

ANGIODYNAMICS®

**DELTA 15/30
DIODE LASER
OPERATOR MANUAL**

Version 2.2

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Manufactured in the United Kingdom by AngioDynamics UK Limited

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SECTION 1 WELCOME

Thank you for purchasing an AngioDynamics 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 1.4 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 **DELTA 15** and the **DELTA 30** (referred to as **DELTA 15/30** in this manual). These lasers are 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.

DELTA 15 The **DELTA 15** is a diode laser capable of delivering up to 15W of continuous wave radiation via an optical fiber, or 119J/cm² of pulsed radiation via a spot handpiece, coupled to the laser aperture.

The **DELTA 15** incorporates a Class IV GaAlAs (Gallium Aluminium Arsenide) diode laser with a wavelength of 810nm (±20nm).

The **DELTA 15** incorporates a visible Class IIIa diode laser aiming beam with a wavelength of 635-660nm and a maximum power output of 5mW.

DELTA 30 The **DELTA 30** is a diode laser capable of delivering up to 30W of continuous wave radiation via an optical fiber, or 226J/cm² of pulsed radiation via a spot handpiece, coupled to the laser aperture.

The **DELTA 30** incorporates a Class IV GaAlAs (Gallium Aluminum Arsenide) diode laser with a wavelength of 810nm (±20nm).

The **DELTA 30** incorporates a visible Class IIIa diode laser aiming beam with a wavelength of 635-660nm and a maximum power output of 5mW.

DESCRIPTION OF THE DELTA 15/30

The **DELTA 15/30** has been designed for use with the AngioDynamics range of procedure kits, such as those for EVLT® (EndoVenous Laser Treatment). It can also be used with a wide range of standard fibers and accessories, further details of which are in section 4 of this manual.

The **DELTA 15/30** 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 or handpiece for delivering the laser radiation to the tissue

Key features of the **DELTA 15/30** include:

- 15W or 30W power output
- Compact & portable
- Intuitive user interface
- Automatic fiber recognition when used with fibers and accessories conforming to the AngioDynamics Fiber Recognition System (FRS)
- Minimal maintenance & service
- Internal power calibration meter (optional on **DELTA 15**)
- Memory card slot for transfer of data between the **DELTA 15/30** and a PC

ABOUT THIS MANUAL

This manual is broken down into six main sections as described below. The contents of each one are detailed at the beginning of the appropriate section.

1	Welcome	
2	Safety & Warnings	Explains the general warnings and precautions that must be followed to ensure that the DELTA 15/30 is used in a safe manner.
3	Operating Instructions	Detailed instructions on how to install and operate the DELTA 15/30 laser.
4	Procedures	Specific information about AngioDynamics fibers and procedure kits, equipped with FRS.
5	Technical Information	This section explains all the maintenance procedures that can be performed by the user.
6	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:

SECTION 2 SAFETY & WARNINGS

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SYMBOLS USED IN THIS MANUAL








 CAUTION	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.
 WARNING	This symbol indicates the possibility of a non-radiation hazard that may result in severe injury to personnel within the vicinity of the equipment.
 WARNING	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.
 WARNING	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 **DELTA 15/30** 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
	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

 WARNING	<p>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.</p>
 WARNING	<p>Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.</p>
 CAUTION	<p>This product must be stored at temperatures between 32°F and 130°F. If stored at temperatures outside these limits for a period of time, the laser requires up to 12 hours to acclimatize, prior to operation. Failure to observe this could result in invalidation of the warranty.</p>
 CAUTION	<p>If the product has been stored at a temperature above 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.</p>
 CAUTION	<p>The laser is not designed to operate at temperatures below 50°F.</p>
 WARNING	<p>The Optical Power Calibration meter, if fitted, is to be used only to calibrate a fiber or spot handpiece in accordance with the instructions detailed in this manual. Under no circumstances may it be used as a beam dump, as this will result in damage to the instrument.</p>
 CAUTION	<p>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.</p>

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 **DELTA 15/30** 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 **DELTA 15/30** should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the **DELTA 15/30** 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 **DELTA 15/30** 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 **DELTA 15/30** as replacement parts for internal components, may result in increased emissions or decreased immunity of the **DELTA 15/30**. '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 **DELTA 15/30**:

- Foot Switch Assembly (supplied with laser):
AngioDynamics part number: AS1/A0/0002.
- 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), maximum length 4 m (13 feet).

Note: The ferrite sleeve should be fitted to the remote interlock cable, at a maximum of 75 mm (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 numbers CBL/02/0040.

SAFETY CLASSIFICATIONS, HAZARDS AND PRECAUTIONS

The **DELTA 15/30** is classified as a Class 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 **DELTA 15/30** 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.



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



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 (except specific treatment) 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 **DELTA 15/30** to reduce the risk of eye damage.



The aiming beam is a Class 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. All screws and ports should be secure. Do not use if there is any sign of damage.



The **DELTA 15/30** Laser is a portable laser weighing 26lb. All standard safety procedures for lifting should be applied when moving the instrument.



There are no user serviceable parts in the **DELTA 15/30** 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 2.20 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 DELTA 15/30 near the eyes.

Near infrared light (810nm) from the **DELTA 15/30** passes through the transparent components of the eye and is focused on the retina at the back of the eye. This light can therefore cause an accidental retinal burn.

All personnel must wear approved protective glasses to reduce the risk of eye damage. The patient should wear protective glasses when not anesthetized. If the patient is anesthetized, the eyelids should be taped shut and covered with moist gauze pads.

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 790 – 830nm.

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 L5 or greater. Contact your local AngioDynamics representative if these are required.

The 'Nominal Ocular Hazard Distance' is 4.4 meters (14.5 feet).

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 tissue 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.

Caution – Laser Plume may contain viable tissue particulates.

CLINICAL INDICATIONS & CONTRA-INDICATIONS**Indications**

The **DELTA 15/30** is intended for the following contact or non-contact laser procedures:

- Incision (only contact)
- Excision (only contact)
- Vaporization
- Coagulation / hemostasis

- of soft tissue in Endovascular, open and endoscopic procedures in Vascular Surgery; General Surgery; Gynecology; Urology; Otorhinolaryngology (ENT)/Head & Neck Surgery; Ophthalmology (oculoplastics); Pulmonology/Thoracic surgery; Plastic Surgery; Gastroenterology and Neurosurgery.

Recommended power levels for the above indications for contact fiber accessories are between 5-30W and for non-contact fibers, 10-30W.

Beginning at low power (5-10W) with short pulse duration, the surgeon should note the surgical effect and increase power or pulse duration until the desired surgical effect is obtained.

Generally, the power requirement will vary depending on the contact fiber core and tip size. Less power will be required to obtain tissue reaction with smaller diameter fibers. Recommended power settings are less important than the visual effect. Changes in tissue texture and color are the best indications of the laser effect. Specific pulse duration is not recommended, but is left to user preference and best medical judgment dependent on the particular application and tissue type.

Contraindications The **DELTA 15/30** should only be used in conditions where its use is appropriate and of proven efficacy. It should never be operated except under the direct supervision of a trained operator.

The potential for complications encountered in surgical laser procedures will be the same as those encountered in any surgical procedures. These complications may be serious and could result in death.

Complications may include:

- Pain
- Fever and Leucocytosis
- Bleeding
- Sepsis
- Perforation

(This is not an exhaustive list.)

Potential complications may be encountered in laser procedures, particularly if inappropriate Fluence settings are used.

Complications in extreme cases may include:

- Pain
- Perforation
- Edema
- Erythema
- Crusting
- Hyper-pigmentation
- Hypo-pigmentation
- Scarring

(This is not an exhaustive list.)

CLINICAL WARNINGS

Diode laser radiation, like Nd:YAG laser radiation, penetrates significantly deeper than CO₂ or argon ion lasers. Caution should be employed until the biological interaction of the laser energy with tissue is fully understood by the operator.

Tissue damage could occur if excessive Power/Fluence is used. Use low power and short pulse duration settings until fully familiar with instrument capabilities and tissue response.



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



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

The **DELTA 15/30** should be used only on tissue that is fully observable. Do not use the laser if the desired field is not visible, either directly or via an imaging modality such as ultrasound.

Do not use coaxial gas/air coolant for non-contact fibers when there is a risk of air/gas embolism.

Do not use the laser close to large blood vessels or in highly vascularized areas, except when these are the target for the laser treatment.

When performing endoscopic surgery it is vital for the surgeon to appreciate that the view provided to the surgeon is monocular (not binocular) and depth perception is decreased. Experience and training in laparoscopic techniques are strongly recommended prior to clinical use.

During ENT procedures, laser safe endotracheal tubes should be used.

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 **DELTA 15/30**. 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.

Although it is difficult to specify the effect that the use of the diode laser will have in each therapeutic situation, it is possible to give a general overview as to what the clinician might expect when using the **DELTA 15/30**. The exact effect depends upon the chosen procedure and, especially when using the laser with manual settings, the Power/Fluence setting, Pulse Duration, Pulse Interval, Spot size (if applicable) and the tissue type being treated.

The diode laser may cause tissue damage if improperly used. Precautions, such as careful assessment of the target tissue during treatment and the use of appropriate Power/Fluence and Pulse Duration, should be taken. Use low Power/Fluence and short Pulse Duration settings until fully familiar with the instrument's capabilities.

Starting at low powers, the operator should note the effect on the tissue and increase Power/Fluence, Pulse Duration or treatment time until the desired effect is obtained.

Specific parameters are not recommended, but are left to operator preference and best medical judgment dependent on the particular application.

The diode laser may not be effective for coagulation for severe hemorrhages. The operator must be prepared to control hemorrhages with strident, alternative non-laser techniques. In contact surgery, the tissue interaction with the **DELTA 15/30** laser is similar to Nd:YAG laser. In non-contact surgery the diode laser wavelength, 810nm, penetrates less in most pigmented tissue types and blood than the Nd:YAG laser wavelength.

Precautions for use with a handpiece

Starting at low powers, the operator should note the effect on the tissue and increase Fluence or Pulse Duration until the desired effect is obtained.

The laser can cause epidermal injury. The risk increases with greater laser Fluence and skin pigmentation.

Specific parameters are not recommended, but are left to operator preference and best medical judgment dependent on the particular application.

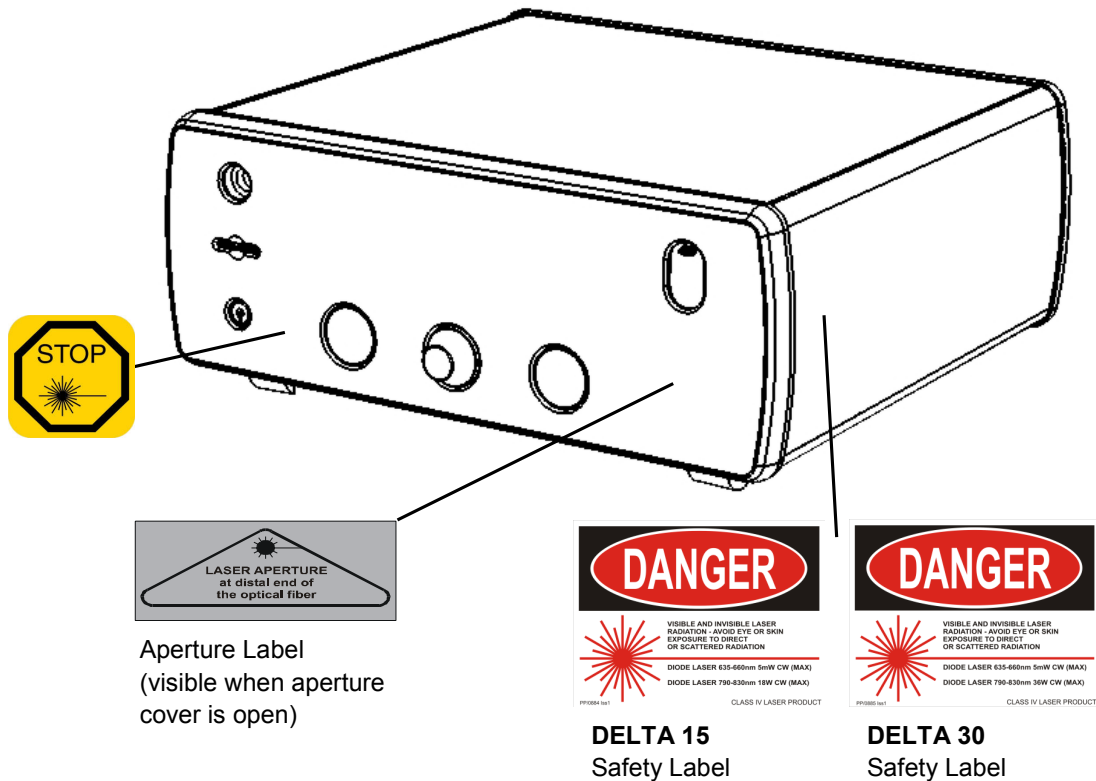
It is strongly recommended that the physician should carry out a small, discrete test patch at the chosen settings prior to undertaking full treatment.

Extreme care should be taken when patients have a recently acquired sun tan, or have a naturally dark skin color.

SAFETY LABELING

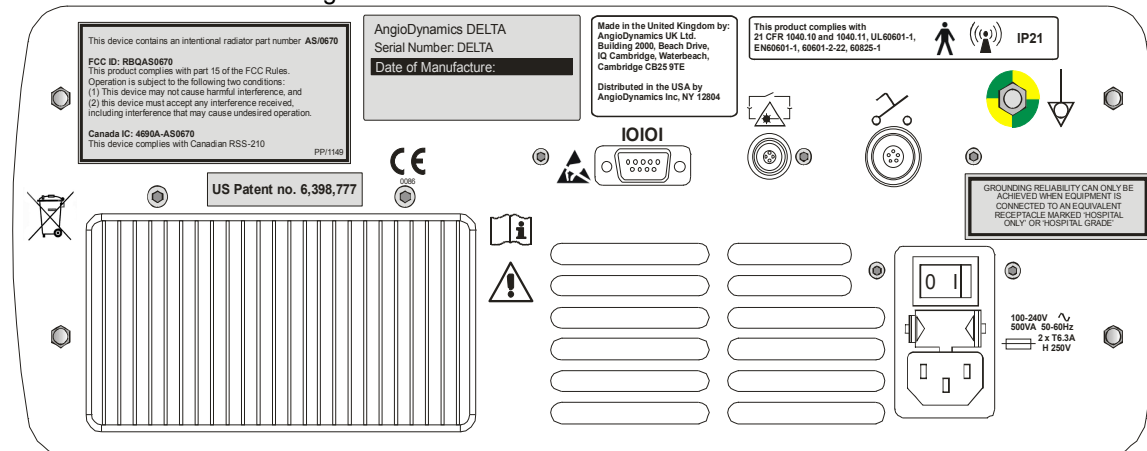
Location of Safety Labeling

Safety labels for the **DELTA 15/30** are positioned as indicated below.



Product Identification Labeling

Product identification labeling is located on the rear of the DELTA 15/30.



SAFETY FEATURES

The **DELTA 15/30** 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)
- internal calibration port (optional on **DELTA 15**)
- calibration procedure for power measurement
- aiming beam


The **DELTA 15/30** 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		
<p>The DELTA 15/30 is intended for use in the electromagnetic environment specified below. The customer or user of the DELTA 15/30 should ensure it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic emissions – guidance
RF emissions CISPR 11	Group 1	The DELTA 15/30 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. The DELTA 15/30 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.
RF emissions CISPR 11	Class B	
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 DELTA 15/30 is intended for use in an electromagnetic environment specified below. The customer or the user of the DELTA 15/30 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 DELTA 15/30 requires continued operation during mains interruptions, it is recommended that the DELTA 15/30 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 DELTA 15/30 Laser is intended for use in an electromagnetic environment specified below. The customer or the user of the DELTA 15/30 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the DELTA 15/30, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance.</p> <p>$d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^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 DELTA 15/30 is used exceeds the applicable RF compliance level above, the DELTA 15/30 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DELTA 15/30.</p> <p>^b Over the frequency range 150 kHz to 800 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications and the DELTA 15/30.

The **DELTA 15/30** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **DELTA 15/30** can help prevent electromagnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the **DELTA 15/30** 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 $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
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 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.

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 **DELTA 15/30** has built-in protection from damage due to ESD, but no protection is 100% effective and precautions should be taken to protect the **DELTA 15/30** and any device connected to it.

When connecting the **DELTA 15/30** with another device, it is very important for the **DELTA 15/30**, the device, and you 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 **DELTA 15/30**, 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 **DELTA 15/30** 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
- The RFID system must not fail to read the fiber's tag

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 radio frequency 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 **DELTA 15/30** laser is capable of working with a wide range of fibers and accessories. The FRS system fitted as standard also allows it to identify the type of fiber or accessory that is connected. This enables the laser to automatically display suitable preset parameters with the minimum of user intervention. Therefore the menus and prompts displayed on the screen will vary depending on the automatically detected settings and it will not be possible to cover every possible scenario in this operator manual.

Depending on the configuration of the **DELTA 15/30** some features may be limited or prohibited. In these situations an explanation will normally be displayed on the screen but, if you have any doubt, please contact your AngioDynamics representative for advice.

The following instructions focus on the most common situations, when the **DELTA 15/30** is being used with an AngioDynamics procedure kit, bare fiber or spot handpiece, fitted with the FRS system.

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CONVENTIONS

The following naming conventions are used throughout these Operating Instructions:

Controls on the front panel are expressed in bold capitals.

Functional modes of the **DELTA 15/30** are expressed in capitals.

Menu items are expressed in bold mixed case.

SCROLL, STANDBY

STANDBY, READY

Main Menu, Language

SUMMARY

1. Place the **DELTA 15/30** in a convenient position on an instrument table no farther than 1.8 metres (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 **DELTA 15/30**.
2. Ensure that the ventilation holes in the base and rear of the **DELTA 15/30** 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 **DELTA 15/30**.
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.
AngioDynamics recommends that the patient's eyes are taped shut if the patient is unconscious.
7. Connect the optical fiber or Spot Handpiece 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 **DELTA 15/30**. 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 required procedure.
10. If required, follow the on-screen instructions to calibrate the fiber or Spot Handpiece.





TO ENSURE BEST PERFORMANCE AND EFFICACY, ALWAYS USE ANGIODYNAMICS FIBERS, PROCEDURE KITS AND ACCESSORIES.

ONLY 600 μ m NON-CONTACT FIBERS WITH A COOLING SHEATH CAN BE CALIBRATED.

CONTACT FIBERS DO NOT REQUIRE CALIBRATING.

THE DISPLAYED POWER WITH A CONTACT FIBER OR UNCALIBRATED NON-CONTACT FIBER IS THE POWER LEVEL AT THE LASER APERTURE. IT SHOULD BE ASSUMED THAT THE POWER LEVEL AT TISSUE IS 10-15% LOWER.

11. 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 **DELTA 15/30** is now ready to begin the treatment.
12. To start treatment and delivery of laser energy, press **STANDBY/READY**, wait for the **DELTA 15/30** to enter READY mode and depress the footswitch. During laser radiation the laser emission indicator will light and an audible warning will be heard.
13. To pause treatment, release the footswitch. To continue treatment, press the footswitch. To end treatment, release the footswitch and return the unit to STANDBY.
14. A summary of laser energy delivered during the current or previous session may be reviewed if required by selecting **Statistics** from the **Main Menu**.
15. To turn the **DELTA 15/30** 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 5 - Technical Information.

INSTALLATION AND SET-UP

Installation of the **DELTA 15/30** can be carried out by the end-user.

Inspection

Inspect the **DELTA 15/30** 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 **DELTA 15/30**.

Check that the following components are included in the packaging:

- **DELTA 15/30** 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 **DELTA15/30**. 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 **DELTA 15/30**. 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 3.28.

The **DELTA 15/30** will operate at voltages between 100 V and 240 V 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 or Spot Handpiece¹ 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 **DELTA 15/30** is now installed and ready for use.

Connecting to the Laser Aperture

Laser energy is delivered to the optical fiber or spot handpiece via the laser aperture located on the front panel of the **DELTA 15/30**. The fiber or handpiece 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).

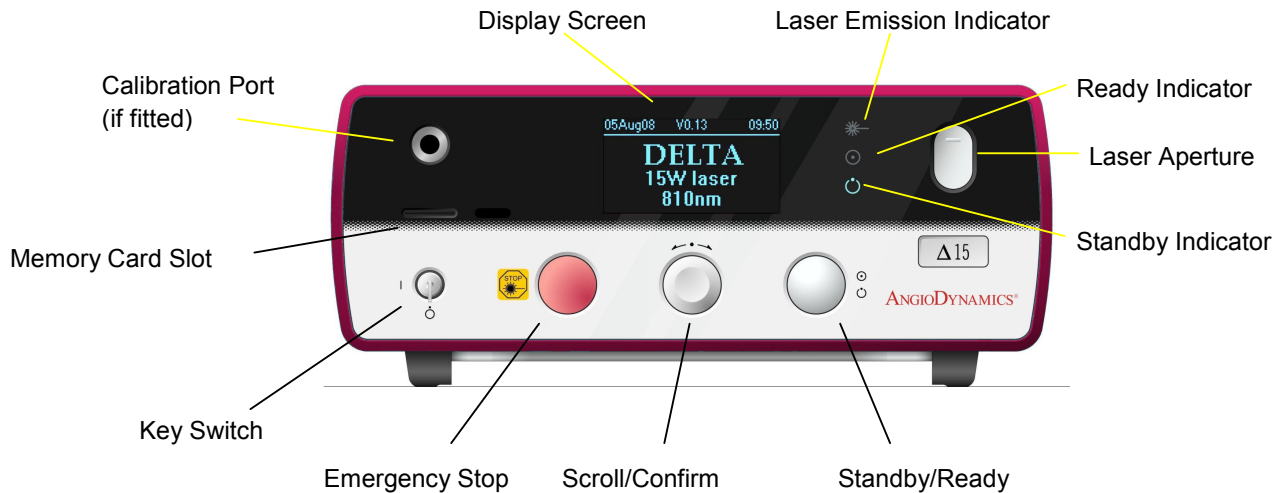


It is essential that the exposed end of the optical fiber be kept clean to prevent damage to the DELTA 15/30 and optical fiber.

To remove the optical fiber connector, turn the gripper anti-clockwise until fully unscrewed and disconnect from the laser aperture. Dispose of the optical fiber according to institution policy. Alternatively, if the optical fiber is permitted for multiple uses, immediately fit a protective cap over the end of the optical fiber to protect the optical surface from contamination.

¹ A Spot Handpiece can only be used with a **DELTA 15/30** laser fitted with an optical power calibration port. The Ø 2mm Spot Handpiece can be used with either laser but the Ø 4mm Spot Handpiece may only be used with the **DELTA 30**.

FRONT PANEL CONTROLS



The main operating controls for the **DELTA 15/30** 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 **DELTA 15/30** 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



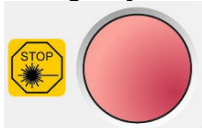
This light will be on when the laser is in READY mode.

Laser Emission Indicator



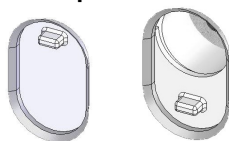
When laser energy is being delivered to the output port, this light will be on.

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

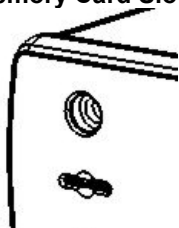


Laser energy is delivered to the optical fiber or handpiece via the laser aperture located on the front panel. The aperture is protected from the ingress of dust etc. by a sliding cover. To gain access to the aperture, slide the cover down using the tab. When the aperture is open, the window beneath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



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

Calibration Port Memory Card Slot

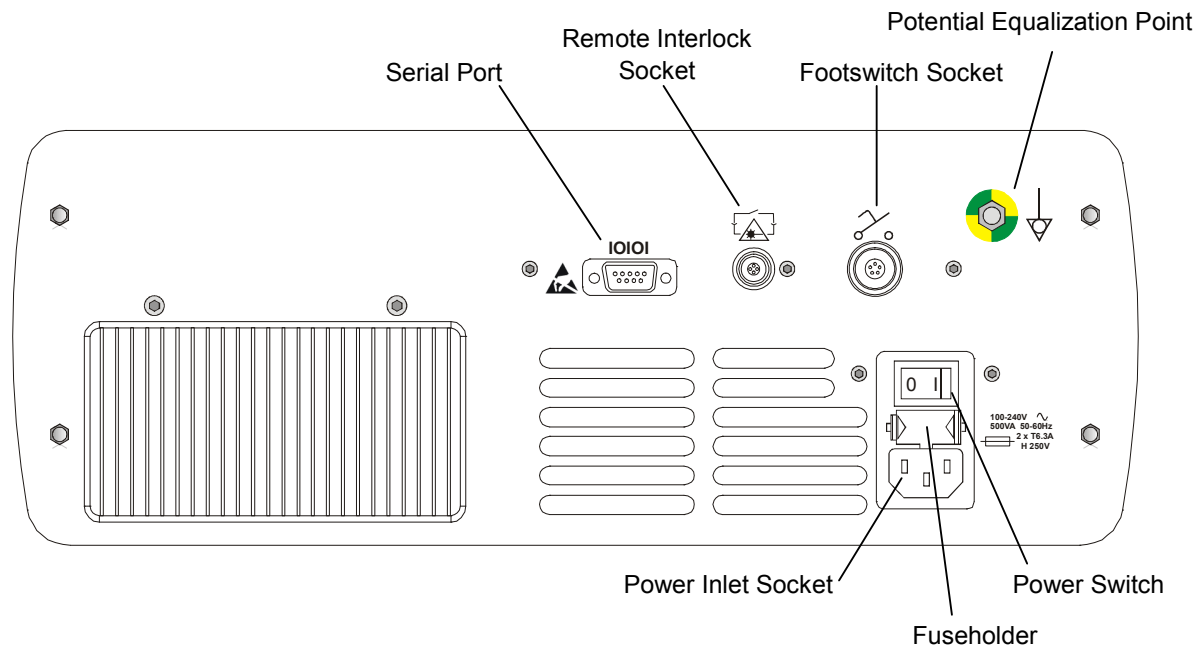


A calibration port is provided on the front panel of some models. This can be used, with the appropriate adaptor, to calibrate a fixed focus spot handpiece or a non-contact optical fiber with a cooling sheath.

The **DELTA 15/30** is compatible with both MultiMedia Card (MMC) and Secure Digital (SD) memory cards. To ensure reliable performance only use cards with the AngioDynamics label. An AngioDynamics memory card available as an accessory (see section 4).

The memory card may be used to transfer data between the **DELTA 15/30** and a PC equipped with a suitable memory card reader interface and the AngioDynamics EVLT-PDM software program. For further details of this software please contact AngioDynamics or your local AngioDynamics representative.

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 **DELTA 15/30** 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 **DELTA 15/30**.



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.

**Fuseholder**

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 **DELTA 15/30** lasers are equipped with the AngioDynamics Fiber Recognition System (FRS). This system provides a means of identifying the fiber that is connected to a **DELTA 15/30**. AngioDynamics fibers are normally supplied in a kit of components for a particular procedure. Therefore, by identifying the fiber, the laser can also tell what procedure is going to be performed. So the **DELTA 15/30** can automatically select suitable preset parameters with the optimum values for that 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 DELTA 15/30 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 **DELTA 15/30** 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 to it. ²
The date when the sterility of the fiber expires	If the current date in the internal clock of the DELTA 15/30 is later than the sterility expiration date, then the fiber is invalid and cannot be used.
How many times the fiber may be safely used	The number of “uses” ³ is decreased each time the system is used with the connected fiber. When the figure reaches zero, the fiber becomes invalid and cannot be used again.

² The system will read the fiber’s data if the power is on and a FRS fiber is connected or if the **DELTA 15/30** is powered up with a FRS fiber already connected.

³ The number of available “uses” is only decreased once per procedure and only after the **DELTA 15/30** has been fired. Subsequent firing of the **DELTA 15/30** during a continuous procedure will not result in the number of available “uses” being further decreased.



What are the benefits of FRS?

- Operation of the **DELTA 15/30** is simplified, because the FRS is able to automatically recognize the attached fiber or Spot Handpiece and load preset parameters that are suitable for the selected procedure.
- 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.
- The number of available “uses”, subject to satisfactory calibration, for Multiple-use and Spot Handpiece fibers is displayed on the screen, giving a clear indication of when a fiber is due for replacement.

In order to obtain full advantage of AngioDynamics FRS you should always use fibers supplied by AngioDynamics. Please contact your AngioDynamics representative for a list of fibers and procedure kits that are compatible with the FRS system.

OPERATING INSTRUCTIONS

Once the **DELTA 15/30** 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 **DELTA 15/30** 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 **DELTA 15/30** 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 **DELTA 15/30** 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 **DELTA 15/30** from being used. Please contact your AngioDynamics representative for further details.

The **DELTA 15/30** should have an annual check of the calibration of the internal power meter (if fitted) and the output power of the laser. If either of these checks is due, a 'spanner' symbol will be displayed on the screen at start-up. This symbol will be removed after the checks are completed.



The **DELTA 15/30** will normally only operate with AngioDynamics FRS fibers. However, if the 'u' symbol shown right is displayed in the bottom left corner of the screen, then other non-FRS fibers may also be used.



The **DELTA 15/30** has an Emergency Override feature that allows a treatment to be continued in the event of a Session Fault (see page 3.24). 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.



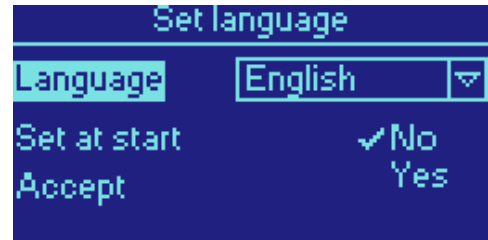
Setting the language at switch-on

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 **DELTA 15/30** is switched on. To prevent this, change the selection to **No** as follows:

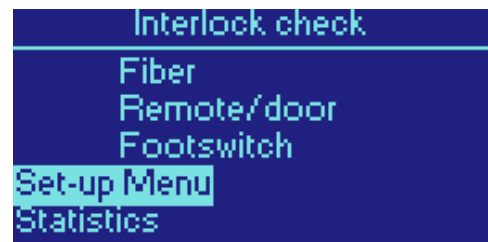
- Turn the **SCROLL** knob until **Set at start** is highlighted.
- Press **CONFIRM** to toggle between **Yes** and **No**.
- Turn the **SCROLL** knob to select **Accept**.
- Press **CONFIRM**.

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

**Interlock Checks**

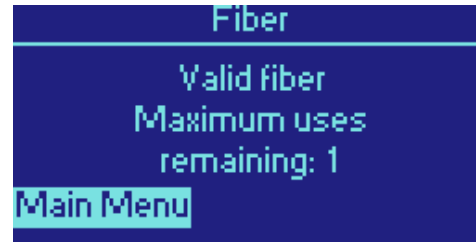
The system will now check that all the safety interlocks are properly in place. If a tick is not shown against one or more of the items in the display, recheck the appropriate connection.

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 **DELTA 15/30** system reads the FRS information stored inside the fiber's gripper. It will check the type of fiber, how many "uses" are available and whether it is within its sterility expiration date.

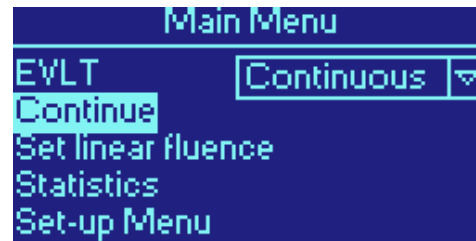


The **DELTA 15/30** will normally only permit a procedure to be carried out if a AngioDynamics FRS fiber is used. An incompatible fiber will be shown on the screen as **Invalid Fiber**.



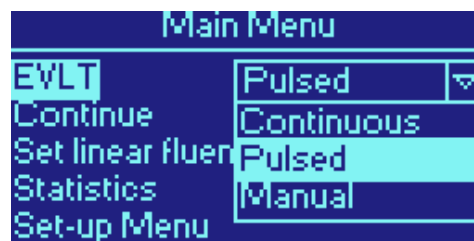
An **Emergency Override** option is included to allow the **DELTA 15/30** to be used once only in the event of a session fault, which has prevented the completion of a treatment. See **Session Fault Emergency Override** below for instructions on how to use this option.

Once the fiber is validated, the **DELTA 15/30** is able to determine which procedures may be performed and can set itself up with the appropriate parameter values for power, pulse duration and interval. Depending on the type of fiber connected, a screen similar to the following will be displayed.



Procedure Selection

In the following example, a fiber from an AngioDynamics EVLT procedure kit has been connected to the laser. The **DELTA 15/30** recognizes this fiber and loads a list of compatible procedures, as shown on the display⁴.



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

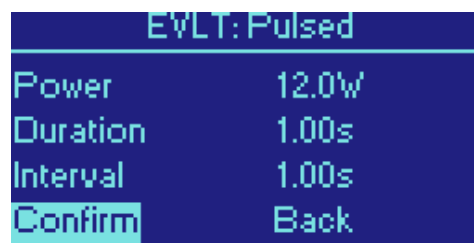
When the procedure has been selected, highlight **Continue** using the **SCROLL** knob and press **CONFIRM**.

Parameter Adjustment

At this point, calibration may be required for certain fibers and procedures. In this case, follow the instructions on page 3.16.

The **DELTA 15/30** will set the default operating parameters for the selected procedure. Some procedures also allow the default parameters to be varied within lower and upper limits, which are defined in the procedure's specification.

To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter (**Power**, **Duration** or **Interval** are all available for the procedure in this example) 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.



When you have completed setting up the operating parameters of the **DELTA 15/30**, 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**.

⁴ The list of procedures shown on this menu will only include those that are installed in the laser. AngioDynamics will, over the lifetime of this system, release new procedures that may be compatible with currently available fibers. Please check with your AngioDynamics representative for the latest information regarding available procedures. Further information on the currently available procedures can be found in section 4.



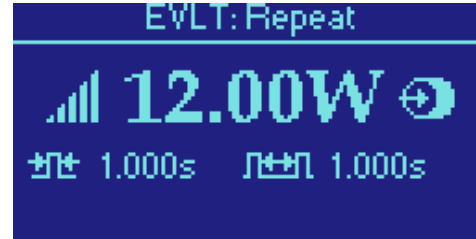
The method of adjusting settings will vary depending on the procedure selected. Please refer to section 4 entitled AngioDynamics Procedures for full details of how to use specific procedures.

Run the Procedure

The **DELTA 15/30** is now ready to start the procedure. Press **STANDBY/READY** and wait for the **DELTA 15/30** 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 **DELTA 15/30** off, turn the key switch anti-clockwise, remove the key and switch off at the rear panel.

Screen Symbols

When the **DELTA 15/30** is in the READY mode the screen may show various symbols. The meanings of which are explained below:



Power output setting



Uncalibrated (displayed power is the power launched into the optical fiber)



Calibrated (displayed power is the power emitted from the optical fiber)



Pulse duration



Pulse interval

Calibration

Calibration is not a requirement for all procedures. However, if necessary, calibration is normally performed after the procedure has been selected. If appropriate, calibration can also be performed by selecting the **Calibration** option in the STANDBY state.

This feature is not available on the **DELTA 15** unless fitted with the optional Optical Power Calibration Port.



This calibration procedure is for 600µm non-contact fibers with a cooling sheath only. **Contact fibers cannot be calibrated.**



Ensure all personnel are wearing approved safety eyewear.

When calibration is carried out, the displayed power will be the power at the distal end of the fiber.

If calibration is **NOT** carried out, the displayed power will be the power at the laser aperture.

Instructions on how to perform the calibration routine are displayed on the screen. Selecting **Cancel** at any time will return the user to the Main Menu leaving the fiber un-calibrated.

1. Screw in the optical fiber calibration port adapter. (The adapter should be sterilized in order to maintain fiber sterility).
2. Guide the fiber into the calibration port using the optical fiber calibration port adapter provided.
3. Place the **DELTA 15/30** in READY mode.
4. Follow the instructions on screen.
5. Fire the **DELTA 15/30** by pressing the footswitch until release is indicated on the display.
6. The screen will display the fiber acceptability and transmission percentage.
7. To proceed, highlight **Continue** and press **SELECT**.

Transmission Acceptability

The **DELTA 15/30** will calculate the percentage transmission of the fiber system, and the results will be shown on screen as **Acceptable** or **Unacceptable**.

- A percentage rating of 75% - 96% indicates that the fiber is **Acceptable**. The power displayed will represent the power output at the distal end of the calibrated fiber and the system will compensate for any fiber transmission losses.
- A percentage rating of 0% - 75% indicates that the fiber is **Unacceptable**. In this case the fiber must be replaced with a new fiber and re-calibrated.

Calibration will be cancelled if:

- The unit is turned off or
- The fiber port interlock is activated (i.e. the user has changed the fiber).

SPOT HANDPIECE MODE

This section includes special instructions to be followed when using a spot handpiece with the **DELTA 15/30**.

Spot Handpiece mode is only available when the **DELTA 15/30** is fitted with a calibration port. This port is optional on the **DELTA 15**.

Fixed Focus Spot Handpiece

The handpiece delivery system consists of a sleeved optical fiber, with an optical fiber connector at one end and a handpiece at the other. The handpiece has a user replaceable protective lens.

A Ø 2mm fixed focus Spot Handpiece is available separately for use with the **DELTA 15/30**. The Ø 2mm fixed focus Spot Handpiece, blue for identification, delivers a 2mm diameter beam of laser energy.



Ø 2mm fixed focus Spot Handpiece



A Ø 4mm fixed focus Spot Handpiece (not illustrated) is available separately for use with the **DELTA 30** only. The Ø 4mm fixed focus Spot Handpiece, yellow for identification, delivers a 4mm diameter beam of laser energy.

New handpieces are supplied with the fiber fitted and with an integrated FRS gripper. If you have an older Spot Handpiece, without a FRS gripper, please contact your local AngioDynamics representative who will be able to supply you with a new fiber.



Great care must be taken in ensuring optical faces are kept clean, particularly at the optical fiber connector end. A protective cap is provided which should be replaced each time the optical fiber end of the fiber is not connected to the Laser aperture.



Before using the handpiece inspect the fiber and connector for signs of damage and check the handpiece to ensure it is clean, correctly assembled and has no signs of damage.

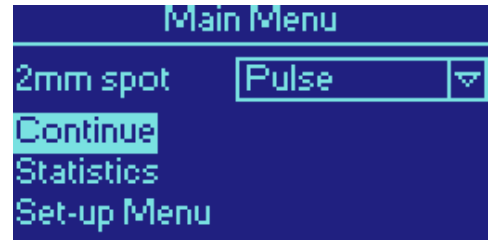
If there is any evidence of handpiece damage or fiber breakage do not use the handpiece as it may cause injury to the operator or patient. Replace the handpiece or fiber immediately. (See fixed focus Spot Handpiece Instructions for Use if the fiber requires changing).



The Ø 2mm fixed focus Spot Handpiece delivers power densities four times greater than the Ø 4mm fixed focus Spot Handpiece at the same power/duration settings.

Handpiece Identification

After it has finished checking the interlocks, the system will read the FRS information stored inside the handpiece's gripper. From this the laser is able to determine whether it is a Ø 2mm or Ø 4mm handpiece. Depending on the type of handpiece connected, a screen similar to the following will be displayed.



If the laser does not detect the presence of a valid FRS Spot Handpiece then it will not permit a procedure to be carried out. Please refer to the Troubleshooting section for help in this situation.

Calibration

Calibration of a Spot Handpiece must be performed either each time the unit is switched ON or each time a new handpiece is connected. This ensures that accurate Fluence is available at the treatment site.



The DELTA 15/30 system will always perform a calibration if the handpiece has not been calibrated.

The Spot Handpiece will require re-calibration if any of the following occur during the treatment session:

- Power failure / unit switched off
- Footswitch disconnected
- Emergency switch pressed
- Handpiece is disconnected
- A new handpiece is used



Ensure all personnel are wearing approved safety glasses.

Ensure that the window cell / treatment window of the handpiece to be calibrated is clean.

Instructions on how to perform the calibration routine are displayed on the screen. Selecting **Cancel** at any time will return the user to the Main Menu leaving the Spot Handpiece un-calibrated.

1. Screw in the Spot Handpiece calibration port adapter.
2. Insert the Spot Handpiece into the calibration port adapter.
3. Ensure that the probe on the Spot Handpiece lines up with the hole on the adapter and is inserted fully into the calibration port.
4. Place the **DELTA 15/30** in READY mode.
5. Follow the instructions on screen.
6. Fire the **DELTA 15/30** by pressing the footswitch until release is indicated on the display.
7. The screen will display the handpiece acceptability and transmission percentage.
8. To proceed, highlight **Continue** and press **CONFIRM**.

Transmission Acceptability

The **DELTA 15/30** will calculate the percentage transmission of the handpiece system, and the results will be shown on screen as **Acceptable** or **Unacceptable**.

Transmission should be 65% or greater. If less than 65% the result will be shown as **Unacceptable** and the handpiece will need cleaning or replacing if damaged (see Fixed Focus Spot Handpiece Instructions for Use supplied with the handpiece).

After carrying out the calibration procedure the **DELTA 15/30** will display that the handpiece has been calibrated.

Fluence

After successful calibration of a Spot Handpiece, the Fluence screen will be displayed.

The Fluence function automatically calculates and displays the laser energy per unit area (J/cm^2) projected onto the patient, using the formula below. If the Duration or Interval values are adjusted, the Power will be automatically re-calculated to obtain the required Fluence.

$$\text{Fluence} = \frac{\text{Power (W)} \times \text{Pulse Duration (s)}}{\pi \times (\text{Spot Radius})^2 \text{ (cm)}}$$

Spot Radius = 0.1 cm (2 mm spot handpiece) or 0.2 cm (4 mm spot handpiece)

Pulse Duration = 50 to 250 ms (2mm spot handpiece) or 50 to 950 ms (4mm spot handpiece) in 10 ms increments.

To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter (**Fluence**, **Duration** or **Interval**) 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.

When you have set up the required value of fluence of the **DELTA 15/30**, turn the **SCROLL** knob to move the highlight to **Confirm** and press **CONFIRM**.

The **DELTA 15/30** is now ready to start the procedure. Press **STANDBY/READY** and wait for the **DELTA 15/30** 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 **DELTA 15/30** off, turn the key switch anti-clockwise, remove the key and switch off at the rear panel.

MANUAL SETTINGS

AngioDynamics supplies a general purpose bare-ended fiber fitted with FRS, that enables the **DELTA 15/30** to use Manual settings. Some other AngioDynamics FRS fibers also allow limited free setting of parameters, by selecting **Manual** from the **Procedure** menu. See section 4 of this operator manual for information about which fibers allow manual settings.

The **DELTA 15/30** will normally only operate with AngioDynamics FRS fibers. However, if the 'u' symbol shown right is displayed in the bottom left corner of the screen, then other non-FRS fibers may also be used.



Please contact your AngioDynamics representative for further details of this feature.

For best results always use the **DELTA 15/30** with an AngioDynamics FRS fiber. This will be detected by the laser, which will automatically select suitable preset parameters.

Please consult with your AngioDynamics representative if you require assistance with setting up your laser.



AngioDynamics do not recommend the use of third party fibers as their quality and efficacy cannot be guaranteed. Any damage caused to your **DELTA 15/30** by using a fiber not supplied by AngioDynamics may not be covered under the AngioDynamics warranty.



If an AngioDynamics FRS fiber is detected but no compatible procedure is installed, please contact your local AngioDynamics representative who will advise on how you can update the procedures installed in your **DELTA 15/30**.

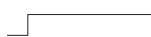
Parameters

Table 1.

The following parameters may be adjusted manually.

Mode

The available modes are:

 Continuous (not with a Spot Handpiece)

 Pulse

 Repeat Pulse

Power (W)

Power may be adjusted in all operating modes:



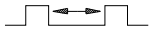
0.5W to maximum W in 0.5W increments

Pulse Duration (s) The pulse duration may be adjusted in Pulse and Repeat pulse modes:



0.1 to 9.9 seconds in 0.1 second increments

Interval (s) The interval between the pulses may be adjusted only in the Repeat pulse mode:



0.1 to 1.0 seconds in 0.1 second increments

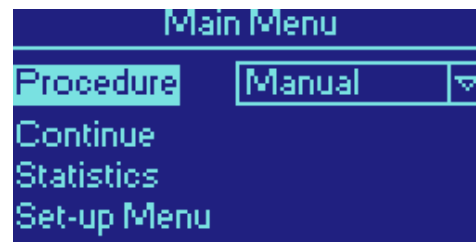
Table 2. The default parameters for each available mode are:

Mode	Power	Pulse Duration	Pulse Interval
Continuous	5 W	Not available	Not available
Pulse	5 W	1 sec	Not available
Repeat Pulse	5 W	1 sec	1 sec

Selecting Manual Operation

Manual operation allows the operator complete freedom over the settings of the **DELTA 15/30** and is enabled by selecting **Manual** from the **Procedure** menu.

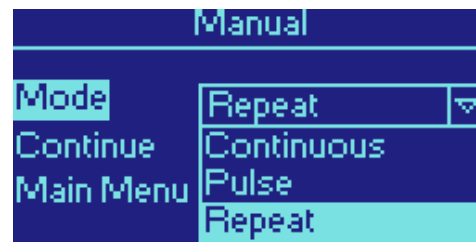
Next, highlight **Continue** using the **SCROLL** knob and press **CONFIRM**.



Setting the Mode

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

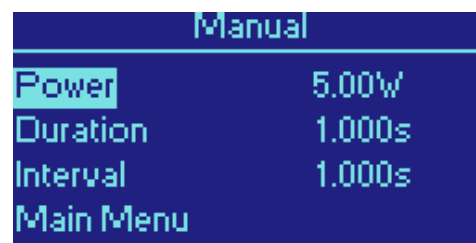
When the mode has been selected, highlight **Continue** using the **SCROLL** knob and press **CONFIRM**.



Setting Power, Pulse Duration and Interval

Depending on the Mode selected, the next screen will show a set of default parameters, as described in table 2 above. To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter and press **CONFIRM**. The highlight will now move to the value on the right hand side of the display. Turn the **SCROLL** knob to adjust the value within the range shown in table 1 and press **CONFIRM**. The highlight will move back to the left hand side of the display. Repeat this process for the other parameters as required.

When you have completed setting up the operating parameters, turn the **SCROLL** knob to highlight **Continue** and press **CONFIRM**.





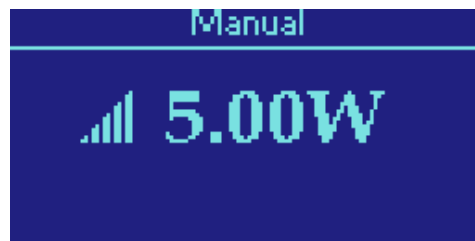
When the operating Mode is **Continuous**, the **Pulse & Interval** parameters are not applicable and cannot be adjusted.
Similarly in **Pulse** mode, the **Interval** parameter cannot be adjusted.

Start the Procedure

The **DELTA 15/30** is now ready to start the procedure.
Press **STANDBY/READY** and wait for the **DELTA 15/30** 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 **DELTA 15/30** off, turn the key switch anti-clockwise, remove the key and switch off at the rear panel.

Countdown Timer

Countdown mode is enabled by selecting the **Countdown** procedure when **Manual** operation is enabled. This mode allows longer CW exposure times than the maximum 9.9 seconds available when using the Pulse mode.

The default time is 20 seconds but the time can be set to any value from 10 to 3200 in 10 second increments.

When the Countdown is active and the footswitch is pressed to start treatment, the display will show a progress bar and count down until zero is reached or the footswitch is released. To restart the countdown after the footswitch has been released press the footswitch and the countdown will resume.

The countdown time cannot be adjusted after the footswitch has been pressed unless the user returns to the Manual control menu, or the countdown time has been completed.

EMERGENCY OVERRIDE

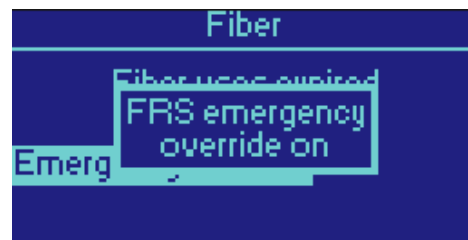
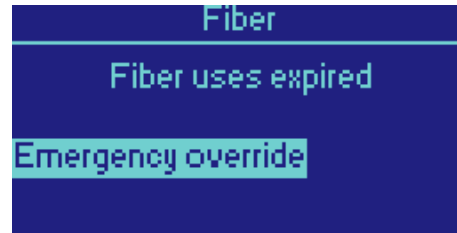
In certain circumstances, such as a technical problem or if the Emergency Stop button is pressed, the fiber in use may become invalid before the completion of the treatment. If this situation should occur, the Emergency Override may be activated to allow treatment to continue. This option is only available 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 **DELTA 15/30** 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 **DELTA 15/30**. 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 **DELTA 15/30** will detect the device and 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 **DELTA 15/30**.

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 **DELTA 15/30** 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

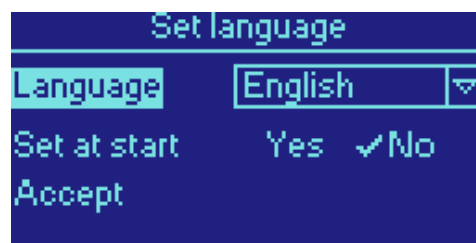
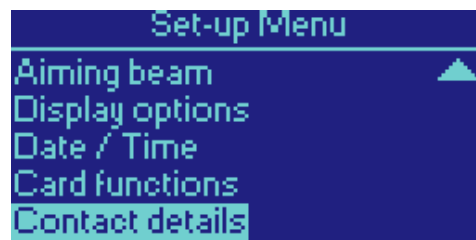
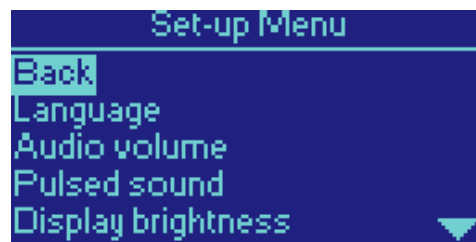
To change the language used for the user interface, turn the **SCROLL** knob to highlight **Language** and press **CONFIRM**. Now use the **SCROLL** knob to select the required language from the drop down list and press **CONFIRM**.

When **Set at start** is set to **Yes**, this language selection screen will occur every time that the **DELTA 15/30** 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.

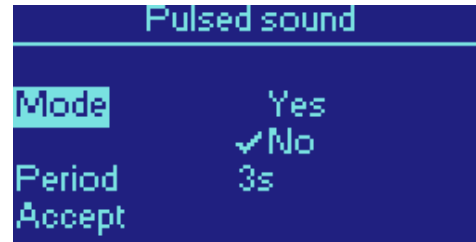
If the volume is set to 0% the audible indicator is switched off. In this case the visible laser emission indicator is the sole indication of laser activity.



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

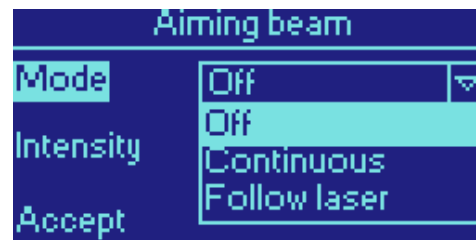
To adjust the brightness of the display, turn the **SCROLL** knob to highlight **Adjust** and press **CONFIRM**. Now use the **SCROLL** knob to select the required brightness. Press **CONFIRM** when finished.



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.



If using the laser in non-contact mode, it is advisable to have the aiming beam switched on to identify the target tissue that will be affected by the laser energy.



To observe the different modes of the aiming beam, place the **DELTA 15/30** 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.



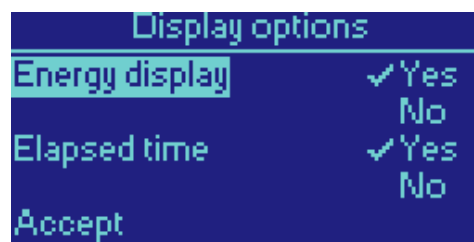
The intensity adjustment will be ignored if the aiming mode is **Off**.



To observe the intensity of the aiming beam, place the **DELTA 15/30** 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 **Yes** and **No**.

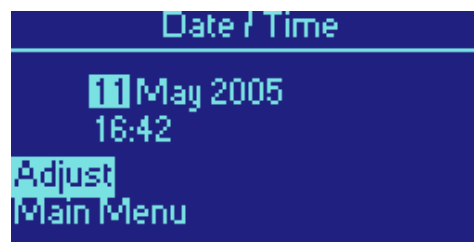


When Energy Display is enabled, the delivered energy will be displayed in the bottom left hand corner of the display when the **DELTA 15/30** is in READY mode. Similarly the Elapsed Time, when enabled, will be shown in the bottom right hand corner.

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 **DELTA 15/30** 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.

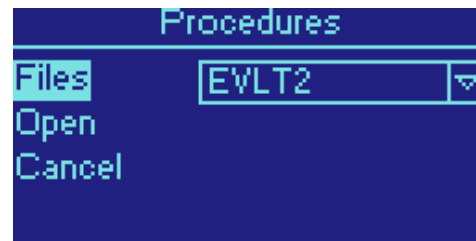
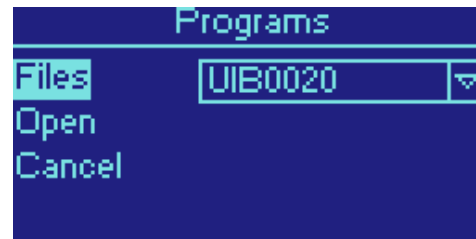
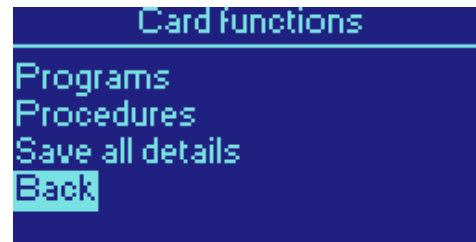
Similarly, the **Procedures** option allows new procedures to be loaded from the memory card into the laser.

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 **DELTA 15/30**, to the memory card. The card can then be removed from the **DELTA 15/30**, 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 **DELTA 15/30** 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 **DELTA 15/30** can display the statistics of the Setups for the current and previous Treatments.

A new Treatment is started when the **DELTA 15/30** is switched on, when the fiber is changed or when **New treatment** is selected on the **Statistics** menu.



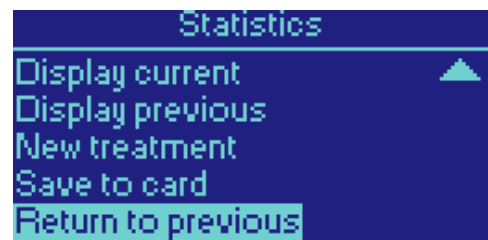
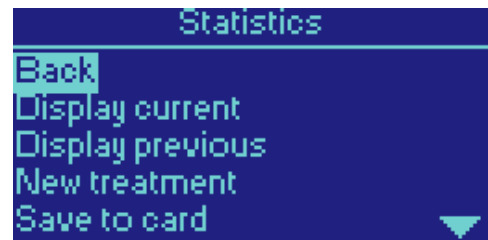
The **DELTA 15/30** can store details of approximately 100 Treatments in its internal memory. When this memory is full then the earliest Treatment Statistics will be erased to make room for new details.



To minimize the risk of error, it is advisable to transfer Treatment Statistics from the **DELTA 15/30** to a PC immediately after the procedure has been completed.

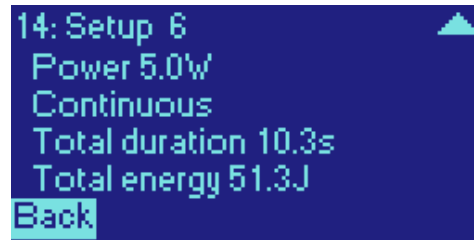
The **Statistics** menu enables the operator to view the statistics from the current or previous Treatments. To access this menu turn the **SCROLL** knob until **Statistics** is highlighted in the **Main Menu** and then press **CONFIRM**.

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.

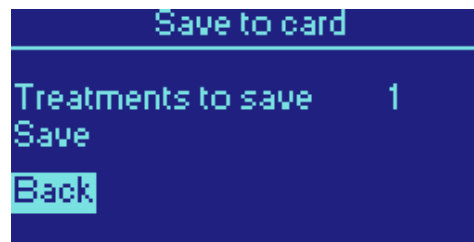
To view the statistics of the previous treatment, select **Display previous**.



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 PROCEDURES

The **DELTA 15/30** lasers are optimized to operate with AngioDynamics fibers and procedure kits that are equipped with the AngioDynamics Fiber Recognition System (FRS). For a full description of this system please see section 3 of this manual.

This section describes the FRS fibers, procedure kits and other accessories that are currently available from your AngioDynamics representative.

AngioDynamics's policy of continual product development and improvement means that fibers and procedure kits may be added to the product range at any time. Therefore the information in this section may change without notice. Please contact your AngioDynamics representative to obtain the latest product information.

CONTENTS

AngioDynamics Fibers and Procedures	4.2
Ordering Information	4.3
EVLT™ Procedures	4.4
PVAK Procedures	4.6
Linear Fluence	4.8
Spot Handpieces.....	4.9
Bare-ended Fiber	4.9
Test Fiber	4.9
Emergency Override Reset Device	4.9

ANGIODYNAMICS FIBERS AND PROCEDURES

When an AngioDynamics fiber fitted with FRS is connected to a **DELTA 15/30** laser, the laser will attempt to recognize the type of fiber from the information stored in the FRS gripper. If successful, it will cross-reference the type of fiber with an internal database of compatible procedures. Any procedures that are compatible with the connected fiber are listed in the Procedure menu and may be selected by the operator.

There are two types of AngioDynamics FRS procedure:

Preset Procedures

Preset procedures have default laser settings which are set to the optimum values for the chosen procedure. These defaults can be adjusted within a set range during the treatment but cannot be changed and retained for future use. Each time the laser is turned on, they revert to their default values. These procedures include the 'Continuous' and 'Pulsed' types used with EVLT™ and PVAK fiber kits.

Manual Procedures

Manual procedures allow laser settings to be adjusted over a wider range compared to a Preset procedure. Also, the settings used for a treatment are retained in the **DELTA 15/30** and restored the next time that the procedure is selected.

Note that the new values are only stored in the memory of the **DELTA 15/30** when the laser is put into the READY mode.

From time to time, AngioDynamics will release new fibers and procedure kits. In order to use these, your **DELTA 15/30** will need to be updated with the latest procedure information.

ORDERING INFORMATION

AngioDynamics has a policy of continual product development and improvement. Therefore the following information may change without notice. Please contact your AngioDynamics representative to obtain the latest product information.

Procedure Kits

AngioDynamics supplies a wide range of procedure kits, which contain all the items necessary to confidently and safely perform a procedure. To obtain information about the availability of procedure kits that are suitable for your application, please contact your AngioDynamics representative.

Accessories

The codes in the following table should be quoted when ordering accessories for your **DELTA 15/30**.

Description	AngioDynamics part number
2mm Spot Handpiece	2mmSHP
4mm Spot Handpiece	4mmSHP
2mm Spot Handpiece replacement fiber only	AS/0618
4mm Spot Handpiece replacement fiber only	AS/0619
EVLT™ Test fiber	AS/0604
Manual Test fiber	AS/0695
Emergency Override Reset Device	AS/0598
Spot Handpiece calibration port adapter	PP/0488
Optical Fiber calibration port adapter	PP/0286
Laser safety glasses	SE/0004
Laser warning sign	PP/1496
AngioDynamics Patient Data Management software	EVLT-PDM
Memory Card	S10/06/0086
USB Memory Card Reader/Writer	S10/06/0087

EVLTM PROCEDURES

There are three procedures that are compatible with the EVLTTM procedure kit. Two of these are designed to cover the currently-approved methods for performing an EVLTTM procedure. The third is intended to allow the operator some freedom in setting parameters manually.

Note: If the **DELTA 15/30** laser is enabled for full Manual operation, then it may also be configured for any parameters within its design specifications.

EVLTM Continuous

The laser output power is preset to 14 W continuous and may be adjusted between 9 W and 15 W. Any changes to the procedure settings are not retained in the **DELTA 15/30**.

EVLTM Pulsed

The laser output power is preset to 12 W in repeat pulse mode, with a 1 second pulse duration and 1 second interval. The power may be adjusted between 9 W and 15 W and the pulse duration and interval between 0.5 and 2 seconds.




Any changes to the procedure settings are not retained in the **DELTA 15/30**.

EVLTM Manual

The laser output power may be varied between 5 W and 15 W. The mode may be switched between continuous and pulsed output. The pulse duration and interval can each be adjusted between 0.1 and 2 seconds.

Also, the settings used for a treatment are retained in the **DELTA 15/30** and restored the next time that the EVLTTM Manual procedure is selected.

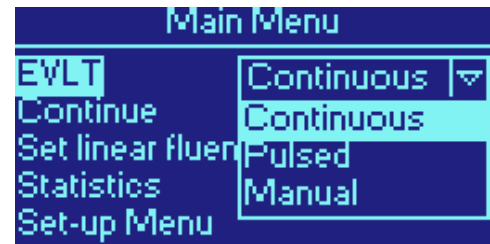
These three procedures are summarized in the following table:

	EVLTM Continuous	EVLTM Pulsed	EVLTM Manual
Mode(s)	Continuous	Repeat Pulse	Continuous or Repeat Pulse
Power (W) 	14W (9 W to 15 W)	12 W (9 W to 15 W)	5 W to 15 W
Pulse Duration (s) 	Not available	1 s (0.5 s to 2 s)	0.1 s to 2 s
Interval (s) 	Not available	1 s (0.5 s to 2 s)	0.1 s to 2 s

Selecting the Procedure

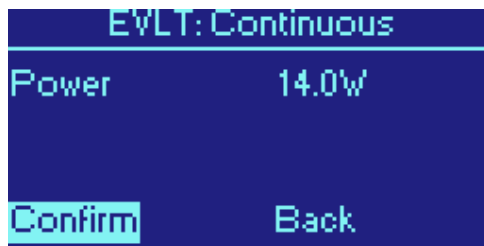
For full instructions on operating the **DELTA 15/30** laser, please refer to section 3 of the operator manual. The following assumes that the system has been correctly set up, switched on and with an EVLT™ fiber connected.

When the fiber has been validated by the FRS system, the **DELTA 15/30** is able to determine which procedures should be available for selection by the operator. The default procedure is shown at the top of the menu. To select a different procedure turn the **SCROLL** knob until **EVLT** is highlighted and press **CONFIRM**. Select the desired procedure with the **SCROLL** knob and press **CONFIRM** again.

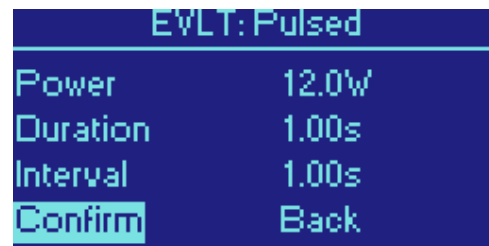


Depending on the procedure selected, the next screen will display the parameters that are preset for the EVLT™ procedure. Adjustments can be made using the **SCROLL** and **CONFIRM** controls.

EVLT™ Continuous

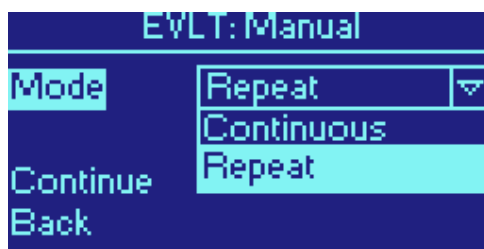


EVLT™ Pulsed

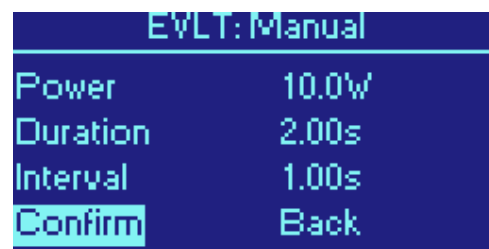


If the EVLT™ Manual procedure is selected, there is an intermediate screen, where the mode of operation can be chosen:

EVLT™ Manual (Mode selection)



EVLT™ Manual



PVAK PROCEDURES

There are three procedures that are compatible with the EVLT™ Perforator Vein Ablation Kit (PVAK) procedure kit. Two of these are designed to provide default settings for cover the currently-approved methods for performing an EVLT™ PVAK procedure. The third is intended to allow the operator more freedom in setting parameters manually.

Note: If the PVAK procedures are not available when the **DELTA 15/30** is used with a PVAK procedure kit for the first time, they may need to be installed. An upgrade pack is available from AngioDynamics for this purpose. Please contact your AngioDynamics representative.

PVAK Pulse

The laser output power is preset to 14 W with a single pulse of 5 seconds duration
The power may be adjusted between 9W and 15W and the pulse duration between 0.5 and 5 seconds.
Any changes to the procedure settings are not retained in the **DELTA 15/30**.



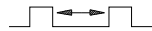
PVAK Continuous

The laser output power is preset to 14 W continuous and may be adjusted between 9W and 15W.
Any changes to the procedure settings are not retained in the **DELTA 15/30**.

PVAK Manual

The laser output power may be varied between 5 W and 15 W. The mode may be switched between continuous, pulse and repeat pulse output. The pulse duration and interval can each be adjusted between 0.1 and 5 seconds.
Also, the settings used for a treatment are retained in the **DELTA 15/30** and restored the next time that the PVAK Manual procedure is selected.

These three procedures are summarized in the following table:

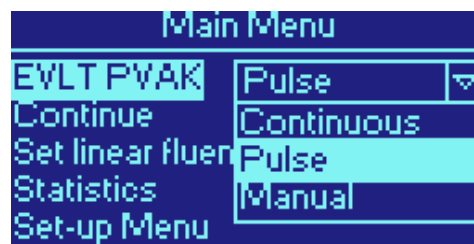
	PVAK Pulse	PVAK Continuous	PVAK Manual
Mode(s)	Pulse	Continuous	Continuous, Pulsed or Repeat Pulse
Power (W) 	14 W (9W to 15W)	14 W (9W to 15W)	5 W to 15 W
Pulse Duration (s) 	5 s (0.5 s to 5 s)	Not available	0.1 s to 5 s
Interval (s) 	Not available	Not available	0.1 s to 5 s

Selecting the Procedure

For full instructions on operating the **DELTA 15/30** laser, please refer to section 3 of the operator manual. The following assumes that the system has been correctly set up, switched on and with a PVAK fiber connected.

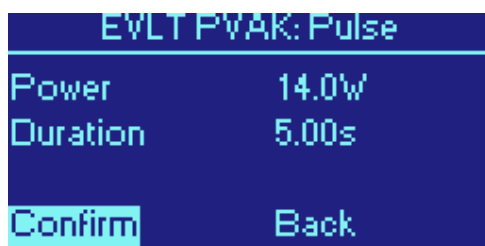
When the fiber has been validated by the FRS system, the **DELTA 15/30** is able to determine which procedures should be available for selection by the operator.

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

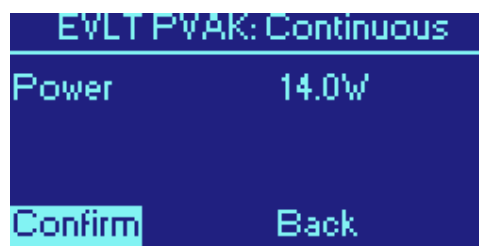


Depending on the procedure selected, the next screen will display the parameters that are preset for the PVAK procedure. Adjustments can be made using the **SCROLL** and **CONFIRM** controls.

PVAK Pulse

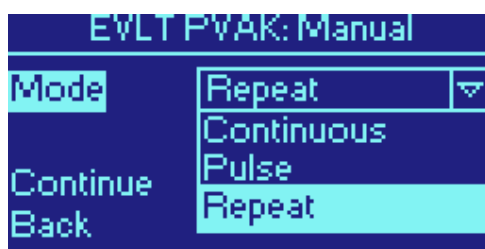


PVAK Continuous

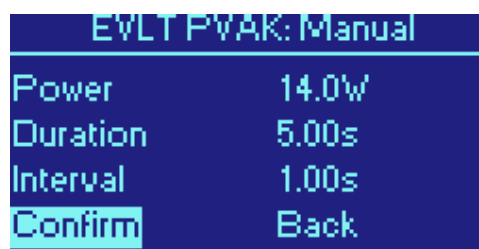


If the PVAK Manual procedure is selected, there is an intermediate screen, where the mode of operation can be chosen:

PVAK Manual (Mode selection)



PVAK Manual



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 of the **DELTA 15/30** and does not alter the actual operation of the laser or the way that statistics are recorded.

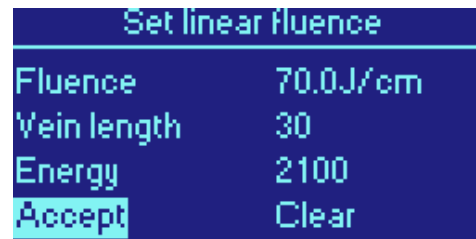
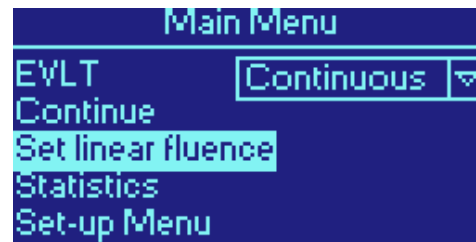
The linear fluence function requires the operator to enter the required linear fluence and length of vein into the **DELTA 15/30** before commencing a procedure. The total energy for the procedure is then automatically calculated.

This function is only available when the **DELTA 15/30** is used with compatible procedures, such as Venacure EVLT™ and PVAK described above.

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 **DELTA 15/30** will continue firing until the footswitch is released.



SPOT HANDPIECES

When an AngioDynamics spot handpiece is connected to the **DELTA 15/30**, FRS will recognize the type of handpiece and automatically displays suitable preset parameters. Follow the operating instructions in section 3.

BARE-ENDED FIBER

When an AngioDynamics bare-ended fiber is connected to the **DELTA 15/30**, FRS will recognize the type of fiber and automatically select the manual mode for the laser. Follow the operating instructions in section 3.

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 **DELTA 15/30** by using a fiber not supplied by AngioDynamics may not be covered under the AngioDynamics warranty.

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SECTION 5 TECHNICAL INFORMATION

This section includes technical data and describes the routine maintenance procedures that you can perform on the **DELTA 15/30** and its accessories.

The **DELTA 15/30** has been designed to operate reliably with minimal maintenance. There are no user-serviceable parts in the **DELTA 15/30**. Always disconnect the **DELTA 15/30** 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.

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SPECIFICATIONS

	DELTA 15	DELTA 30	
Laser Type	Diode laser, CW		
Centre wavelength	810 nm		
Spectral bandwidth	90% of optical power contained within 810 ± 20 nm		
Delivery fiber	Minimum 400 µm diameter, 0.37 Numerical Aperture (NA)		
Fiber connector	Optical SMA-905 to MIL STD		
Maximum Power	15 W to the laser output port	30 W to the laser output port	
Minimum Power	1.0 W to the laser output port		
Set power accuracy	Better than ± 10% of displayed power		
Output power stability	± 5% maximum		
Aiming beam	Red Class 3R diode laser, ≤ 5 mW at port, wavelength 635-660 nm		
Pulse duration	100 ms – 9900 ms		
	Continuous Wave (CW)		
Pulse Interval	100 ms – 1000 ms		
Countdown timer	10 – 3200 seconds		
Fibers	Contact fibers, 400µm, 600µm and 1000µm		
	Non-contact fibers, 600µm & 1000µm		
Calibration	Internal power calibration meter for handpiece or fiber calibration (Optional on DELTA 15)		
Spot Handpiece Mode	Spot handpiece mode is available on the DELTA 30 and on the DELTA 15 when fitted with the optional calibration meter		
Spot size	Ø 2mm	Ø 2mm	Ø 4mm
Single/Repeat Pulse	50ms – 250ms	50ms – 250ms	50ms – 950ms
Pulse Interval	100ms – 1000ms	100ms – 1000ms	100ms – 1000ms
Fluence	Up to 119J/cm ²	Up to 119J/cm ²	Up to 226J/cm ²
Fiber Recognition System (FRS)			
Operating Frequency	125 kHz ± 1 kHz		
Operating Range	Maximum of 40 mm (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 – 240 V AC, 50 – 60 Hz, 500 VA max.		
Dimensions (H x W x D)	150 x 370 x 325 mm (± 5 mm) (5.9" x 14.6" x 12.8" (± 0.2"))		
Weight	12 kg max. (26.4 lb)		
Operating Temperature	10°C to 40°C (50°F to 104°F)	Up to 15W CW 10°C to 40°C (50°F to 104°F)	
		Over 15W CW 10°C to 30°C (50°F to 86°F)	
Operating Humidity	Up to 75% relative humidity, non-condensing		
Operating Pressure	Normal atmospheric pressure		
Storage Temperature	0°C to 55°C (32°F to 130°F)		
Storage Humidity	Up to 90% relative humidity, including condensing		
Storage Pressure	500 hPa to 1014 hPa		
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 **DELTA 15/30** 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 fiber tip protector in place during the uncoiling and connection process.

To verify the integrity of the fiber, check the fiber for any breaks by overall visual inspection. For non-contact fibers, 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.

Delivery Fiber Calibration

Non-contact fibers with a cooling sheath can be calibrated using the calibration procedure described in Section 3 – Operating Instructions. **Contact laser fibers do NOT require calibration.**

Cooling for reusable tip contact and non-contact fibers with gas/fluid cooling

Fibers with gas/fluid cooling have a protective catheter with the distal tip secured in a metal ferrule. Fibers with reusable contact tips have threaded ferrules for contact tip connection. On this type of fiber, gas, air or distilled water is introduced near the proximal end through an auxiliary line that has a luer lock connection. The purpose of the cooling is to keep the distal end of fibers clean and cool during use. Gas, air or fluid supply is not provided with the laser system. Typical flow rates for the gas and air are from 0.2 to 1.5 l/min with minimum pressure of 50-60 psi and for the fluid cooling from 2 to 20 ml/min.

Application to tissue

When using a conical tip contact fiber, all of the energy is being delivered out of the tip. There is a minimal tissue effect with the side of the tip. The best results will be obtained when holding the tip of the fiber perpendicular to the tissue and applying extremely light pressure with the tip. Hemostasis occurs as the tissue is incised. The orb tip contact fiber is also used for cutting tissue. The laser energy is displaced outwards from the side of the fiber, providing the added advantage of coagulating larger tissue surfaces. Both styles of tips work best when applied lightly to the surface and not buried in the tissue. Cross traction on tissue increases laser effect and extends life of fiber tip.

TROUBLESHOOTING**Error Messages**

The **DELTA 15/30** 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 or	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.
59	Checksum error	
70	Power at calibration port	Power has been detected at the calibration port when not calibrating. Do not insert fibers into this port unless performing a calibration.
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	All the available uses of the connected fiber have expired. Replace the fiber with a fiber that has uses remaining.
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 DELTA 15/30 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 **DELTA 15/30**. This will cause the unit to try and read the fiber's data again.
- (2) Switch the **DELTA 15/30** off and on at the power inlet.
- (3) Ensure that the **DELTA 15/30** 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.

I need to use a non-FRS system fiber

The **DELTA 15/30** will normally only operate with AngioDynamics FRS fibers. However, if the 'u' symbol shown right is displayed in the bottom left corner of the screen, then other non-FRS fibers may also be used. Please contact your AngioDynamics representative for further details of this feature.



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 **DELTA 15/30** is set correctly. The procedure for setting the clock is described in Section 3 - Operator Instructions.

ACCESSORIES**Optical Fibers**

The **DELTA 15/30** 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 **DELTA 15/30** can be obtained from your AngioDynamics representative.

STERILIZATION OF OPTICAL FIBERS**Intra-operative cleaning****Fiber Disposal**

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 LABELLED OR ANGIODYNAMICS APPROVED FIBERS.

Failure to observe this could invalidate the Laser Warranty.

If the tip accumulates debris, turn the laser to the STANDBY mode and then carefully wipe the tip clean with a wet sponge/swab.

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

**Calibration Port Adapter****Steam Sterilization**

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.

The optical fiber calibration port adapter provided should be sterilized and used to locate the fiber in the calibration port.

The calibration port adapter should be sterilized before use in accordance with ISO 11134 1994 'Sterilization of Healthcare Products, Requirement for Validation and Routine Control, Industrial Moist Heat Sterilization.

A validated cycle of $\geq 134^{\circ}\text{C}$ (273°F) for ≥ 3 minutes sterilizing time should be used to give a sterility Quality Assurance of 10^6 .

SURGICAL HANDPIECES

Surgical handpieces with either rigid or malleable cannulae can be obtained from your AngioDynamics representative. These are available in a range of lengths and internal /external diameters.

A full description and list of handpieces is available from your local AngioDynamics representative.

Guidelines

If the requirement is to use a fiber with a separate handpiece, the following guidelines must be followed:

1. Remove the fiber from the sterile packaging in accordance with the fiber instructions.
2. Ensure that the handpiece is sterile, loosen the locking nut at the rear of the handpiece.



To prevent any premature damage to the fiber when using malleable handpieces, ensure that the malleable part on the handpiece has been straightened before inserting the fiber. Only shape the handpiece after the fiber has been inserted.

	<ol style="list-style-type: none"> 3. Insert the fiber down the handpiece from the rear until the fiber 'tip' protrudes approximately 10mm from the distal end of the handpiece. 4. Tighten the lock nut at the rear of the handpiece finger tight. 5. The fiber is now ready for use.
Cleaning and Sterilization	After use, remove the fiber from the handpiece, wipe down the outside of the handpiece with alcohol. Insert a syringe full of water into the rear of the handpiece and depress the plunger to flush out any remaining debris. The handpiece can now be sterilized using a validated steam sterilization cycle.
Steam Sterilization	Reusable handpieces should be sterilized before use in accordance with ISO 11134 1994 'Sterilization of Healthcare Products, Requirement for Validation and Routine Control, Industrial Moist Heat Sterilization. A validated cycle of $\geq 134^{\circ}\text{C}$ (273°F) for ≥ 3 minutes sterilizing time should be used to give a sterility Quality Assurance of 10^6 .

FIXED FOCUS SPOT HANDPIECE MAINTENANCE

For information on the care and maintenance of the Fixed Focus Spot Handpieces, see the Instructions for Use supplied with each handpiece.

FUSE REPLACEMENT

Spare power fuses are supplied with the **DELTA 15/30**. Further spares can be obtained from AngioDynamics. They can be replaced as follows:

1. Disconnect the **DELTA 15/30** 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 its life the **DELTA 15/30** 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 **DELTA 15/30**. As a registered owner you will be notified of these when they become available.

SERVICING

The **DELTA 15/30** does not require regular servicing or maintenance, with the exception of annual checks of the calibration of the internal power meter (if fitted) and the output power of the laser. If either of these checks is due, a 'spanner' symbol will be displayed on the screen at start-up. This symbol will be removed after the checks have been completed.



CALIBRATION

Checking the Calibration of the Internal Power Meter

The LASER SAFETY OFFICER or suitably trained service personnel should check the calibration of the internal power meter of the **DELTA 15/30** at least annually from the date of installation, by following the procedure described below.

Equipment Required

- AngioDynamics test fiber (AS/0695)
- JIG/87 calibration port adapter
- A sampling power meter or an independent energy (integrated power) meter of known calibration

Procedure

Screw the calibration port adapter into the port.

Attach the fiber to the adapter.

From the Main menu, select the Manual procedure, then select Calibration and follow the instructions on the display.

After the calibration process has finished the display will show a figure for fiber transmission.

Remove the fiber and adapter from the calibration port and connect to the power meter.

Select the Manual procedure and set the laser for continuous operation at the maximum power available.

Put the laser into ready mode and fire. Allow up to 30 seconds for the power meter display to stabilize.

Record the power shown on the laser and that displayed on the meter.

If the difference between these two measurements exceeds $\pm 10\%$ contact AngioDynamics.

Calibrating the Internal Power Meter

Calibration of the internal power meter 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.

Calibrating the Internal Power Meter**THE FOLLOWING INFORMATION IS PROVIDED FOR REGULATORY PURPOSES**

INCORRECT CALIBRATION MAY CAUSE INJURY DURING TREATMENT. THE ENGINEERS INTERFACE MAY BY-PASS MANY OF THE NORMAL SAFETY SYSTEMS.



DO NOT attempt the following procedures unless specifically authorized to do so by AngioDynamics. Such action may cause exposure to hazardous laser radiation and a risk of electrical shock. It may also result in damage to the instrument and invalidate warranty cover. ONLY TRAINED LASER SERVICE PERSONNEL AUTHORIZED BY ANGIODYNAMICS SHOULD PERFORM SERVICE AND MAINTENANCE. AngioDynamics will not accept liability for the use of this equipment when calibrated by unauthorized personnel.

Calibrating the internal power meter

To ensure accurate calibration of the delivery fiber, the internal power meter should be checked at least annually and re-calibrated if necessary. This section describes the procedure undertaken to re-calibrate the internal power meter.

Equipment required

- AngioDynamics Engineer Interface software.
- Traceable power meter capable of recording a 10W, one second pulse of 810nm Infra Red laser light.
- 600µm reference fiber.

Procedure

The calibration of the internal power meter is controlled by two electronically controlled potentiometers (EPOTs). These need to be set to scale the output of the power meter correctly. These are normally adjusted for gain and settling time using a production jig. Only the facility to adjust the gain is used here.

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.

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.

Connect the fiber to the calibration port using a suitable adapter. In the engineer interface, open the 'Non-volatile details' tab. Note down pot settings 1 and 2 from the Calibration Port group. Set the laser to continuous mode, 10W and put the laser into the ready state.

In the engineer interface, select `Tests/ Read radiometer ADC`. A dialog box is shown, headed 'Reading radiometer' Fire the laser for not more than 10s. The ADC readings are shown in the dialog. Note down the second

ADC reading. This does not have to be very accurate – we are just scaling the radiometer output to fit in the ADC range. Put the value in the table below.

Pot 1 setting	Pot 2 setting	Stage 2 ADC reading

Change the value of the Pot 1 setting to scale the stage 2 ADC reading to around 700. This is done by closing the 'Reading radiometer' window, altering the setting for pot 1, and clicking on the 'Update' button. Now repeat the sequence, recording the new settings and ADC reading in the table. Repeat until the ADC reading is between 650 and 750 counts.

Close the 'Reading radiometer' window and put the laser into the standby state.

The radiometer amplifier circuit should now be scaled correctly. The next step is to calibrate the radiometer, using calibration points for 1W and 10W, which are stored in the on-board EEPROM. This step will require the calibrated power meter.

With the laser in the standby state, select `Set up/ Set up radiometer` from the engineer interface menu. The following prompt should be displayed: 'Put fiber in external meter and fire laser. Adjust power and press control when set'. Set the power to 10W and fire the laser into the meter. When the power reading has settled make adjustments using the rotary control until the power displayed is exactly 10W.

When the power setting is achieved, release the footswitch and press the rotary control. The following prompt should be displayed: 'Put fiber in internal meter and fire laser until cal pulse stops.'

Attach the fiber to the calibration port, put the laser into the ready state and fire until the laser stops (allow about 8s). Release the footswitch.

The following prompt should be displayed: 'Put fiber in external meter and fire laser. Adjust power and press control when set'.

Adjust the power setting to 1W and put the laser back into the ready state. Fire the laser into the meter and, when the power reading has settled, make adjustments using the rotary control until the power displayed is as close as possible to 1W.

When the power setting is achieved, release the footswitch and press the

rotary control.

The following prompt should be displayed: 'Put fiber in internal meter and fire laser until cal pulse stops.'

Attach the fiber to the calibration port, put the laser into the ready state and fire until the laser stops (allow about 8s). Release the footswitch.

Select 'Back'

In the engineer interface, update the 'Non-volatile details' tab and read the calibration port data. Write the data down in the table.

Pot setting 1	
Pot setting 2	
ADC at 1W port power	
ADC at 10W port power	
Checksum	

The 'ADC at 10W port power' figure is the calibration point for 10W, which we have just obtained with the set-up routine. Compare this with the value noted previously when setting the radiometer gain. That reading was obtained with 10W port power, while the calibration point was taken with 10W distal power, so the calibration point should be 1.1x the previous ADC reading at 10W, allowing for a 90% fiber.

LASER POWER OUTPUT

Measuring the Laser Power Output

The LASER SAFETY OFFICER or suitably trained service personnel should check the output power of the DELTA 15/30 at least annually from the date of installation, by following the procedure described below.

Equipment Required	<ul style="list-style-type: none"> • 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	<p>Calibrate the fiber.</p> <p>Connect the fiber to the Laser unit output port and present the distal end of the fiber to the external power meter.</p> <p>1. Record the Laser unit's actual and displayed outputs at various different power/energy settings e.g. 5W, 10W, 15W etc.</p> <p>Calculate the percentage difference between the displayed and the actual power/energy output as taken from the external power meter.</p> <p>2. If calculated disparity exceeds $\pm 20\%$, contact AngioDynamics.</p>
Adjusting Laser Power Output	<p>Power output adjustments can only be made by suitably trained AngioDynamics service personnel.</p> <p>For regulatory purposes, the method for carrying out these adjustments is described below.</p> <p>Please contact your AngioDynamics representative for further advice.</p>

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	<ul style="list-style-type: none"> • 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	<p>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.</p> <p>Connect the calibrated fiber from the laser unit output port to the external power meter.</p> <p>Turn on the laser.</p> <p>Load and run the AngioDynamics Engineer Interface program on the PC. From the <code>Connection</code> menu, select <code>Connect to Laser</code>, choose the appropriate Comms Port and press <code>Connect</code>.</p> <p>From the <code>Connection</code> menu select <code>Enter EI</code> and enter the password.</p> <p>Select the <code>Non-volatile data</code> tab.</p> <p>Diode calibration is stored in both the Monitor MCU and in the laser</p>

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 15W, 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 15W 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 **DELTA 15** and **DELTA 30** lasers contain 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 **DELTA 15/30** lasers are 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
- Optical Power Calibration Module (OPCM)

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 I²C 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 (I²C) 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.

Optical Power Calibration Meter

The Optical Power Calibration Meter (OPCM) is only fitted as standard to the **DELTA 30** laser. It is optional on the **DELTA 15**. If the **DELTA 15** laser is not fitted with an OPCM, then the laser's software does not permit the use of a spot handpiece.

The OPCM consists of a power meter head unit, which has a voltage output proportional to the applied laser power. This is conditioned, amplified and converted to a digital signal. Calibration of the meter is achieved by a digitally-controlled potentiometer and the calibration figure is stored in an EEPROM.

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 ² C	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

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SECTION 6 WARRANTY

MANUFACTURER'S WARRANTY POLICY

AngioDynamics warrants the **DELTA 15/30** against defects in materials and workmanship for a period of 2 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, handpieces and accessories
- Maintenance Instruments
- All other accessories supplied by AngioDynamics



CAUTION

WARRANTY CLAIMS

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.

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

<http://www.angiodynamics.com>

AngioDynamics UK Limited
Building 2000, Beach Drive
IQ Cambridge, Waterbeach
Cambridge CB25 9TE
United Kingdom

Tel: +44 1223 729372

Tel: 0800 013 0859 (UK only - free phone)

Fax: +44 1223 729320

Email: customerservice@angiodynamics.com

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