ANGIODYNAMICS®

630 PDT Laser

FOR PHOTODYNAMIC THERAPY
Model T2USA

Operator's Manual

Version 6.0 US
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PRODUCT INFORMATION

630 PDT Laser serial number _____

Software versions

Main Program _____

Display Program _____

[Note: This information is displayed on the 'Statistics' screen of the **630 PDT Laser**]

Date Installed _____

Installed by

Signed _____

Print Name _____

Organization _____

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

CONTENTS

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.

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.

WARNINGS

The 630 PDT Laser is intended for use only by trained physicians.

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

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous Laser Radiation exposure.

It is strongly recommended that the 630 PDT Laser should be stored at temperatures between 36°F and 122°F (2°C - 50°C). Failure to observe this could result in invalidation of the warranty. If stored at temperatures out of this range for a period of time, the 630 PDT Laser requires up to 6 hours to acclimatize prior to operation.

Operating temperature should be between 61°F and 86°F (16°C - 30°C) or the 630PDT will not function.

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 **630 PDT 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 **630 PDT Laser** should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the **630 PDT 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 **630 PDT 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 **630 PDT Laser** as replacement parts for internal components, may result in increased emissions or decreased immunity of the **630 PDT 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 **630 PDT Laser***:*

- Hand Switch Assembly
  AngioDynamics part no. AS/246 (supplied with laser)

- Remote Interlock Lead (if required).
  Lemo connector (supplied with laser): AngioDynamics part no. CON/51/0003
  Ferrite sleeve (Farnell part no. 898-454).
  Screened twisted pair cable 7/0.2 (Farnell part no. 140-457).

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

- Remote Interlock Shorting Plug (supplied with laser).
  AngioDynamics part no. AS1/A3/0024

- IEC Mains Lead (supplied with Laser)
  AngioDynamics part numbers: CBL/02/0002, CBL/02/0040, CBL/02/0042, CBL/02/0046, CBL/02/0051, CBL/02/0063.

INTRODUCTION

This manual describes the operation of the **630 PDT Laser** Model T2USA, which is to be used only by experienced, trained surgeons/physicians familiar with laser procedures and photodynamic therapy. Throughout this manual the **630 PDT Laser** Model T2USA will be described as the **630 PDT Laser**.

The **630 PDT Laser** is a diode laser for photodynamic therapy (PDT) providing 2000 mW of continuous wave Laser Radiation to the tip of a delivery fiber. The **630 PDT Laser** is a Class IV InGaAlP diode laser with a nominal wavelength of 630nm ± 3nm.

Before using this instrument for the first time, read the Safety Requirements and Operating Instructions outlined in this manual.

It is strongly recommended that the operator becomes familiar with all the controls before commencing any therapy.

CLINICAL INDICATIONS

The **630 PDT Laser** is intended for use in photodynamic therapy (PDT) as a source for the photoactivation of PHOTOFRIN® (porfimer sodium) for Injection for:

- palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy;
- reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC); and
- treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated.

Warnings and Precautions

Adverse effects of the AngioDynamics **630 PDT Laser** could be related to inappropriate laser powers or improper use. Such situations should not occur if the conditions and instructions for use, as fully described in the PHOTOFRIN® and OPTIGUIDE™ Fiber Optic Diffuser Package Inserts, are followed.

Use of incompatible Lasers or delivery fibers that alter the required output characteristics of light for the photoactivation of PHOTOFRIN® could result in incomplete treatment due to partial photoactivation of PHOTOFRIN®, overtreatment due to over activation of PHOTOFRIN®, damage to surrounding normal tissue, and/or damage to the fiber optic diffuser which could additionally create an optical hazard for medical personnel and/or patients.

Clinical Indications (continued)

Adverse Effects of the Device on Health

If the laser power drops so that the light dose delivered to tissue is below that needed to activate PHOTOFRIN®, the treatment will fail. If the power is greater than expected, so that an excess light dose is delivered to tissue, then some areas of adjacent normal tissue that should have been spared treatment could be damaged by the PDT effect. At very high laser power levels, greater than the OPTIGUIDE™ Fiber Optic Diffuser rated value, there is a risk of damaging the OPTIGUIDE™ Fiber Optic Diffuser, which could cause non-uniform output, heating of the diffusing tip and eventual tip destruction. The inclusion of the built-in integrating sphere power meter is intended to reduce these possible events.

Refer to the PHOTOFRIN® package insert for information and instructions for use of the drug. Refer to OPTIGUIDE™ package insert for information and instructions for use of the delivery fiber, information on laser power, duration and light dose.

Precaution

Only use AngioDynamics labeled or AngioDynamics approved fibers with the AngioDynamics **630 PDT Laser**. Use of unapproved fibers may cause injury, ineffectual treatment or damage to the **630 PDT Laser**. Damage caused using unapproved fibers may invalidate the product guarantee.

TECHNICAL SPECIFICATIONS

Laser Type	InGaAlP Laser Diode, CW
Wavelength	630nm ± 3nm
Spectral Bandwidth	≥90% of optical power contained within 630nm ± 3nm
Beam Output Profile	360-380μm diameter, 0.37 Numerical Aperture (NA) at input to delivery fiber SMA
Power	Maximum output to fiber port: 2660mW Maximum power output to fiber tip (assuming minimum fiber transmission 75%): 2000mW, limited by software Minimum power output to fiber tip: 100mW
Output Power Stability	± 1-2% typical, ± 5% maximum (averaged over any one second period) over 3200s (53min 20s)
Delivery Fiber Calibration Power	400mW for 2 seconds
Aiming Beam	InGaAlP (nominal wavelength 630nm) diode laser, ≤ 5mW at delivery fiber tip. Modes: On/Off/Flash
Cooling	Forced air
Power Supply	115 VAC ± 10%, 60 Hz < 10A, single phase or 230V VAC ± 10%, 50Hz < 5A, single phase (User selectable)
Delivery fiber Connector	Standard SMA 905
Dimensions (H x W x D)	19 in x 8½ in x 16 in (485mm x 220mm x 405mm) nominal
Weight	43lb (19.5kg) nominal
Environmental Temperature	Ambient temp. 36°F to 122°F (2°C - 50°C) (storage) 61°F to 86°F (16°C - 30°C) (operating) Humidity <90%, RH non-condensing (storage) <90%, RH non-condensing (operating)
Lifetime	Diodes 500 hours at maximum rated power. System 5 years.
Safety Standards	EN 60601-1, EN 60601-1-2,EN 60601-2-22, EN 60825-1 21 CFR 1040.10, 1040.11, UL 60601-1

SAFETY CLASSIFICATIONS, HAZARDS AND PRECAUTIONS

The **630 PDT Laser** is a Class IV laser product in compliance with EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1, 21 CFR 1040.10, 21 CFR 1040.11 and UL 60601-1 and is manufactured in compliance with 21 CFR 820.

The **630 PDT 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

A Class 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 Laser Radiation. Take all necessary protective measures in areas where the **630 PDT Laser** is being used.

The **630 PDT Laser** is a portable laser weighing 43lb. All standard safety procedures for lifting should be applied when moving the instrument.

The use of an uninterruptible or back up power supply may be considered in order to avoid cessation of treatment during a main power supply failure.

EYE INJURY

Visible light (630nm) from the **630 PDT Laser** passes through the transparent components of the eye and is focused on the retina at the back of eye. This light can therefore cause an accidental retinal burn.

The Laser Safety Officer should review all procedures for safety.

ALL PERSONNEL MUST WEAR PROTECTIVE GLASSES APPROPRIATE TO THE PROCEDURE TO ELIMINATE THE RISK OF EYE DAMAGE

When operating the **630 PDT Laser**, ensure that the patients' eyes are fully protected from possible laser exposure at all times.

Eye Injury (continued)

All protective glasses should be designed for protection from laser radiation in the wavelength range 625nm to 640nm. 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.

The recommendation of European Standards EN60825-1 or EN207 are appropriate to assess laser eye risk. Note that the standards assume a viewing distance from the source of light of more than 3.9 inches (100mm).

AngioDynamics can supply laser safety glasses in accordance with EN207.

The 'Nominal Ocular Hazard Distance' 6 feet (2 meters)

To protect against possible misdirected laser light from a bare ended optical fiber, at a distance greater than 100mm, an OD >3 is suggested. Appropriate safety eyewear for this should be labeled in accordance with EN207 as L3 or greater.

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.

BURNS

Accidental irradiation of any substance or material other than the target tissue may result in a laser burn. Where anatomically possible, ensure that the area surrounding the target tissue is protected appropriately.

REFLECTION WARNING

Avoid placing reflective materials such as glass, metals and polished plastic in the path of the **630 PDT Laser** beam.

EXPLOSION HAZARD WARNING

Do not use flammable or explosive anesthetic gases that may be ignited by the **630 PDT Laser**. Avoid using other flammable or fume-emitting substances (e.g. ether, iodine solution, collodion, and alcohol) in the operative field.

SAFETY LABELING AND CONTROLS FOR THE 630 PDT LASER

FIGURE 1: FRONT PANEL & SIDE PANEL

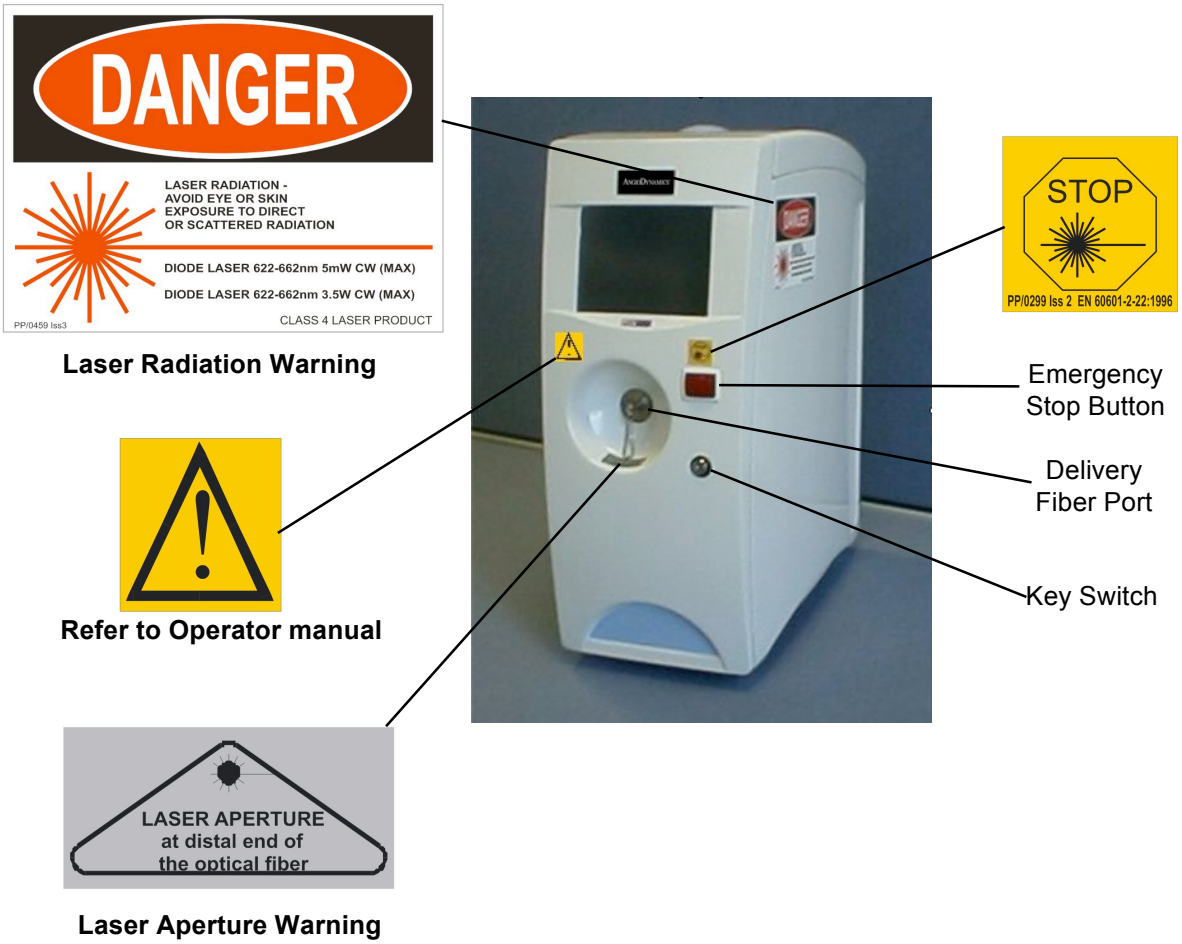
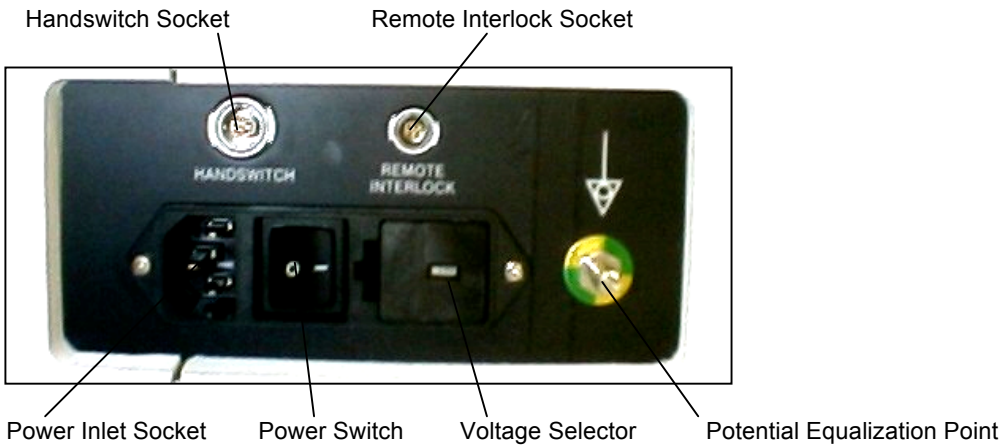
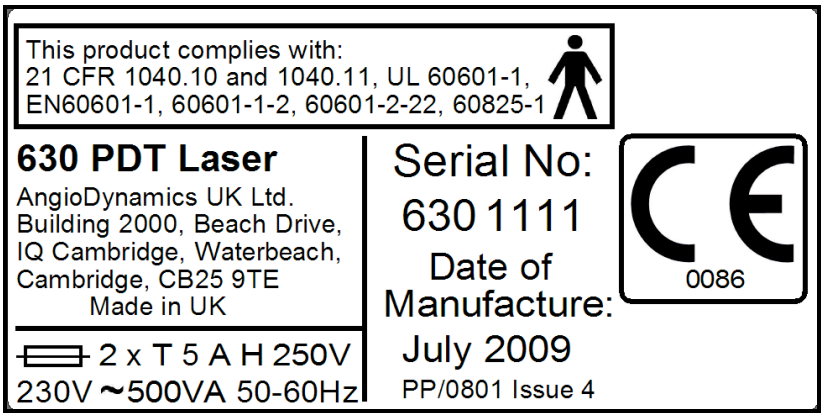
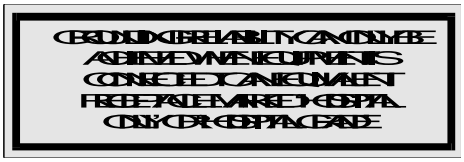


FIGURE 2: REAR PANEL



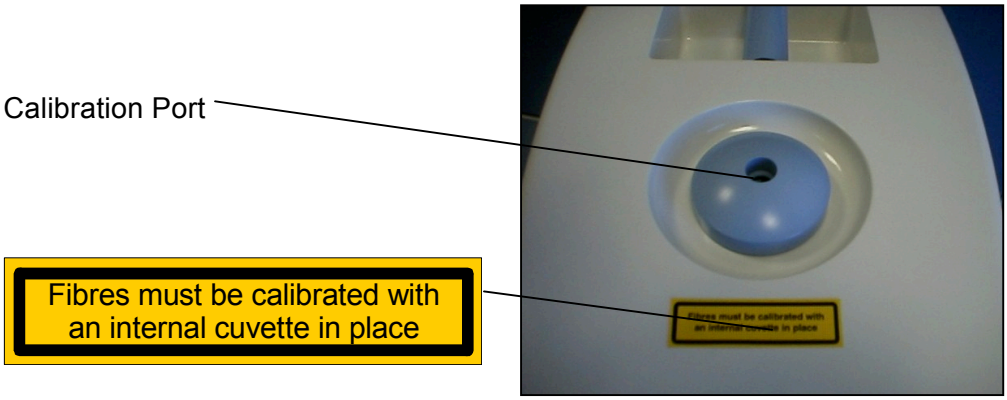


Product Identification Label – Located on the rear of the unit

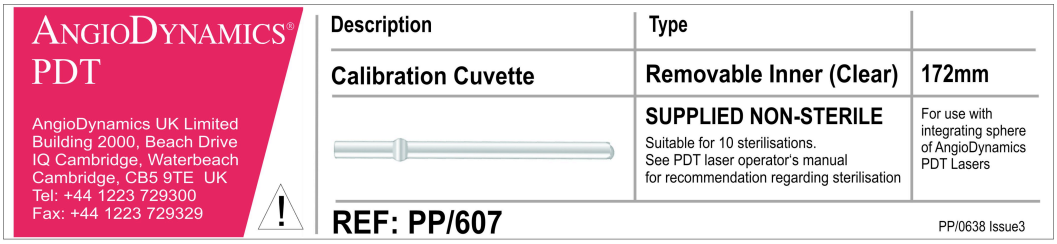


Grounding Reliability Statement Label – Located on the rear of the unit

FIGURE 3: TOP PANEL



Removable Inner Cuvette Labeling



SAFETY FEATURES OF THE 630 PDT Laser

The **630 PDT Laser** includes a number of safety features that are provided in accordance with the requirements of the appropriate standards. The **630 PDT Laser** is built in compliance with: European Harmonized Standards EN 60601-1, EN 60601-1-2, EN 60601-2-22 and EN 60825-1 USA Standards 21 CFR 1040.10, 1040.11 and UL 60601-1.

In order to comply, the **630 PDT Laser** has the following standard safety features incorporated:

Protective housing
Remote interlock bypass (Figure 2)
Key control (Figure 1)
Laser radiation emission indicators:
- visible (**STANDBY** soft key text changes to **READY** and turns yellow in color)
- audible (beep)

READY and **STANDBY** modes
Manual reset mechanism
Shutter (not mechanical)
Fiber optic interlock
Emergency switch (Figure 1)
Warning labels (Figure 1)
Compliance label (Figure 2)
Aiming beam

The **630 PDT Laser** is equipped with the following additional safety features:

Self test
Time out (automatic return to **STANDBY** mode)
Laser condition monitoring
Power diode watchdog
Microprocessor watchdog
Power fail protection
Power supply monitor
Temperature monitors
Session statistics

Safety Features of the 630 PDT Laser (continued)

KEY SWITCH

(Figure 1)

The unit cannot be turned on without the key switch. It is recommended that the keys be assigned to one or two key-holders that should make the keys available for scheduled procedures only, thus preventing unauthorized use of the system.

REMOTE INTERLOCK

(Figure 2)

The system is provided with a remote interlock socket, which can be connected to a door switch. If connected to a door switch this will automatically turn 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.

DESCRIPTION OF THE 630 PDT LASER

Components

The **630 PDT Laser** consists of two main components:

The main enclosure provides the housing for the **630 PDT Laser** module containing all the optics, heatsink, microprocessor based control electronics, integrating sphere and power supplies.

The handswitch to activate the radiation when in **READY** mode.

Handswitch

The **630 PDT Laser** is activated by a latching handswitch. The handswitch is in the **OFF** position when the switch button is black. The handswitch is in the **ON** position when the switch button is green. A single press and release of the button changes the state of the switch.

When switching the **630 PDT Laser** on or switching to **READY** mode the handswitch should be in the **OFF** position.

To activate the **630 PDT Laser**, place the unit in **READY** mode and switch the handswitch to **ON**. An audible tone indicates the emission of laser energy.

630 PDT Laser Latching Handswitch

630 PDT Laser emission is terminated when the handswitch is switched to the **OFF** position or when the countdown has ended. In the latter case the handswitch must be returned to the **OFF** position when the countdown has ended otherwise the **630 PDT Laser** will display “Handswitch Closed” when **READY** is reactivated. No further adjustment or use of the **630 PDT Laser** will be allowed until the handswitch is returned to **OFF**.

FRONT PANEL

(Figure 1)
The main operating controls, apart from the power switch, for the **630 PDT Laser** are located on the front panel of the main enclosure.

Key Switch
The key switch (located on the front panel) provides the master control for the device. The key is removable in the **OFF** position and the **630 PDT Laser** is not operable when the key is removed. The key switch activates the self-test program.

Emergency Switch
The emergency switch is the red button located on the front panel. Press to immediately shutdown the **630 PDT Laser** in case of emergency. After emergency activation the key switch must be used to restart the system, otherwise the system will not return to **READY** mode.

Delivery Fiber Port

Located on the front panel of the system is an interlocked delivery fiber port with an SMA-905 connector for the delivery fiber.

All delivery fibers used with the **630 PDT Laser** are coupled to the device by an SMA-905 connector, attached to the proximal end of the delivery fiber. The output power of every delivery fiber should be calibrated with the built in integrating sphere power meter prior to use. See ‘Calibration’ section.

REAR PANEL CONTROLS

(Figure 2)

The following sockets are located on the rear panel of the unit:

Power Switch

The power switch is located adjacent to the main power supply inlet on the rear panel.

Power Cord Socket

To connect an IEC power cord.

Remote Interlock

To connect the interlock cable connector. Otherwise fit the supplied remote interlock bypass.

Handswitch Port

To connect the handswitch cable connector.

Potential Equalization Point

To connect possible potential equalization line.

Voltage Selector

Voltage selector to set different power voltages.

Fuses

2 x T5A H 250V for 230/200V operation
2 x T10A H 250V for 115/100V operation

TOP PANEL

(Figure 3)

Calibration Port

Located on the top of the unit is the port to the AngioDynamics Integrating Sphere Power Meter for delivery fiber calibration.

INSTALLATION

Installation of the **630 PDT Laser** can be carried out by the end user.

Inspection

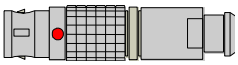
Inspect the **630 PDT Laser** and contents for signs of damage. If the unit is damaged **DO NOT USE**; contact your local AngioDynamics representative at the address shown on page 2 of this manual or customer services at the address shown in the Guarantee section. If there are no signs of damage and all components are present, assemble the **630 PDT Laser**.

Components

630 PDT Laser unit

1 x Handswitch

1 x IEC Power cable

2 x Remote Interlock bypass 

2 x Keys

2 x Removable Inner Cuvettes

1 x Operator's Manual

2 x Warning Signs

10 x 10A fuses

2 x pairs Safety Glasses

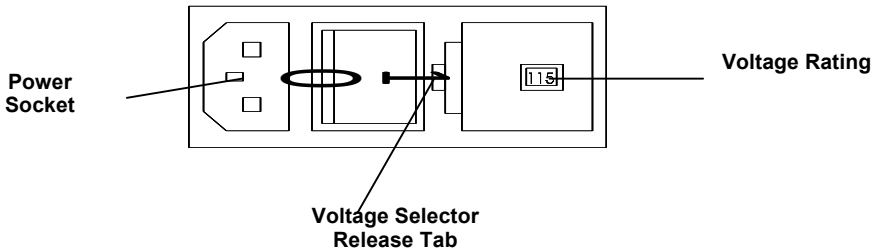
Installing the 630 PDT Laser

Before connecting the unit to the main power outlet, ensure that the voltage selector at the rear of the unit is set to the correct voltage for the USA (115V).

Ensure the voltage selector is set to 115V (USA).

If it is set to 230V (Europe):

a) Insert a small flat-headed screwdriver into voltage selector release tab and pry the assembly out.
b) This assembly contains two fuses.
c) Pry out the inner right side assembly.
d) Rotate the assembly such that the voltage rating facing towards the user reads 115.



e) Replace the assembly in this position.
f) Ensure 10A fuses are fitted and replace the fuse assembly.
g) The unit is now set for use in the USA.

Assembly

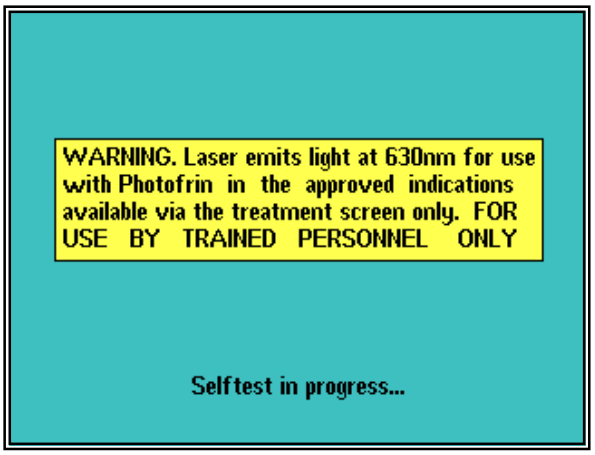
- Connect the handswitch to the handswitch socket (line up red dots and insert).
- Connect a remote interlock bypass to the remote interlock socket (line up red dots and insert).
- Select the appropriate delivery fiber and connect the fiber to the laser aperture using the optical fiber connector.
- Insert the IEC Power cord into the power inlet socket and connect to the main power supply.
- Switch the power switch to **ON**.
- Insert a key into the key switch.
- The **630 PDT Laser** is now installed and ready for use.
- Refer to sections on ‘Calibration’ and ‘Operating Instructions’ to check that the system functions correctly and to gain familiarity with the controls.

TOUCH-SCREEN CONTROLS

The main operating controls, apart from the power switch, key switch and emergency switch, are located on the touch-sensitive screen on the front panel of the main enclosure (see Figure 1). To operate the touch-sensitive controls, lightly touch the screen with one finger on the desired text or soft key.

START

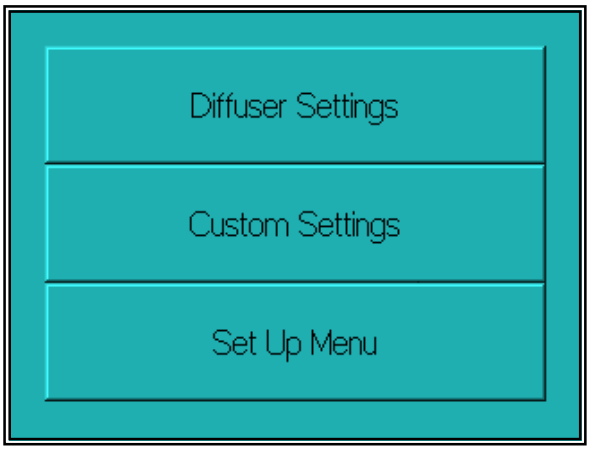
To start the **630 PDT Laser** connect the power lead, remote interlock bypass and handswitch. Ensure the power switch is switched to on (I), select and connect the delivery fiber and turn the key switch clockwise. The system will perform a **Self-Test** program and the screen will show:



MAIN MENU

After the self-test program has been completed, touch the screen and the **Main Menu** screen is accessed.

The **Main Menu** is provided as the main access to all of the treatment modes and system set-up parameters and can be returned to at any stage by touching **Back**.



TREATMENT MODES

At the main Menu the user is presented with three options: **Diffuser Settings, Custom Settings**, and **Set Up Menu**

Selecting **Set Up Menu** will enable system functions to be accessed and treatment summaries to be viewed.

Selecting **Diffuser Settings** or **Custom Settings** will enable the relevant treatment mode.

When selecting either **Diffuser Settings** or **Custom Settings** treatment modes the system will first enter the delivery fiber Calibration mode before any treatment can be commenced.

Calibration must be performed before treatment to allow the system to compensate for delivery fiber transmission losses. The **630 PDT Laser** will then automatically provide the power selected by the operator to the tip of the delivery fiber.

CALIBRATION

Calibration of the delivery fiber must be performed to ensure correct power output at the tip of the delivery fiber.

Calibration will also be required if any of the following occur during the treatment session:

- Power failure / unit switched off
- Handswitch disconnected
- Emergency switch pressed
- Fiber is disconnected

Ensure both inner (removable) and outer (fixed) cuvettes are used during calibration. Absence of either cuvette will result in incorrect calibration and patient dosing.
Ensure both cuvettes are clean (see 'Cleaning the cuvettes'). Contamination of either of the cuvettes will result in incorrect calibration.

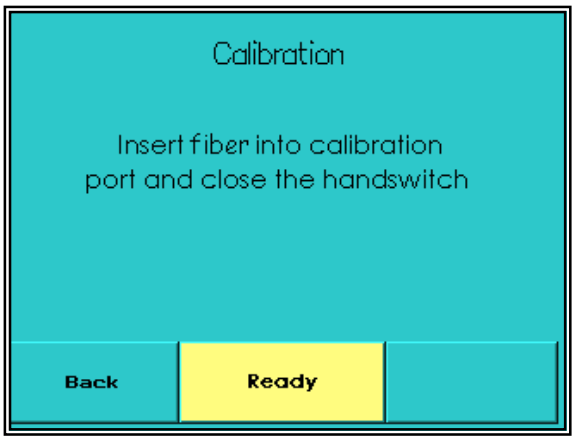
To calibrate the delivery fiber power output:

- Remove the dust cap from the calibration port on the top of the Integrating Sphere (Figure 3).
- Ensure that the outer (fixed) cuvette is clean and is securely attached to the delivery fiber port. If in doubt, replace the outer (fixed) cuvette with a new one.
- Insert sterile inner (removable) cuvette into the outer (fixed) cuvette.
- With the delivery fiber connected to the **630 PDT Laser**, place the distal end of the delivery fiber into the inner (removable) cuvette until it rests on the bottom of the outer (fixed) cuvette. Pull the delivery fiber back approximately $^{1}/_{8}$ – $^{3}/_{16}$ in (3-5mm) and hold the delivery fiber at this position during calibration.

Calibration (continued)

Place the unit in READY mode

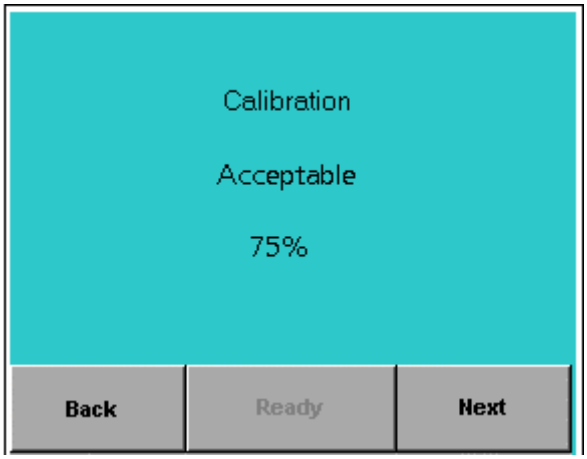
To continue, touch **STANDBY**. After a 2-second delay the soft key text will change to **READY** and the button will turn yellow in color.



Insert delivery fiber into calibration port and close the handswitch

- Depress the handswitch. The **630 PDT Laser** will fire and an audible sound is heard. The **630 PDT Laser** will provide an on-screen indication of when the calibration of the delivery fiber is complete.
- Release the handswitch. The **630 PDT Laser** will return to **STANDBY** mode.

The screen will indicate delivery fiber acceptability, as **Acceptable** or **Unacceptable**.



A transmission value of 75% to 96% is acceptable. Delivery fibers outside this range will be rejected and displayed as unacceptable. If **Unacceptable** is displayed, the delivery fiber must be changed and the calibration procedure repeated.

If the delivery fiber transmission is low, check that the distal end of the delivery fiber is correctly placed in the inner (removable) cuvette, and that the proximal (SMA) end of the fiber is clean.

Displayed Power Output

CAUTION

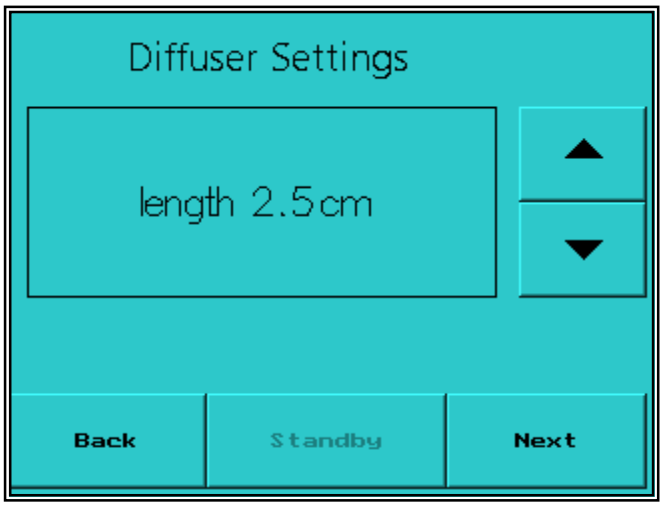
After the calibration procedure the power indicated on the display will be the power output at the tip of the delivery fiber. The 630 PDT Laser automatically adjusts the power at the delivery fiber port to compensate for the delivery fiber transmission losses.

After calibration touch **Next** to set the treatment parameters. Exiting from the calibration menu can be achieved by touching **Back**.

DIFFUSER SETTINGS MODE

Diffuser Settings mode enables the use of the **630 PDT Laser** pre-set settings provided for different lengths of delivery fibers. Select the diffuser length that is relevant to the size of the tumor to be treated.

After selecting **Diffuser Settings** at the main menu and following the calibration procedure, touch the **Next** soft key and the following screen will be displayed:



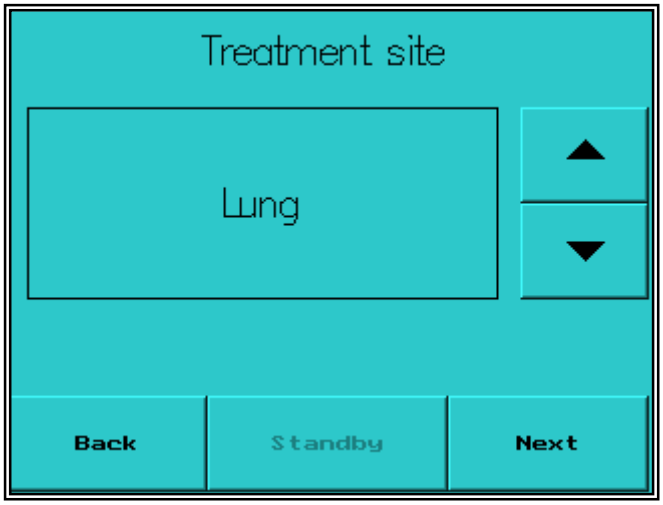
Delivery fiber diffuser length is selected at this screen, by touching the relevant text and using the (▲) up and (▼) down arrows to modify parameters.

Delivery fiber diffuser lengths are 1cm, 1.5cm, 2cm, 2.5cm, 3cm, 4cm, 5cm. The **630 PDT Laser** will display a default value of 2.5cm.

The delivery fiber diffuser length must be entered correctly. Failure to do so could result in incorrect dosing of the patient.

To continue touch the **Next** soft key.

The following screen will be displayed:

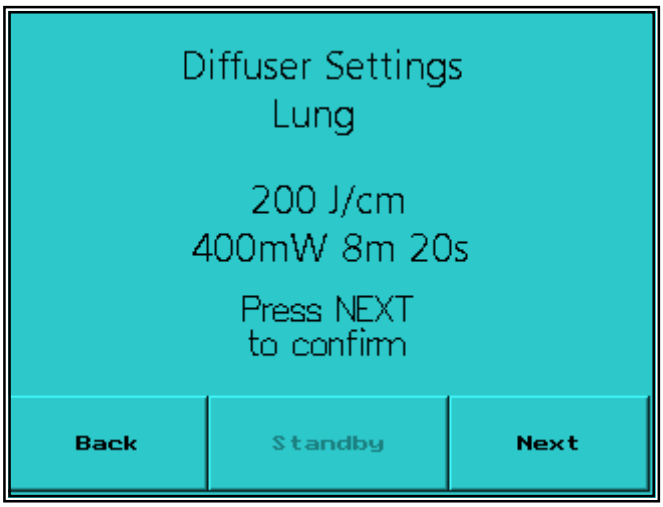


Depending upon the anatomical site being treated, select either **Lung** or **Esophagus** by using the (▲) up and (▼) down arrows.

Lung Selecting Lung pre-sets the **630 PDT Laser** to a treatment time of 8m 20s (500s) and an energy level of 200J/cm. The power is adjusted automatically to provide correct energy delivery for the selected delivery fiber tip length.

Esophagus Selecting Esophagus pre-sets the **630 PDT Laser** to a treatment time of 12m 30s (750s) and an energy level of 300J/cm. The power is adjusted automatically to provide correct energy delivery for the selected delivery fiber tip length.

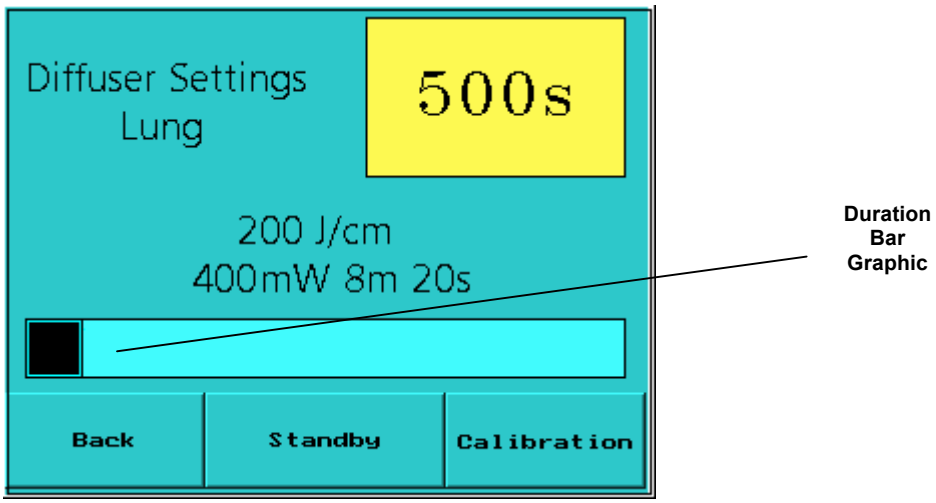
To continue touch the **Next** soft key. The following information screen will be displayed:



After confirming the settings touch the **Next** soft key.

Diffuser Settings Mode (continued)

The following treatment screen will be displayed.



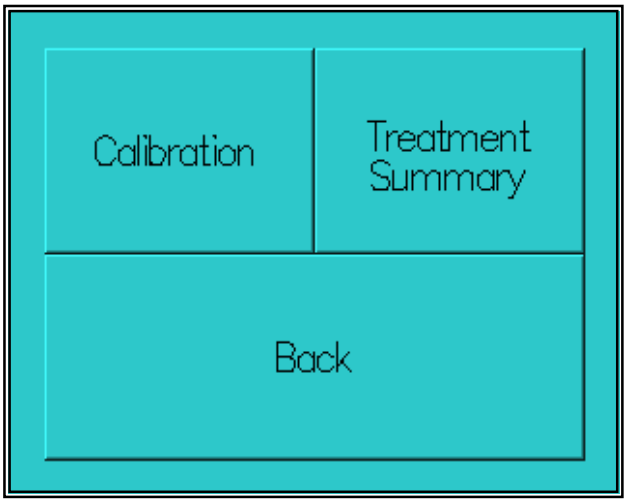
To continue touch **STANDBY** and after a 2-second delay, the soft key text will change to **READY** and the button will turn yellow in color.

To fire the **630 PDT Laser**, depress the handswitch. Treatment will begin, the unit will count down on the seconds display and the duration bar graphic will fill from left to right. Calibration can be checked at any time during treatment by touching the **Calibration** soft key.

When the treatment time has elapsed the unit will enter **STANDBY** mode and the **Calibration** soft key will change to **Next**.

Touch the **Back** soft key to return to the **Main Menu**.

Touch **Next** and the following screen will be displayed:



To calibrate the delivery fiber, touch **Calibration** and follow the instructions on screen.
To view a summary of the treatment, touch **Treatment Summary**. Touch **Back** to return to the main menu.

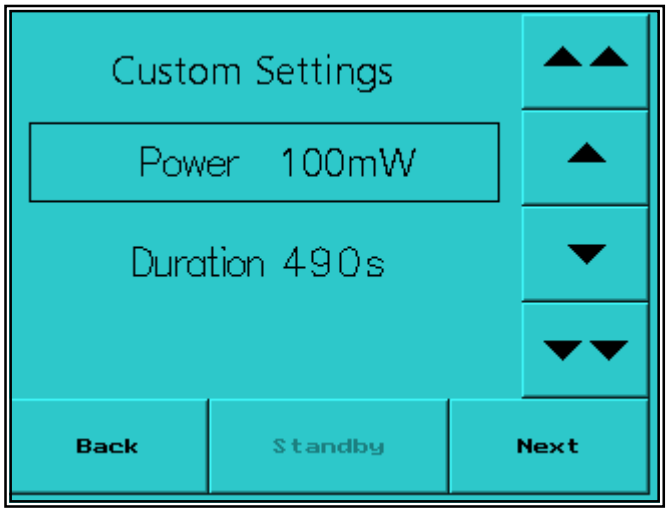
CUSTOM SETTINGS MODE

Custom Settings mode is provided to enable the user to manually set both **Power** and **Duration** parameters on the **630 PDT Laser**.

Parameters:

Power	100 mW min.	2000 mW max.
Duration	4s min.	3200s (53m 20s) max.

After selecting **Custom Settings** at the main menu and following the calibration procedure, touch the **Next** soft key and the following screen will be displayed:

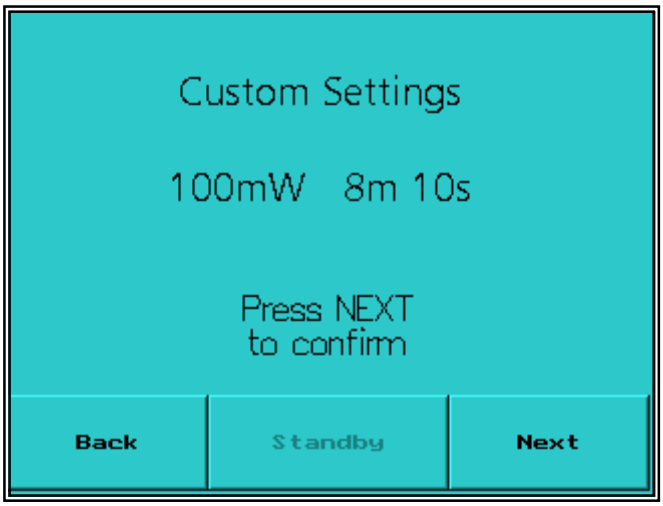


Using **Custom Settings** treatment mode, **Power** and **Duration** may be set manually. To modify values, touch the **Power** or **Duration** text and use:

(▲▲)	To coarse adjust up
(▲)	To fine adjust up
(▼▼)	To coarse adjust down
(▼)	To fine adjust down

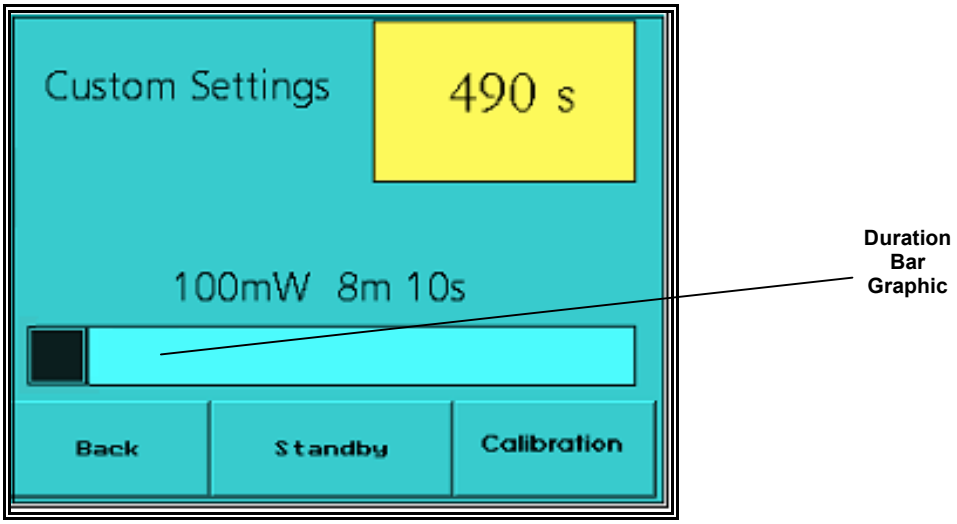
To continue touch **Next**. The following information screen will be displayed:

Custom Settings Mode (continued)



Touch **Next** to confirm settings.
Touch **Back** to readjust settings

The following treatment screen will be displayed.



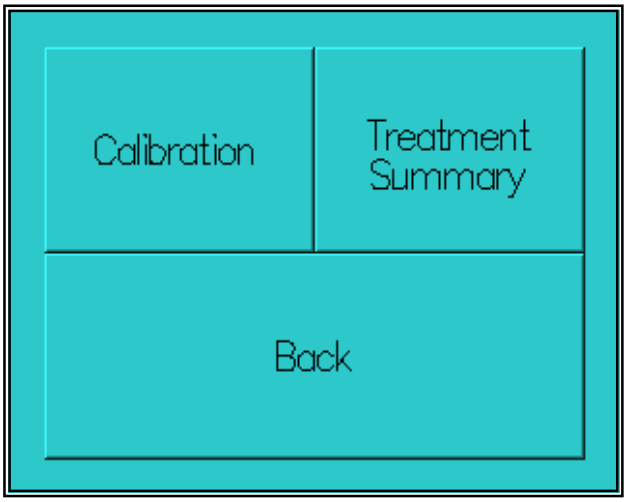
To continue touch **STANDBY** and after a 2-second delay, the soft key text will change to **READY** and the button will turn yellow in color.

To fire the **630 PDT Laser**, close the handswitch. Treatment will begin, the unit will count down on the seconds display and the duration bar graphic will fill from left to right.

When the treatment time has elapsed the unit will enter **STANDBY** mode and the **Calibration** soft key will change to **Next**.

Touch the **Back** soft key to return to the **Main Menu**.

Touch **Next** and the following screen will be displayed:

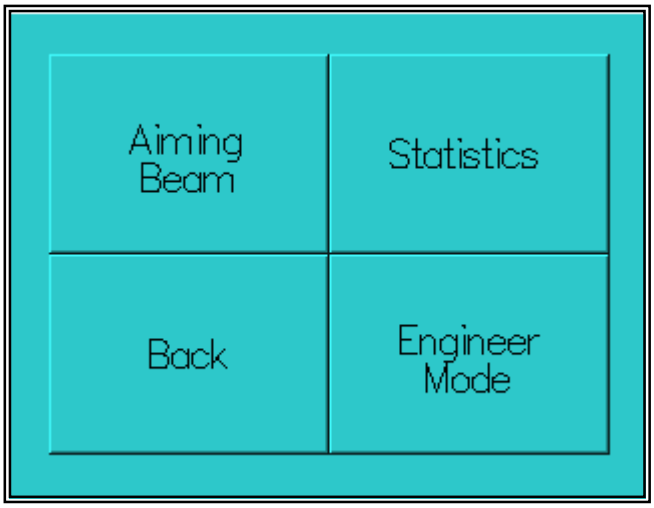


To calibrate the delivery fiber, touch **Calibration** and follow the instructions on screen.
To view a summary of the treatment, touch **Treatment Summary**. Touch **Back** to return to the **Main Menu.**

SET UP MENU

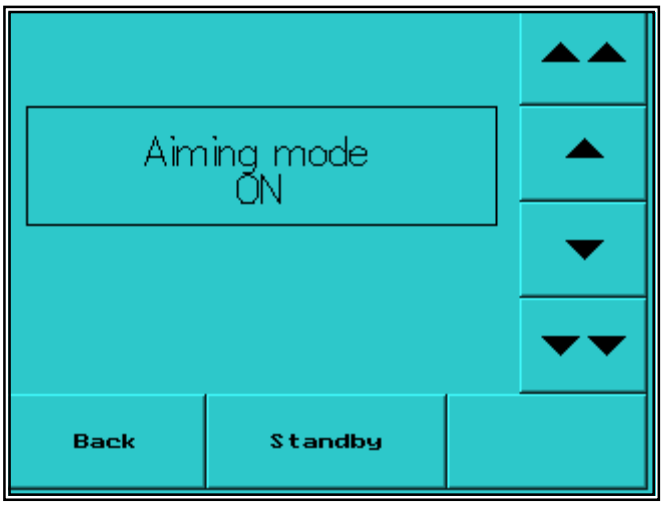
Aiming beam parameters, **Statistics** and **Engineer Mode** can all be accessed using the **Set Up Menu** soft key.

To enter the **Set Up Menu**, touch **Set Up Menu** at the **Main Menu** screen. The following screen will be shown.



AIMING BEAM MODE

Touching **Aiming Beam** at the **Set Up Menu** accesses the aiming beam mode screen.



The **630PDT Laser** has an aiming beam incorporated, which is activated and is visible at the tip of the delivery fiber when the laser is in the **READY** mode. The aiming beam indicates the distribution of laser energy emission.

Aiming modes can be set by using either the coarse or fine adjust buttons. The following parameters can be set:

ON	Aiming beam on.
OFF	Aiming beam off.
FLASH	Aiming beam flashes on and off.

To check the selected mode the **630 PDT Laser** can be put into **READY** mode by touching **STANDBY**. To return to **STANDBY** mode touch the **READY** button.

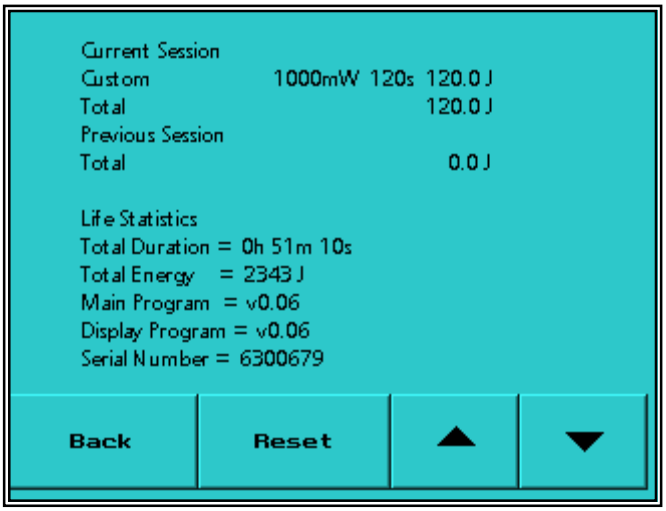
For safety reasons the **630 PDT Laser** cannot be fired when in **READY** mode at this screen.

SESSION STATISTICS

A Session is defined as the period of time from when the **630 PDT Laser** is switched on until it is switched off – this may entail several treatments. **Resetting Session Statistics** without switching the **630 PDT Laser** off will also end a session and in this way a new session may be started.

Session Statistics is viewed by selecting **Set Up Menu** from the **Main Menu** and then selecting **Statistics.**

There will be a short wait when selecting **Statistics**, and then the following screen will be displayed:



To reset the session statistics touch **Reset** and the display will zero the **Current Session** and record that information in the **Previous Session** statistics.

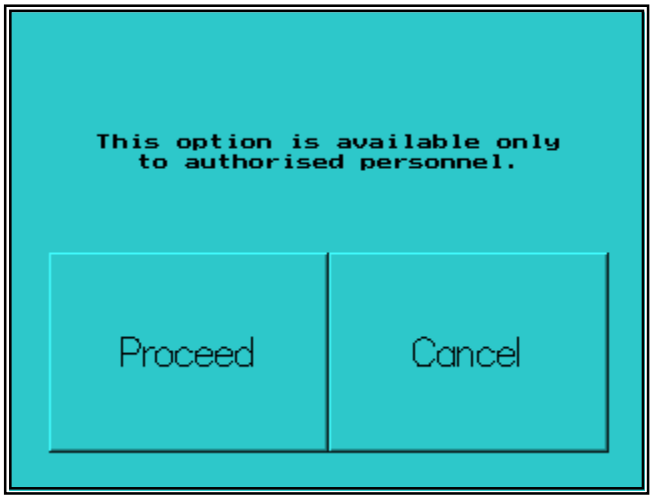
The (▲) screen up and (▼) screen down arrows enable the screen to be scrolled. **Current Session** and **Previous Session** summaries each contain up to 20 treatments.

Touch **Back** to return to **Set Up Menu** and **Back** again to return to the **Main Menu.**

ENGINEER MODE

Only qualified service personnel authorized by AngioDynamics can use this option.

By selecting Engineer Mode the following screen will be displayed:

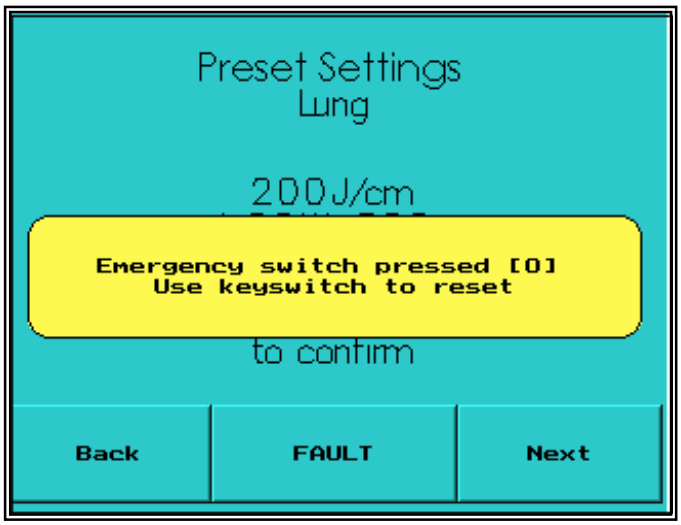


If **Proceed** is selected, the user will be prompted for a password. If the password is not entered or entered incorrectly, the unit will default back to the **System Set Up** screen.

There are no functions to be carried out in **Engineer Mode** by the user. This is a facility for use by AngioDynamics authorized service personnel only.

Passwords are only distributed to AngioDynamics authorized service personnel.

FAULTS SCREEN



Any faults with the system will be shown as above, with the fault message displayed in a yellow box.

Follow the onscreen instructions to rectify the fault.

Certain fault types will require the 630PDT Laser to be restarted. In this case, Session Statistics will be retained.

FAULT MESSAGES

Safety Interlock messages are displayed across the Menu Display on the **630 PDT Laser**. If the **630 PDT Laser** is not responding as expected, check the display for any messages and take the associated action indicated below:

Fiber Not Connected	The **630 PDT Laser** system will not go to **READY** mode unless the delivery fiber has been connected. Please connect the delivery fiber.
Remote Interlock	Remote interlock has been violated. Please close the entryway door or insert the remote interlock bypass.
Emergency Switch Pressed: Use Key Switch to Reset	The operator has pressed the emergency switch. The **630 PDT Laser** will require switching **OFF** at the key switch. When the **630 PDT Laser** is switched back on again, it will carry out a self-test and the message will clear automatically.
Setting the Wavelength	Unit is setting the wavelength to 630nm. Wait until the message disappears.
Handswitch Not Connected	Please connect the handswitch.
High Temperature Warning	The laser diode temperature is close to its upper or lower limits. Check that the ambient air temperature is within acceptable levels and that the cooling vents on the rear and underside of the unit are not obstructed. Touching the screen will clear the message and allow the operator to continue.
Temperature Too High	The laser diode temperature is outside its acceptable operating limits, causing the wavelength to be on the limit of the tolerance range. The **630 PDT Laser** should be allowed to return to an appropriate operating temperature level. **Operating temperature should be between 61°F and 86°F (16°C to 30°C) or the 630PDT Laser will not function.** If the working environment is within the stated range and the fault does not clear, call a service engineer from your local AngioDynamics representative.

Fault messages (continued)

Handswitch Failure	The **630 PDT Laser** has detected a problem with the handswitch. Check that the correct handswitch has been connected and it is set to the **OFF** position. If the correct handswitch is connected and it is in the **OFF** position, press the **SELECT** button and the message should clear. If the message does not clear, switch the **630 PDT Laser OFF** and then **ON** at the key switch. If this does not clear the problem, call a service engineer from your local AngioDynamics representative.
Handswitch On	There is a two-second-safety delay when the **630 PDT Laser** is placed from **STANDBY** to **READY**. If the handswitch is **ON** during this time **Handswitch On** will be displayed. Ensure the handswitch is **OFF** until after the two-second delay and the audible tone is heard.
Call Service Engineer	If this message appears, switch the **630 PDT Laser OFF** at the key switch and then **ON**. If the message does not disappear, call for a service engineer from your local AngioDynamics representative.

The **630 PDT Laser** is designed to operate at ambient temperatures of between 61°F and 86°F (16°C to 30°C).

1. Check that suitable safety glasses are available and laser-warning signs are provided at entrances.
2. Place the **630 PDT Laser** in a convenient position no further than 2 meters from the operating field.
3. Connect the power cord.
4. Connect the handswitch and place it in a convenient operating position.
5. Insert either a remote interlock bypass or, if appropriate, connect the door interlock cable to the remote interlock connector socket.
6. Check that a sterile, removable inner cuvette is in place in the calibration port
7. Turn on the power switch.
8. Prior to turning on the key switch ensure that the handswitch and interlock have been connected and the handswitch is in the **OFF** position. If any of the above have not been connected, the appropriate error message will be displayed.
9. Turn on the key switch to activate the control circuits. The self-test program will be activated.
10. After self-testing the system, touch the screen to continue. The **Main Menu** will be displayed.
11. Connect the delivery fiber to the unit.
12. Select the desired treatment mode or **Set Up Menu** to change system parameters.
13. Check that all personnel, including the patient, are wearing appropriate safety glasses.
14. Calibrate the delivery fiber following the instructions given.
15. Set the treatment mode parameters.
16. Press **STANDBY** to enter **READY** mode.
17. If needed, alter the operating mode and parameter settings.
18. Guide the delivery fiber to the operating field.
19. Switch the handswitch to **ON** to fire the **630 PDT Laser**.
20. When the **630 PDT Laser** has finished its pre-set exposure, switch the handswitch to **OFF**.

Operating Instructions (continued)

21. To interrupt the exposure, switch the handswitch to OFF.

22. If any faults are present, the **630 PDT Laser** will be prevented from firing and will immediately return to **STANDBY** mode.

23. The fault message will be shown. The **630 PDT Laser** will not enter **READY** mode until the fault is cleared.

24. The **630 PDT Laser** will automatically return to the **STANDBY** mode if the touch-sensitive screen or handswitch is not used for 5 minutes.

25. Treatment parameters will be recorded in **Session Statistics**.

26. To turn the **630 PDT Laser OFF** press **STANDBY/READY** to take the system to the **STANDBY** mode and turn the key control switch to the **OFF** position.

If an interlock message or error message is displayed and the system refuses to go to **READY** status, refer to the 'Fault Messages' section.

INTEGRATING SPHERE

The **630 PDT Laser** is supplied with an integral integrating sphere power meter. This is specifically designed for calibrating the output of delivery fibers with an active length of up to 3½ inches (9cm).

The integrating sphere power meter is designed with an outer (fixed) and inner (removable) cuvette.

Outer (fixed) Cuvette

The outer (fixed) cuvette is inserted and screwed into the integrating sphere port. During use, the outer (fixed) cuvette should remain attached to the Integrating Sphere. When not being actively used for calibration, ensure that the dust cap is attached. Periodically and before every calibration, inspect the outer (fixed) cuvette to ensure it is clean. Any dirt or staining may lead to incorrect calibration and incorrect dosing of the patient. If in doubt replace the outer (fixed) cuvette with a new clean unit. Avoid fluid spills into the outer (fixed) cuvette. **Do not place delivery fibers directly into the outer (fixed) cuvette.**

Inner (removable) Cuvette

Insert a clean, sterile inner (removable) cuvette into the outer (fixed) cuvette to provide a holder for the delivery fiber during calibration. The inner (removable) cuvette supplied by AngioDynamics is suitable for up to 10 repeat sterilizations using the recommended sterilization technique.

Cleaning the cuvettes

The calibration of the integrating sphere is extremely dependent on the cleanliness of the inner (removable) and outer (fixed) cuvettes and the fiber.

Clean the inside of both the inner (removable) and outer (fixed) cuvettes using a mild detergent solution and a bottle brush. Ensure that the cuvettes are rinsed thoroughly to remove any residual detergent and finally rinse with a small amount of Isopropyl Alcohol. Dry thoroughly using warm air. Clean the outside of both cuvettes using Isopropyl Alcohol.

Sterilizing the Inner (removable) Cuvette

The inner (removable) cuvette is supplied unsterile and should be cleaned as described and sterilized before each use. The sterilization time should be at least 3 minutes at a temperature of 134°C. AngioDynamics recommend that the inner (removable) cuvette be steam sterilized using a validated process in accordance with:

ISO 11134 1994 ‘Sterilization of Healthcare products, requirements for validation and routine control, industrial moist heat sterilization’.

Proper calibration requires both an inner (removable) and an outer (fixed) cuvette. Accurate calibration requires clean cuvettes and integrating sphere. If in doubt use new cuvettes. If the interior of the Integrating Sphere has become contaminated, contact your local AngioDynamics representative for advice.

The Integrating Sphere Power Meter should be calibrated at least annually from the date of installation. See ‘Calibrating the Internal Integrating Sphere Power Meter’.

MAINTENANCE

Cleaning

The **630 PDT Laser** has been designed to operate reliably with no maintenance. The outer casing of the **630 PDT Laser** may be wiped down periodically with a cloth dampened with a mild antiseptic solution. **Ensure the laser is disconnected from the main power supply when cleaning.**

There are no other user serviceable parts in the 630 PDT Laser.

DISPOSAL OF PRODUCT

At the end of the life of the **630 PDT Laser**, it should be disposed of according to national environmental requirements or be returned to AngioDynamics.

LASER POWER OUTPUT

To ensure accurate power output from the laser, calibration of the measurement system should be checked at least annually from the date of installation.

MEASUREMENT SYSTEM CALIBRATION

The LASER SAFETY OFFICER or suitably trained service personnel should carry out this procedure.

Equipment Required
An independent integrating sphere power meter of known calibration.
A delivery fiber.
Laser unit to be tested.

Procedure

Connect the delivery fiber to the Laser unit output port.

After calibrating the delivery fiber, present the distal end of the delivery fiber to the external power meter.

Record the Laser unit's actual and displayed outputs at various different power settings.

Calculate the percentage difference between the displayed power output and the actual power output as taken from the external power meter.

If calculated disparity exceeds ± 20%, contact your AngioDynamics representative.

If carrying out the check in uncalibrated mode allow up to 15% transmission loss for the delivery fiber.

CALIBRATING THE INTERNAL INTEGRATING SPHERE POWER METER

To ensure accurate calibration of the delivery fiber, the internal integrating sphere power meter should be calibrated at least annually.

The LASER SAFETY OFFICER or suitably trained service personnel should carry out the above procedure and if the calculated disparity exceeds ± 20%, contact your AngioDynamics representative.

Adjusting the Calibration of the internal integrating sphere power meter can only be carried out by suitably trained AngioDynamics service personnel.

The method for carrying out these adjustments is described in the Appendix 'Adjusting the Calibration of the Internal Integrating Sphere Power Meter '.

POWER OUTPUT ADJUSTMENTS

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

The method for carrying out these adjustments is described in the Appendix 'Calibrating the Measurement System'.
Please contact your local AngioDynamics representative for further advice.

MANUFACTURER'S GUARANTEE POLICY

AngioDynamics Limited guarantees the **630 PDT Laser** against defects in materials and workmanship for a period of 12 months. The guarantee period begins on the date of installation.

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

GUARANTEE CLAIMS

To make a guarantee claim the purchaser shall, promptly following discovery of the basis of claim, contact the local AngioDynamics representative or AngioDynamics Ltd. in writing or by telephone or fax at the following address:

AngioDynamics Inc
603 Queensbury Ave.
Queensbury, NY 12804
Customer Service Tel: +1 800 772 6446
Laser Service Tel: +1 866 883 8820
Fax: +1 518 798 1360
Email: customerservice@angiodynamics.com
http://www.angiodynamics.com

Manufactured in the United Kingdom by:

AngioDynamics UK Limited
Building 2000, Beach Drive
IQ Cambridge, Waterbeach
Cambridge CB25 9TE
United Kingdom
Service Tel: +44 1223 729372
Service Tel: 0800 013 0859 (UK only - free phone)
Fax: +44 1223 729320
Email: customerservice@angiodynamics.com

APPENDIX

WARNING INCORRECT CALIBRATION MAY CAUSE INJURY DURING TREATMENT

WARNING THERE IS A DANGER OF ELECTRICAL SHOCK WHEN THE COVER OF THE LASER IS REMOVED.

Only trained service personnel authorized by AngioDynamics to carry out the procedures described in the Appendix are to undertake the following.

All warranty will become void if attempted by unauthorized personnel.

AngioDynamics will not accept liability for the use of this equipment when calibrated by unauthorized personnel.

ADJUSTING THE CALIBRATION OF THE INTERNAL INTEGRATING SPHERE POWER METER

Introduction

This procedure applies to the Integration Sphere assembly as used on the AngioDynamics **PDT 630 Laser** unit.

Photocopy the result sheet to record the results.

Equipment Required

- Traceable power meter capable of measuring 3 Watts continuous power at 630nm from a diffusing fiber.
- A diffusing fiber.
- A Voltmeter, range 0 – 3 Volts resolution 1%.(capable of measuring to 3 decimal places (i.e. 1.999))

Procedure

a. Note the serial number of the external integrating calibration power meter on the results sheet.
b. Remove the cover from the AngioDynamics **PDT 630 Laser** unit and attach a 2.5cm diffusing fiber to the output port.
c. Place an inner (removable) cuvette into the internal integrating sphere.
d. Connect a calibrated DVM that is capable of measuring to 3 decimal places (i.e. 1.999) between the 0V link and test point PL7on the interlocks board.
e. Place the output fiber into the external Calibration Power meter and fire the laser. Adjust the power setting until a reading of 0.4 nominal Watts is measured. Stop firing. Record the power on the result sheet. **Note: The calibration of the integrating sphere is extremely dependent on the cleanliness of the inner (removable) and outer (fixed) cuvettes and the fiber.**
f. Clean the inside of both the inner (removable) and outer (fixed) cuvettes using a mild detergent solution and a bottle brush. Ensure that the cuvettes are rinsed thoroughly to remove any residual detergent and finally rinse with a small amount of Analar IPA. Dry thoroughly using warm air. Clean the outside of both cuvettes using Analar IPA. **Note: Do NOT clean the fiber diffuser tip with acetone; it will dissolve. Only use IPA.**
g. Place the fiber into the internal integrating sphere and fire the laser. Adjust the potentiometer on the integrating sphere until the DVM reads a value of 5 V per Watt e.g. 2.000 V for 0.4W. Record the voltage on the result sheet.
h. Calculate the Volts/Watt value and record on the result sheet. This value should be within the range 4.9 – 5.1 V/W.
i. NOTE STEPS (g) and (h) MAY NEED TO BE REPEATED SEVERAL TIMES AS THE LASER OUTPUT POWER MAY VARY OVER TIME.
j. From the main menu, calibrate the laser in the manner described in the user manual. Fire the laser into the power meter. If within the required range then sign and date a cal due label (re-calibration due in 1 year) and affix it in a visible location on the integrating sphere. If the sphere is not within the required range then repeat the calibration.

INTERNAL POWER METER CALIBRATION RESULTS SHEET

Stamp:

Laser Serial No:..... **Sign:…….....** **Date: .....**

Calibration power meter	

0.4W power measured	**W**
Output for 0.4W	**V**
Sphere calibration	**Volts/Watt**
1W Calibrated (user mode)	**W**

CALIBRATING THE MEASUREMENT SYSTEM – POWER OUTPUT ADJUSTMENTS

WARNING INCORRECT CALIBRATION MAY CAUSE INJURY DURING TREATMENT

WARNING THERE IS A DANGER OF ELECTRICAL SHOCK WHEN THE COVER OF THE LASER IS REMOVED.

Only trained service personnel authorized by AngioDynamics to carry out the procedures described in the Appendix are to undertake the following.

All warranty will become void if attempted by unauthorized personnel.

AngioDynamics will not accept liability for the use of this equipment when calibrated by unauthorized personnel.

- Check servo operation of Peltier cooler and adjust to approx. operating temperature for diode as specified in diode data sheet.
- Connect the UUT to a monitored Variac set to 115V.
- Connect handswitch, remote interlock bypass, serial line from PC running REL30_00 and 400µm cleaved reference fiber between the UUT and a calibrated power meter capable of measuring light power at 630nm >3W.

Set up I_{op} with demand of 250:

- Ensure RV1 (CAL pot) is fully acw and all readings at zero before enabling and firing diode.
- Go to “READY” and enable diode.
- Test fire initially with a demand of 100 to confirm control loop is stable.
- Increase I in increments of 50 to a max of 250, providing the next step is not too great. If it is likely that I_{op} will be exceeded before 250 is reached change R22 to 4K7.
- With demand set to 250 turn RV1 (CAL pot) clockwise to increase diode current to 95% of I_{op} quoted on diode data sheet (to do this take threshold current of 4A off of I_{OP}, multiply remainder by 0.95 and add back the 4A). If end of pot is reached before I_{op}, change R22 to 470R.
- Confirm that there is no instability in the control loop.

Fine tune peltier temperature to get correct temperature when operating close to full power.

- Measure resistance across monitor thermistor while still firing as above and adjust RV6 (TEMP pot) very carefully to bring resistance to the value quoted on diode data sheet.

Fine-tune I_{op} with temperature correct. Record I_{op}, I_{Prim}, P_{Fib} V_{MPDTOT} and Thermistor.

- Adjust RV1 (CAL pot), while still firing as above, to set Diode current exactly to I_{op} quoted on diode data sheet and record I_{op} from current probe on diode data sheet.
- Measure P_{Fib} from power meter and V_{MPDTOT} from oscilloscope. Note both on diode data sheet.
- Move the current probe to the pink wire supplying the 60V rail from the PSU to the diode driver circuit and use the measurement obtained as an indication of the primary current.
- Record this on the diode data sheet and then return the current probe to the red diode drive lead.
- Measure and record the thermistor value, which should still be that, quoted on the diode data sheet.
- Stop firing. Fire a second time and check I_{sec}, P_{Fib} V_{MPDTOT} and Thermistor values to confirm repeatability. Disable diode, check that I_{SEC} drops to zero and go to Standby.
- Re-connect monitoring thermistor (4 way Molex).

Determine required Diode Offset.

- Again go to Ready and re-enable the diode.
- Set the Demand to zero and hold the distal end of the fiber in a safe fashion such that the emitted aiming beam can be seen scattered on the bench surface.
- Now fire the Diode at zero demand and the aiming beam will go out.
- Increment I by a count at a time whilst still firing until laser light first becomes visible.
- Should the laser flash then increase I by a further count to get a stable intensity.
- Record the required offset based on 10mV per count of I to produce a stable beam.
- Disable diode and go to Standby

Set V_{Trip}.

- Ensure relays are closed and that main power voltage is exactly 115V.
- Set trip voltage according to V_{Trip} = (1.25 x I_{Prim} x 0.47R x 10) = I_{Prim} x 5.875

Enter P_{Port}, Offset and V_{MPDTOT}.

- Derive P_{Port} by dividing P_{Fib} by 0.91 (based on standard fiber efficiency of 91%), record value on diode data sheet and enter it into the Diode Data table.
- Confirm that V_{MPDTOT} is in the range 2.55V to 2.65V. Assuming so, decrement the value by 200mV and enter the result into the Diode Data table.
- Enter the Offset in mV into the Diode Data table.

Fire in User mode (uncalibrated) and check accuracy of powers.

- Use diffusing fiber and Integral integrating sphere.
- Set max power and fire in user mode.
- Record max power in user mode.
- Reduce mains voltage to 104V.
- Fire again at max power and check that:
- I_{SEC} and V_{MPDTOT} (both displayed on scope) are steady DC levels.
- Power o/p is maintained.
- No trip errors are reported.
- If successful, further reduce mains voltage and test again.
- Be on the lookout for the onset of oscillations in V_{MPDTOT} and over current trip errors (#32).
- Continue reducing mains voltage while tests are successful down to a limit of 98V.
- Record either the fact that the unit operates down to 198V, or the mains voltage at which it first failed.
- Remove scope probe and current clamp.
- Return mains voltage to 115V.

EMC DECLARATION

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The 630 PDT Laser is intended for use in the electromagnetic environment specified below.
The customer or user of the 630 PDT Laser should ensure it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic emissions – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The 630 PDT 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The 630 PDT 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The **630 PDT Laser** is intended for use in an electromagnetic environment specified below. The customer or the user of the **630 PDT 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	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 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 differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV 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 **630 PDT Laser** requires continued operation during mains interruptions, it is recommended that the **630 PDT Laser** be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/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 **630 PDT Laser** is intended for use in an electromagnetic environment specified below. The customer or the user of the **630 PDT Laser** should assure that it is used in such an environment.

Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment - guidance***
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **630 PDT Laser**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800MHz to 2,5 GHz 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 metres (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 80 MHz and 800 MHz, 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 **630 PDT Laser** is used exceeds the applicable RF compliance level above, the **630 PDT 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 **630 PDT Laser**.

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

Recommended separation distances between portable and mobile RF communications and the 630 PDT Laser.

The **630 PDT Laser** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **630 PDT Laser** can help prevent electromagnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the **630 PDT Laser** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter ***W***	***Separation distance according to frequency of transmitter*** ***m***		
	150kHz to 80 MHz ***d = 1.2 √P***	***80MHz to 800MHz*** ***d = 1.2 √P***	***800 MHz to 2,5 GHz*** ***d = 2.3 √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 metres (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 80 MHz and 800 MHz, 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.

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12 MONTH MANUFACTURER'S GUARANTEE REGISTRATION CERTIFICATE

Laser Type: **630 PDT Laser** Laser Serial No: _____

Customer / Registered User Information:

Institution:

_____

Specialist: Name: _____ Speciality: _____

Address: Street: _____

City: _____ Zip / Post Code: _____

Country: _____

Telephone: _____ Fax: _____

Email: _____

Date Installed: _____

Installed by: Signed: _____ Print Name: _____

Organization: _____

Local ANGIODYNAMICS representative details:

Representative Signature: _____ Print Name: _____

- Registered User and Representative to fully complete this Certificate.
- Registered User must keep this certificate in a safe place for reference.
- The accompanying Registration Form must be completed and sent to AngioDynamics Inc, 603 Queensbury Ave, Queensbury, NY 12804, USA, by mail or fax (518) 798 1360 within 28 days of date of Product installation. **This Registered User information is essential in the event of a Guarantee Claim.**

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12 MONTH MANUFACTURER'S GUARANTEE REGISTRATION FORM

Laser Type: **630 PDT Laser** Laser Serial No: _____

Customer / Registered User Information:

Institution:

_____

Specialist: Name: _____ Speciality: _____

Address: Street: _____

City: _____ Zip / Post Code: _____

Country: _____

Telephone: _____ Fax: _____

Email: _____

Date Installed: _____

Installed by: Signed: _____ Print Name: _____

Organization: _____

Local ANGIODYNAMICS Representative details:

Representative Signature: _____ Print Name: _____

Registered User / Representative to fully complete, detach and return this Registration form to AngioDynamics Inc, 603 Queensbury Ave, Queensbury, NY 12804, USA, by mail or fax (518) 798 1360 within 28 days of date of laser installation. **This Registered User information is essential in the event of a Guarantee Claim.**