can be obtained from your AngioDynamics representative.

Test Fiber

The test fiber is a special type of FRS fiber used during testing and evaluation only.

Emergency Override Reset Device

The Emergency Override Reset Device consists of a special FRS gripper, supplied without a fiber. Instructions on when and how to use this device are in section 3.

AngioDynamics does not recommend the use of third party fibers as their quality and efficacy cannot be guaranteed. Any damage caused to your **VenaCure 1470** laser by using a fiber not supplied by AngioDynamics may not be covered under the AngioDynamics warranty.

Ordering Information

The codes in the following table should be quoted when ordering accessories for the **VenaCure 1470** laser.

Description	AngioDynamics part number
Test fiber	AS/0604
Manual Test fiber	AS/0695
Emergency Override Reset Device	AS/0598
Laser safety glasses (premium quality)	SE/0005
Laser safety glasses (standard quality)	SE/0006
Laser warning sign	PP/1579
Memory Card	S10/06/0086
USB Memory Card Reader/Writer	S10/06/0087

STERILIZATION OF OPTICAL FIBERS

Optical fibers are provided sterile as a disposable, single-use product.
DO NOT RE-STERILIZE THE FIBERS.
DO NOT RE-USE THE FIBERS.
USE ONLY ANGIODYNAMICS LABELED OR ANGIODYNAMICS APPROVED FIBERS.
Failure to observe this could invalidate the Laser Warranty.

Intra-operative cleaning

If the tip accumulates debris, turn the laser to the STANDBY mode and then carefully wipe the tip clean with a wet sponge/swab. **Do not disconnect the fiber as this will not allow it to be reconnected.**

Fiber Disposal

After use, the single-use optical fibers should be disposed of in accordance with local regulations regarding disposal of contaminated waste.

AngioDynamics labeled optical fibers have undergone stringent evaluation and testing to ensure that they are of the highest quality and that they operate safely, effectively and efficiently with AngioDynamics lasers.

The exact alignment of the interface between the laser aperture and the SMA-905 connector is critical. Misalignment (as may occur with non-approved fibers) can result in damage to the laser and poor delivery of laser energy to the patient.

FUSE REPLACEMENT

Spare power fuses are supplied with the **VenaCure 1470** laser. Further spares can be obtained from AngioDynamics. They can be replaced as follows:

1. Disconnect the **VenaCure 1470** laser from the AC supply.
2. Use a small flat-bladed screwdriver to release the fuse compartment from the mains inlet on the rear panel.
3. Remove the two fuses from the holder and replace with new ones of the same type and rating: T6.3A H 250V. Fuses with a different rating or specification must not be used.

DISPOSAL

At the end of its life, the **VenaCure 1470** laser should be disposed of according to national environmental requirements or be returned to AngioDynamics.

SOFTWARE UPDATES

From time to time AngioDynamics may issue new procedures, upgrades and feature enhancements for the **VenaCure 1470** laser. As a registered owner you will be notified of these when they become available.

SERVICING

The **VenaCure 1470** laser does not require regular servicing or maintenance, with the exception of annual checks of the calibration of the output power of the laser. If either of these checks is due, a ‘wrench’ symbol will be displayed on the screen at start-up. This symbol will be removed after the checks have been completed.

LASER POWER OUTPUT

Measuring the Laser Power Output

The LASER SAFETY OFFICER or suitably trained service personnel should check the output power of the **VenaCure 1470** laser at least annually from the date of installation, by following the procedure described below.

Equipment Required

- A sampling power meter or an independent energy (integrated power) meter of known calibration
- A bare-ended optical fiber
- Laser unit to be tested

Procedure

Calibrate the fiber.

Connect the fiber to the laser unit output port and present the distal end of the fiber to the external power meter.

1. Record the laser unit's actual and displayed outputs at various different power/energy settings e.g. 5W, 10W etc.
2. Calculate the percentage difference between the displayed and the actual power/energy output as taken from the external power meter.
3. If calculated disparity exceeds ± 10%, contact AngioDynamics.

Adjusting Laser Power Output

Power output adjustments can only be made by suitably trained AngioDynamics service personnel.

For regulatory purposes, the method for carrying out these adjustments is described below.

Please contact your AngioDynamics representative for further advice.

Adjusting the Laser Power Output

THE FOLLOWING INFORMATION IS PROVIDED FOR REGULATORY PURPOSES

The procedure below will explain how to adjust the power output of the laser.

Equipment Required

- A sampling power meter or an independent energy (integrated power) meter of known calibration
- A calibrated bare-ended optical fiber
- Laser unit to be tested

Procedure

Connect the laser to a PC via a null-modem serial cable between the port on the rear panel and a serial port on the PC.

Connect the calibrated fiber from the laser unit output port to the external power meter.

Turn on the laser.

Load and run the AngioDynamics Engineer Interface program on the PC. From the **Connection** menu, select **Connect to Laser**, choose the appropriate Comms Port and press **Connect**.

From the **Connection** menu select **Enter EI** and enter the password.

Select the **Non-volatile** data tab.

Diode calibration is stored in both the Monitor MCU and in the laser module itself. The values in these locations are shown on the screen – if there are any discrepancies then an error message is displayed.

The laser is calibrated at three different power settings: 2W, 5W and 12W, by entering the required diode feedback value (in mV) into the appropriate boxes on the form. Always change the values for both the Monitor params and Diode data at the same time, then press Update to reconfigure the laser.

Start with the 2W setting by entering a default value (no more than 150) into the two appropriate boxes and pressing Update.
Calculate the expected power at the distal end of the fiber, i.e. measured at the power meter, from the required port power and the known efficiency of the fiber.

Fire the laser and record the power measured by the power meter.
Adjust the value of the feedback according to this result and enter new values until the correct power is observed when the laser is fired.

Repeat this process for the 5W and 12W settings, starting with default values of 400 and 1000 respectively.

Finally, check that the laser outputs the correct power at all three settings.

TECHNICAL DESCRIPTION

The **VenaCure 1470** laser contains no user-serviceable components. In the event that repair or service is required please contact your local AngioDynamics representative. More detailed service instructions, including schematic diagrams, are available only to suitably-qualified and trained technical personnel.

The **VenaCure 1470** laser is built in a modular fashion, enabling ease of test, assembly and service. The system has been designed so that any one module can be replaced with no performance effect on the other modules or the product as a whole.

The modules present in a complete unit are:

- Laser Module
- Power Supply / Laser & TEC Driver
- Monitor & Control PCA
- User Interface PCA

Laser Power Control Overview

Optical power control is achieved using a monitor photodiode measuring the output of the laser diode. This is used to derive a control signal proportional to the total power output of the laser unit. The feedback signal in this control loop is monitored for errors from the expected value.

In addition to this, an over-current trip circuit will operate to disable the laser driver rapidly should an overcurrent / overpower situation be detected. Diode current is monitored while firing to ensure that it is within acceptable limits.

Laser Module

The Laser Module consists of a laser diode, TECs, optics and an electronic control module. These components are all mounted on a stable metal platform which doubles as a heatsink. Two fans are mounted at one end of the heatsink to provide air-assisted cooling. The laser and TECs are located inside a hermetically-sealed enclosure.

Semi-transmissive mirrors in the optics path allow for the addition of the visible laser diode and for output power to be measured by means of a photodiode. The laser output port (SMA) incorporates a thermistor, to measure the temperature of the port close to the fiber connection and two micro-switches, which detect when a fiber has been correctly connected to the port.

PSU / Laser & TEC Driver

The power supply, laser driver and TEC driver are contained in their own enclosure. The power supply accepts an input from 100V to 240V and provides auxiliary power rails for the system electronics. The drivers are controlled via an interface with the Monitor & Control PCA.

Monitor & Control PCA

The Monitor & Control PCA consists of the laser power control loop, Control and Monitor microcontrollers, control logic, external interlock interfaces, power supply monitoring, cooling fan control and the RS232 serial port connection. This PCA connects to the Laser Module, the User Interface and the Power Supply.

Two separate microcontrollers are used to independently Control and Monitor the laser diode. Instructions and information are passed from these two devices to the User Microcontroller via a dedicated RS232 serial interface.

Monitoring of the laser diode and peripheral functions such as temperature is performed by the Monitor MCU. The values obtained are also sent to the User Microprocessor. The Monitor MCU additionally monitors the state of many of the Control MCU outputs to check that their status is correct for the operating mode.

The Footswitch and Remote Interlock interface connectors are located on the rear panel. All signals on these connectors are filtered for EMC and protected against ESD. The Remote Interlock connector also includes an electrically-isolated 'READY OUT' output.

The two cooling fans attached to the heatsink may be run at four different speeds, depending on the temperature of the heatsink, the power of the laser output and the magnitude of the TEC drive level.

The signals for the RS232 serial port come direct from the User Microcontroller. The pins of the 9-pin D-type connector are electrically isolated from the rest of the circuit using opto-couplers and a transformer.

Ambient temperature is monitored using a digital temperature sensor, which is read by the User Microcontroller over the I^2C bus.

User Interface PCA

The User Interface PCA consists of the User Microcontroller, display and all the controls and indicators required by an operator to use the product.

The User Microcontroller is from the Renesas H8 family. It is supplemented by 256Kb of SRAM memory, 4Mb of Flash program memory and 256Kb of serial FRAM memory for non-volatile data storage. A Real Time Clock (RTC) function provides the time and date features for the user interface. This microcontroller system interfaces to the rest of the product via a Serial Peripheral Interface (SPI) bus, Inter-Integrated Circuit (I^2C) bus and RS232 serial interface.

The user interface display is a Vacuum Fluorescent Display (VFD) of 128 x 64 pixels. This is controlled directly by the User Microcontroller. The display is filtered to mid-blue.

The control of the level of TEC drive is a software function within the User Microcontroller. It operates in a feedback loop with the objective of keeping the laser diode at a fixed temperature.

A memory card interface allows a MMC or SD memory card to be inserted into an aperture on the front panel. This card is used to transfer usage data from the laser to the user's PC. It can also be used to transfer updated software and new procedure information into the laser.

Glossary

ADC	Analogue to Digital Converter
DAC	Digital to Analogue Converter
EMC	Electro-Magnetic Compatibility
EEPROM	Electrically Erasable Programmable Read Only Memory
ESD	Electro-Static Discharge
FRS	Fiber Recognition System
I^2C	Inter-Integrated Circuit
I/O	Input/Output
Kb	Kilobits
LED	Light Emitting Diode
MCU	Microprocessor Control Unit
ms	Milliseconds
MMC	MultiMediaCard
OPCM	Optical Power Calibration Meter
PCA	Printed Circuit Assembly
PCB	Printed Circuit Board
PSU	Power Supply Unit
PWM	Pulse Width Modulation
RAM	Random Access Memory
RTC	Real Time Clock
SD	Secure Digital memory card
SFC	Single Fault Condition
SPI	Serial Peripheral Interface
TTL	Transistor-Transistor Logic
TEC	Thermo Electric Cooling
UART	Universal Asynchronous Receiver/Transmitter
V	Volts
VFD	Vacuum Fluorescent Display

SECTION 5 WARRANTY

MANUFACTURER'S WARRANTY POLICY

AngioDynamics warrants the **VenaCure 1470** laser against defects in materials and workmanship for a period of 3 years. The warranty period begins on the date of purchase.

To enable timely registration of the warranty, the owner/purchaser must complete and return the Warranty registration form located in the warranty booklet within 28 days of purchase.

The following items are expressly excluded from this Warranty:

- Safety eyewear
- All optical fibers and accessories
- Maintenance instruments
- All other accessories supplied by AngioDynamics

Any attempt to repair, adjust or modify the system beyond those procedures described in the Operator Manual by any person not authorized by AngioDynamics, will invalidate the Warranty.

WARRANTY CLAIMS

To make a warranty claim the purchaser shall, promptly following discovery of the basis of claim, contact AngioDynamics in writing, by telephone, fax or Email at the following address:

ANGIODYNAMICS®

AngioDynamics Inc
603 Queensbury Ave.
Queensbury
NY 12804
USA

Customer Service Tel: +1 800 772 6446
Laser Service Tel: +1 866 883 8820
Fax: +1 518 798 1360
Email: customerservice@angiodynamics.com
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