DIOMED DELTA 15/30
DIODE LASER
OPERATOR MANUAL

Version B.2 July 2005 MAN/26/0068

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Manufactured in the United Kingdom by DIOMED Limited

SECTION 1 WELCOME

Thank you for purchasing a DIOMED 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. The Guarantee Registration Certificate and Guarantee Form in section 5 must also be filled in and the form returned to DIOMED to complete the registration process.

INTRODUCTION

This manual describes the operation of the **DIOMED DELTA 15** and the **DIOMED DELTA 30**, (referred to as **DIOMED 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 and the Operating Instructions.

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

DIOMED DELTA 15 The **DIOMED DELTA15** 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 **DIOMED DELTA 15** incorporates a Class IV GaAlAs (Gallium Aluminium Arsenide) diode lasers with a wavelength of 810nm (±20nm).
The **DIOMED DELTA 15** incorporates a visible Class IIIa diode laser aiming beam with a wavelength of 635-660nm and a maximum power output of 5mW.

DIOMED DELTA 30 The **DIOMED DELTA 30** is a diode laser capable of delivering up to 30W of continuous wave radiation via an optical fiber, or 400J/cm² of pulsed radiation via a spot handpiece, coupled to the laser aperture.
The **DIOMED DELTA 30** incorporates Class IV GaAlAs (Gallium Aluminium Arsenide) diode lasers with a wavelength of 810nm (±20nm).
The **DIOMED 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 DIOMED DELTA 15/30

The **DIOMED DELTA 15/30** has been designed for use with the DIOMED 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 **DIOMED 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 **DIOMED DELTA 15/30** include:

- 15W or 30W power output
- Compact & portable
- Intuitive user interface
- Automatic procedure recognition when used with fibers and accessories conforming to the DIOMED FRS fiber system
- Minimal maintenance & service
- Internal power calibration meter (optional on **DIOMED DELTA 15**)

ABOUT THIS MANUAL

This manual is broken down into five 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 **DIOMED DELTA 15/30** is used in a safe manner.
3	Operating Instructions	Detailed instructions on how to install and operate the **DIOMED DELTA 15/30** laser.
4	Procedures	Specific information about DIOMED 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	Guarantee	Contains the DIOMED guarantee policy and your guarantee certificate. Ensure that the accompanying form is returned to DIOMED and that the certificate is kept in a safe place.

PRODUCT INFORMATION

Laser Serial Number .....

Software Version .....

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

Date Installed .....

Installed by .....

Signed .....

Print Name .....

Organisation .....

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

SECTION 2 SAFETY & WARNINGS

CONTENTS

SYMBOLS USED IN THIS MANUAL

This symbol indicates caution should be taken, as there may be a potentially hazardous situation that could result in injury to personnel or damage to the equipment.

This symbol indicates the possibility of a non-radiation hazard that may result in severe injury to personnel within the vicinity of the equipment.

This symbol indicates the possibility of an electrical hazard that could cause injury to personnel within the vicinity of the equipment or damage to the equipment.

This symbol indicates the possibility of exposure to hazardous laser radiation that could cause injury to personnel within the vicinity of the equipment.

This symbol indicates personnel within the vicinity of the equipment should wear appropriate eye protection.

This symbol indicates an important point to be noted.

WARNINGS

	US Federal Law restricts the use of this device to sale by or on the order of a physician. Intended for use only by trained physicians/surgeons familiar with laser procedures.
	Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
	This product must be stored at temperatures between 0°C and +55°C. If stored at temperatures below 10°C for a period of time, the l aser requires up to 12 hours to acclimatise, prior to operation. Failure to observe this could result in invalidation of the guarantee.
	The laser is not designed to operate at temperatures below 10°C.
	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.
	This product contains a lithium battery, which should only be replaced by authorised service personnel. Replace the battery only with the same or equivalent type. Dispose of used batteries according to the manufacturer’s instructions and local disposal requirements.

EMC Warning

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

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

- Foot Switch Assembly
  Diomed part no. AS1/A0/0002

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

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

- Remote Interlock Bypass (supplied with laser).
  Diomed part no. AS1/A3/0024

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

SAFETY CLASSIFICATIONS, HAZARDS AND PRECAUTIONS

This product 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.

This product conforms to the requirements of Council Directive 93/42/EEC of the Council of European Communities (Medical Devices Directive). Affixing the 'CE Mark' to the instrument indicates conformity to this directive.

CE
0086

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

A Class 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 **DIOMED 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 **DIOMED DELTA 15/30** Laser is a portable laser weighing 11kg. All standard safety procedures for lifting should be applied when moving the instrument.

There are no user serviceable parts in the **DIOMED DELTA 15/30** Laser. The exterior cover should only be removed by a trained and authorised 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 in Appendix D 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 DIOMED DELTA 15/30 near the eyes.

Near infrared light (810nm) from the **DIOMED 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 anesthetised. If the patient is anesthetised, 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.

DIOMED supplies laser safety glasses marked in accordance with EN 207 as L5 or greater. Contact your local DIOMED distributor if these are required.

The ‘Nominal Ocular Hazard Distance’ is 8 metres.

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

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

- Incision (only contact)
- Excision (only contact)
- Vaporisation
- Coagulation / haemostasis

- of soft tissue in Endovascular, open and endoscopic procedures in Vascular Surgery, General Surgery, Gynaecology, 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 colour are the best indications of the laser effect. Specific pulse duration is not recommended, but is left to user preference and best medical judgement dependent on the particular application and tissue type.

Contraindications

The **DIOMED 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
- Oedema
- 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 CO_2 or argon 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 **DIOMED 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 vascularised 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 **DIOMED 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 DIOMED Ltd. or your **DIOMED DELTA 15/30** distributor 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 **DIOMED 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 judgement dependent on the particular application.

The diode laser may not be effective for coagulation for severe haemorrhages. The operator must be prepared to control haemorrhages with strident, alternative non-laser techniques. In contact surgery, the tissue interaction with the **DIOMED 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 judgement 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 colour.

SAFETY LABELLING

Location of Safety Labelling

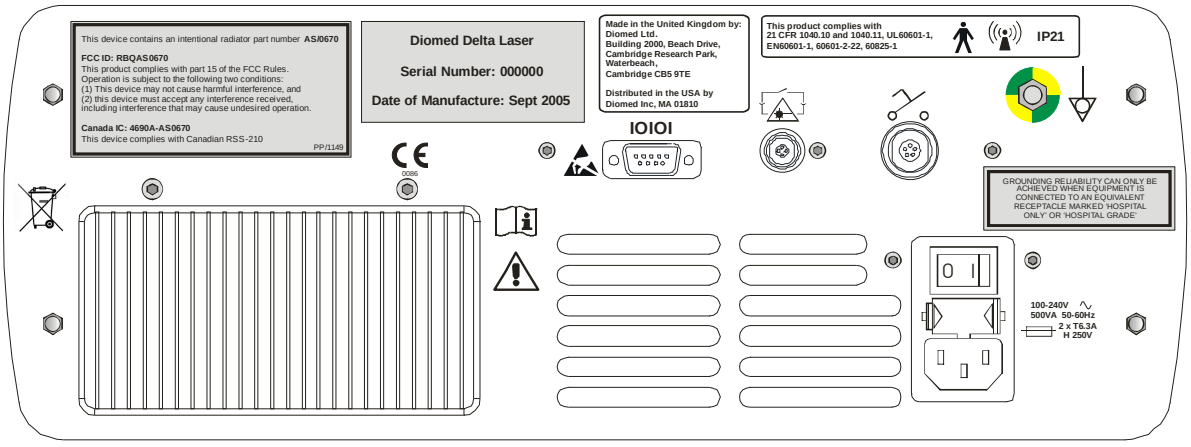
Safety labels for the **DIOMED DELTA 15/30** are positioned as indicated below.

DIOMED DELTA 15
Safety Label

DIOMED DELTA 30
Safety Label

Product Identification Labelling

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



SAFETY FEATURES

The **DIOMED 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 (Figure 1)
- identification and compliance label (Figure 2)
- internal calibration port (optional on DELTA 15)
- calibration procedure for power measurement
- aiming beam

The **DIOMED 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

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The DIOMED DELTA 15/30 is intended for use in the electromagnetic environment specified below.
The customer or user of the DIOMED DELTA 15/30 should ensure it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic emissions – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The DIOMED 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The DIOMED 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity

The **DIOMED DELTA 15/30** is intended for use in an electromagnetic environment specified below. The customer or the user of the **DIOMED 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 **DIOMED DELTA 15/30** requires continued operation during mains interruptions, it is recommended that the **DIOMED 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 **DIOMED DELTA 15/30** Laser is intended for use in an electromagnetic environment specified below. The customer or the user of the **DIOMED 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **DIOMED DELTA 15/30**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d = 1.2 √P d = 1.2 √P 80MHz to 800 MHz d = 2.3 √P 800MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as determined by an electronic site survey. a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by			

absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **DIOMED DELTA 15/30** is used exceeds the applicable RF compliance level above, the **DIOMED 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 **DIOMED DELTA 15/30**.
b Over the frequency range 150 kHz to 800 MHz, field strengths should be less than 3 V/m.

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

The **DIOMED 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 **DIOMED DELTA 15/30** can help prevent electromagnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the **DIOMED 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 √P**	**80MHz to 800MHz** **d = 1.2 √P**	**800 MHz to 2,5 GHz** **d = 2.3 √P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

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 **DIOMED 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 **DIOMED DELTA 15/30** and any device connected to it.

When connecting the **DIOMED DELTA 15/30** with another device, it is very important for the **DIOMED 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 **DIOMED 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

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 **DIOMED 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 **DIOMED 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 DIOMED representative for advice.

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

CONTENTS

CONVENTIONS

The following naming conventions are used throughout these Operating Instructions

Controls on the front panel are expressed in bold capitals.	**SCROLL**, **STANDBY**
Functional modes of the **DIOMED DELTA 15/30** are expressed in capitals.	STANDBY, READY
Menu items are expressed in bold mixed case.	**Main Menu**, **Language**

SUMMARY

1. Place the **DIOMED DELTA 15/30** in a convenient position on an instrument table no farther than 1.8 metres from the patient. Ensure that all controls are within easy reach of the operator.

2. Ensure that the ventilation holes in the base and rear of the **DIOMED 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 **DIOMED 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. DIOMED 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 **DIOMED 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 DIOMED FIBERS, PROCEDURE KITS AND ACCESSORIES.

ONLY 600µm 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 **DIOMED 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 **DIOMED 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 may be reviewed if required by selecting **Statistics** from the **Main Menu**.

15. To turn the **DIOMED 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 **DIOMED DELTA 15/30** can be carried out by the end-user.

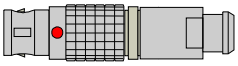
Inspection

Inspect the **DIOMED DELTA 15/30** and contents for signs of damage. If the unit is damaged **DO NOT USE** - contact DIOMED or your local DIOMED representative. If there are no signs of damage and all components are present, assemble the **DIOMED DELTA 15/30**.

Check that the following components are included in the packaging

DIOMED DELTA 15/30 Laser unit

- Footswitch
- IEC Power cable
- 2 x Remote Interlock bypass connectors



- 2 x Keys
- 4 x T6.3A fuses
- Operator Manual

The **DIOMED DELTA 15/30** will operate at mains 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 Handpiece[1] 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 **DIOMED 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 **DIOMED DELTA 15/30**. The fiber or handpiece is connected by means of an SMA-905 type optical fiber connector.

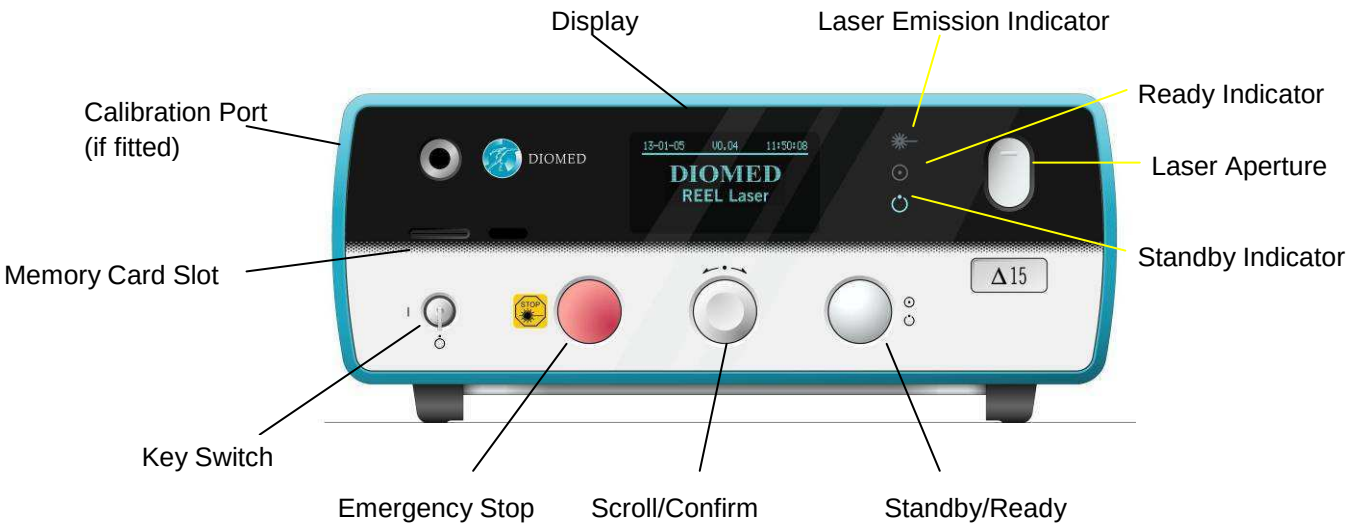
To insert the optical fiber connector, first remove the protective cap from the end of the fiber. Then press down on the tab of the spring-loaded dust cover, insert the optical fiber connector into the laser aperture on the **DIOMED DELTA 15/30** and turn the gripper clockwise until secured in place (light finger tight only).

[1] A Spot Handpiece can only be used with a **DIOMED 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 **DIOMED DELTA 30**.

It is essential that the exposed end of the optical fiber be kept clean to prevent damage to the DIOMED 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.

FRONT PANEL CONTROLS



The main operating controls for the **DIOMED 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

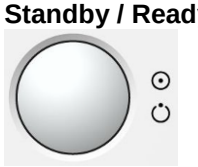
The key switch is used to start the **DIOMED DELTA 15/30** and is the main control for the device. The key is removable only in the OFF position and the laser is not operable when the key is removed.
DIOMED recommends that the keys are assigned to one or two key-holders, who should keep the keys in a secure place and make them available for scheduled procedures only, thus preventing unauthorised use of the system.
DIOMED 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 a READY request is made or during the flashing of the READY light, the message 'Footswitch held down' 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.

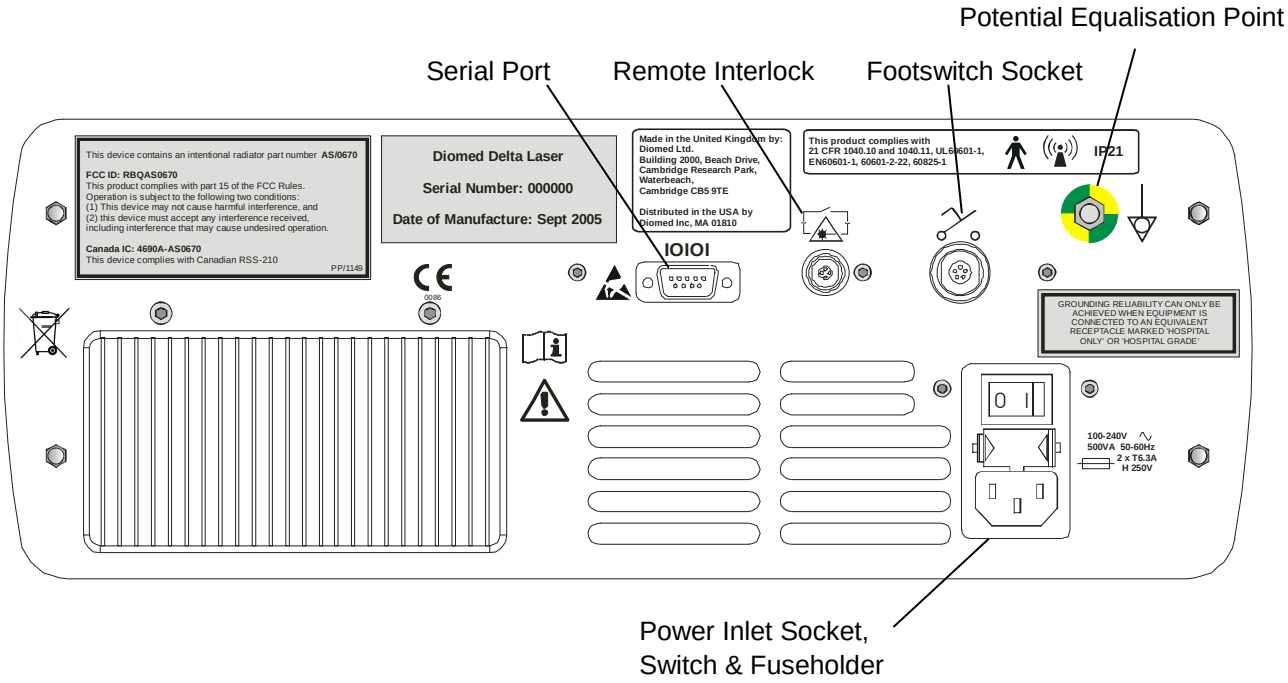
Laser Emission Indicator When laser energy is being delivered to the output port, this light will be on.

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 key switch 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. Slide the cover down to access the aperture.
Use only DIOMED approved or DIOMED labelled optical fibers. Damage caused by use of unapproved handpieces or fibers may invalidate the guarantee.

Calibration Port 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 an optical fiber.

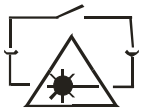
REAR PANEL CONTROLS



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. DIOMED can supply these on request. These precautions will ensure that the possibility of electromagnetic emissions is minimised.

DIOMED supplies two remote interlock bypasses for facilities without or not wishing to use the door switch option. The **DIOMED DELTA 15/30** will not operate without the remote interlock bypass being inserted into the remote interlock socket on the rear of the laser.

Footswitch Socket To connect the footswitch to the **DIOMED DELTA 15/30**.

Serial Port
IOIOI

This connection is normally only used for diagnostic purposes by authorised DIOMED personnel.

Potential To connect a potential equalisation line, for common grounding between

Equalisation Point equipment(s), 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 **DIOMED DELTA 15/30** lasers are equipped with the DIOMED Fiber Recognition System (FRS). This system provides a means of identifying the fiber that is connected to a **DIOMED DELTA 15/30**. DIOMED 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 **DIOMED 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.

Some versions of the **DIOMED DELTA 15/30** can also operate with non-DIOMED fibers, as long as they are fitted with a DIOMED adapter at the laser end of the fiber. This adapter is available as an accessory from your DIOMED representative and it will allow the **DIOMED DELTA 15/30** to be used in Manual mode only.

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 **DIOMED 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 sterility expiration date is earlier than the current date in the internal clock of the **DIOMED DELTA 15/30** 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 **DIOMED DELTA 15/30** is powered up with a FRS fiber already connected.

What are the benefits of FRS?

- 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.
- Operation of the **DIOMED DELTA 15/30** is simplified, because the FRS is able to automatically recognize devices independently of the user – for example, the type of Spot Handpiece.

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

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

OPERATING INSTRUCTIONS

Once the **DIOMED 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 **DIOMED 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.

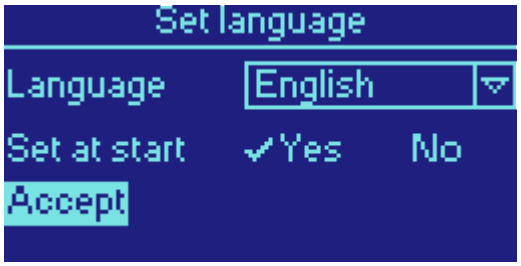
Switching On

Ensure that the **DIOMED 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.

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 **DIOMED 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**.

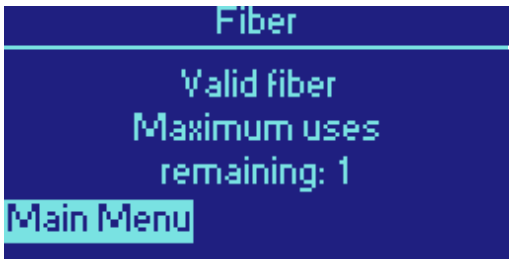
You will still be able to change the language setting from the Setup menu option on the Main menu.

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.

Fiber Identification & Validation

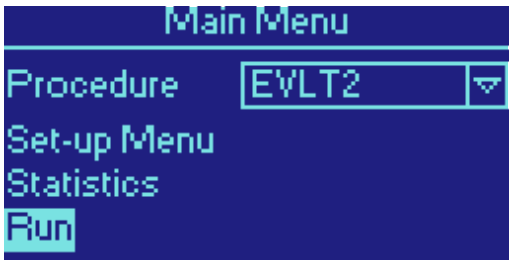
After it has finished checking the interlocks, the **DIOMED DELTA 15/30** system reads the FRS information stored inside the fiber's gripper. It will check the type of fiber, how many "uses" are available and whether it is within its sterility expiration date. This information will be displayed on the screen for a few seconds.



If the **DIOMED DELTA 15/30** does not detect the presence of a valid DIOMED FRS fiber or adapter then it will not permit a procedure to be carried out.
An error message will be displayed on the screen – see **Troubleshooting** in the **Technical Information** section.

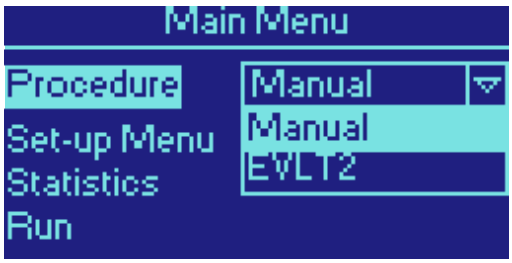
An **Emergency Override** option is included to allow the **DIOMED DELTA 15/30** to be used once only in the event of a session fault, which has prevented the completion of a treatment. See **Session Fault Emergency Override** below for instructions on how to use this option.

Once the fiber is validated, the **DIOMED 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 a DIOMED EVLT procedure kit has been connected to the laser. The **DIOMED DELTA 15/30** recognises this fiber and loads a list of compatible procedures into the top, as shown on the display[4].



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

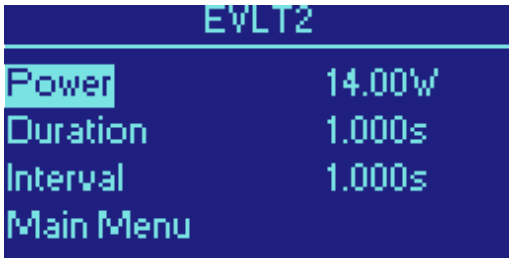
When the procedure has been selected, highlight **Run** using the **SCROLL** knob and press **CONFIRM**.

Parameter Adjustment

At this point, calibration may be required for certain fibers and procedures. In this case, follow the instructions on page 14.

The **DIOMED 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**, **Pulse** 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 completed setting up the operating parameters of the **DIOMED DELTA 15/30**, turn the **SCROLL** knob to move the highlight to **Continue** and press **CONFIRM**.

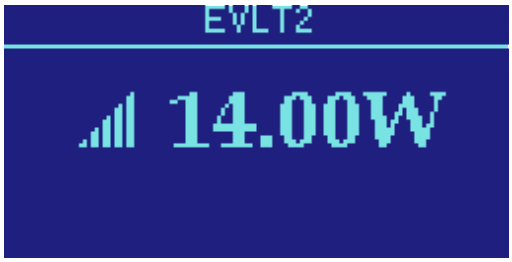
The method of adjusting settings will vary depending on the procedure selected. Please refer to section 4 entitled DIOMED Procedures for full details of how to use specific procedures.

[4] The list of procedures shown on this menu will only include those that are installed in the laser. DIOMED will, over the lifetime of this system, release new procedures that may be compatible with currently available fibers. Please check with your DIOMED representative for the latest information regarding available procedures. Further information on the currently available procedures and the methods of installing them into the **DIOMED DELTA 15/30** can be found in section 4.

Run the Procedure

The **DIOMED DELTA 15/30** is now ready to start the procedure. Press **STANDBY/READY** and wait for the **DIOMED 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.



Note: the **DIOMED DELTA 15/30** will automatically return to STANDBY if treatment is paused for 3 minutes.

To turn the **DIOMED DELTA 15/30** off, turn the key switch anti-clockwise, remove the key and switch off at the rear panel.

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 at the main menu screen.

This feature is not available on the **DIOMED 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 sterilised 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 **DIOMED DELTA 15/30** in READY mode.
4. Follow the instructions on screen.
5. Fire the **DIOMED 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 **DIOMED 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% - 100% indicates that the fiber is **Acceptable**, and 'Cal' is displayed in the top right corner of the display showing that the fiber has been calibrated. 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 **DIOMED DELTA 15/30**.

Spot Handpiece mode is only available when the **DIOMED DELTA 15/30** is fitted with a calibration port. This port is optional on the **DIOMED 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 **DIOMED DELTA 15/30**. The Ø 2mm fixed focus Spot Handpiece, colour-coded 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 **DIOMED DELTA 30** only. The Ø 4mm fixed focus Spot Handpiece is colour-coded yellow for identification and 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 DIOMED 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.

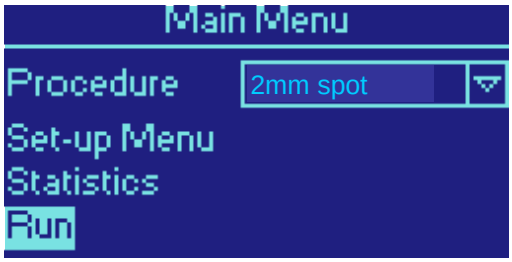
Before using the handpiece inspect the fiber and connector for signs of damage and check the handpiece to ensure it is clean, correctly assembled and has no signs of damage.

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 DIOMED 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 **DIOMED DELTA 15/30** in READY mode.
5. Follow the instructions on screen.
6. Fire the **DIOMED 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 **SELECT**.

Transmission Acceptability
The **DIOMED 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 **DIOMED 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. If the Power and Pulse duration are adjusted, the Fluence will be automatically re-calculated and the display updated.

Fluence (J/cm^2) is calculated using the formula:

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

where Spot Radius = 0.1 cm for a Ø 2 mm spot handpiece.

To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter (**Power**, **Pulse** 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 **DIOMED DELTA 15/30**, turn the **SCROLL** knob to move the highlight to **Continue** and press **CONFIRM**.

The **DIOMED DELTA 15/30** is now ready to start the procedure. Press **STANDBY/READY** and wait for the **DIOMED 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.

Note: the **DIOMED DELTA 15/30** will automatically return to STANDBY if treatment is paused for 3 minutes.

To turn the **DIOMED DELTA 15/30** off, turn the key switch anti-clockwise, remove the key and switch off at the rear panel.

MANUAL OPERATION

Manual operation is not enabled on all versions of the **DIOMED DELTA 15/30**. Please consult with your DIOMED representative if you require assistance with setting up your laser.

For best results always use the **DIOMED DELTA 15/30** with a DIOMED FRS fiber. This will be detected by the laser, which will automatically select suitable preset parameters. However it is also possible to manually configure the settings **DIOMED DELTA 15/30** in the following situations:

- Some DIOMED FRS fibers allow free setting of parameters. This is enabled by selecting **Manual** from the **Procedure** menu.
- DIOMED supply a general purpose bare-ended fiber fitted with FRS, that sets the **DIOMED DELTA 15/30** to use Manual settings.
- Third party fibers[5] may also be used with the **DIOMED DELTA 15/30**. But these must first be fitted with a special DIOMED FRS adapter, available from your DIOMED representative.

If a DIOMED FRS fiber is detected but no compatible procedure is installed, please contact your local DIOMED representative who will advise on how you can update the procedures installed in your **DIOMED 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

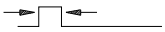
 Repeat Pulse

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

Fiber:
0.5W to 5W in 0.5W increments
5W to maximum W in 1W increments

Spot Handpiece:
0.5W to maximum W in 0.1W increments

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



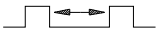
Fiber:

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

0.1 to 9.9 seconds in 0.1 second increments in single pulse mode
0.1 to 1.0 seconds in 0.1 second increments in repeat pulse mode

Spot Handpiece:
50 to 250 ms in 10 ms increments in single or repeat pulse mode

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

Timer (s) Provides a countdown timer in Continuous and Repeat Pulse modes:

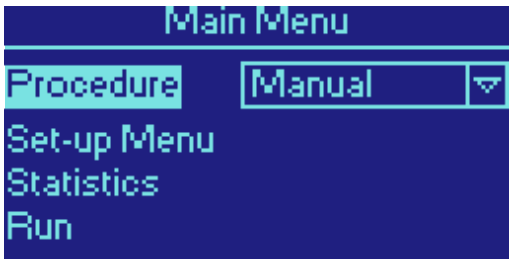
OFF to 120 seconds in 10 second increments
120 to 9999 seconds in 30 second increments (final increment of 9 seconds)

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

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

Selecting Manual Operation

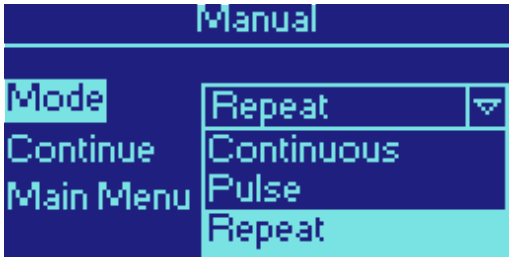
Manual operation allows the operator complete freedom over the settings of the **DIOMED DELTA 15/30** and is enabled by selecting **Manual** from the **Procedure** menu.



Setting the Mode

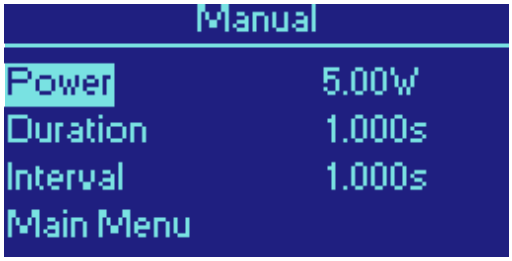
The default mode is shown at the top of the menu. To select a different mode turn the **SCROLL** knob until **Mode** is highlighted and press **CONFIRM**. Select the desired mode with the **SCROLL** knob and press **CONFIRM** again.

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



Setting Power, Pulse Duration and Interval

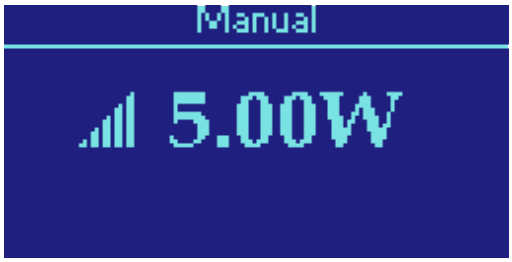
Depending on the Mode selected, the next screen will show a set of default parameters, as described in table 2 above. To adjust a parameter, turn the **SCROLL** knob to highlight the required parameter and press **CONFIRM**. The highlight will now move to the value on the right hand side of the display. 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 and the **Timer** is not available.

Start the Procedure



The **DIOMED DELTA 15/30** is now ready to start the procedure. Press **STANDBY/READY** and wait for the **DIOMED 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 **DIOMED 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 setting the value of the **Timer** parameter to any value except OFF. This mode allows:

- Longer CW exposure times than the maximum 9.9 seconds allowed when using the Pulse mode
- A train of pulses to be output for a fixed time in Repeat Pulse mode

The Timer is not available if the Pulse mode is selected. The default time is 60 seconds but the time can be set to any value between 10 and 3200 seconds.

When the Timer is active and the footswitch is pressed to start treatment, the display will show a countdown 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. When the countdown reaches zero the system will automatically enter STANDBY mode.
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.

SESSION FAULT EMERGENCY OVERRIDE

In extreme circumstances, such as a power cut or a technical problem, the **DIOMED DELTA 15/30** will need to be restarted and will log a Session Fault. If this occurs during a treatment then the fiber in use may become invalid before the completion of the treatment.

In these circumstances, the Emergency Override may be activated to allow treatment to continue. This option is only available immediately after the Session 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.

Select Emergency Override to use this option or Main Menu to cancel.

If the Emergency Override has already been used, then this option is not available.

Resetting the Emergency Override

The Emergency Override can be reset by means of a special reset device (DIOMED part number AS/598). One of these is supplied with the **DIOMED DELTA 15/30**.

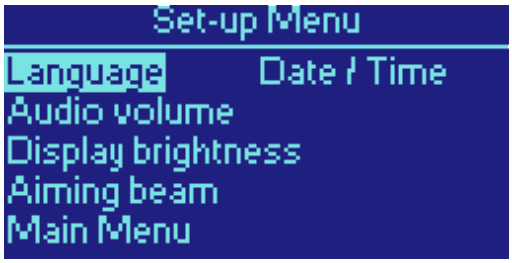
Each device can only be used once, after which it is advisable to contact your DIOMED representative as soon as possible to obtain a replacement.

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 **DIOMED 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 customise certain properties of the **DIOMED 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**.

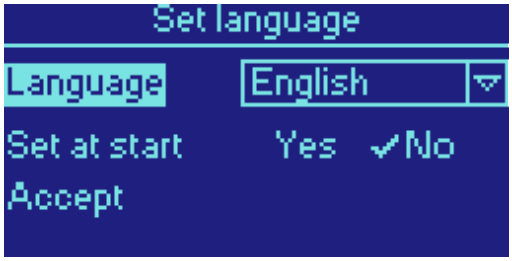
To return to the **Set-up Menu** from any of these functions, highlight **Accept** and press **CONFIRM**.

All of the changes made from this menu will be retained when the **DIOMED DELTA 15/30** is switched off.

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 **DIOMED 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

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

- **Pulsed** – the audible indicator pulses in time with the laser output (as long as the pulses are long enough to be discernable)
- **Continuous** – the audible indicator sounds continuously when the laser is firing

Display Brightness

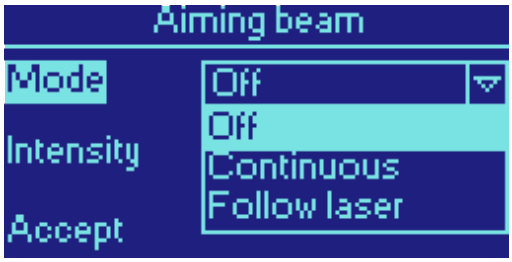
To adjust the brightness of the display, turn the **SCROLL** knob to highlight **Adjust** and press **CONFIRM**. Now use the **SCROLL** knob to select the required brightness. Press **CONFIRM** when finished.

Aiming Beam

Mode

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 **DIOMED 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 **DIOMED 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.

Time & Date

To set the internal clock and calendar of the **DIOMED 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.

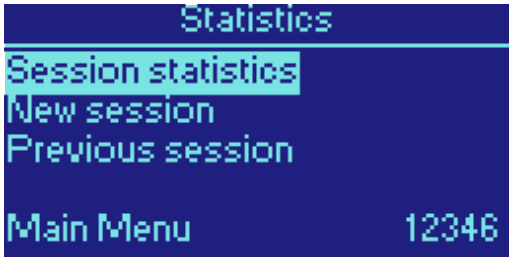
SESSION STATISTICS

Session Statistics can be defined as a summary of the laser energy delivered and are recorded for the time that the **DIOMED DELTA 15/30** is switched on. Session Statistics will be displayed as the amount of joules of energy delivered.
Each time the treatment parameters are changed, the Session Statistics will be shown on a separate line of the screen. The total amount of laser energy used in this session will be displayed on the screen.

Session Statistics are stored in the **DIOMED DELTA 15/30** internal memory. They may also be transferred to a PC using a MMC memory card.

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

The **Statistics** menu enables the operator to view the session statistics from the current or previous sessions.
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 Session Statistics menu turn the **SCROLL** knob until the function is highlighted and then press **CONFIRM**.



SYMBOLS USED ON DIOMED PRODUCTS

The following symbols are used on the **DIOMED DELTA 15/30** laser and on accessories provided by DIOMED.

	Refer to instructions
	Refer to instructions (alternative)
	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
	Single-use
	Do not use if packaging is damaged
	Expiry date
	Batch number
	Product re-order code
	Sterile by Ethylene Oxide

SECTION 4 PROCEDURES

The **DIOMED DELTA 15/30** lasers are optimised to operate with DIOMED fibers and procedure kits that are equipped with the DIOMED 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 DIOMED representative.

DIOMED'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 DIOMED representative to obtain the latest product information.

CONTENTS

DIOMED FIBERS AND PROCEDURES

When a DIOMED fiber fitted with FRS is connected to a **DIOMED DELTA 15/30** laser, the laser will attempt to recognise 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.

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

ORDERING INFORMATION

The following order codes should be quoted when ordering replacement procedure kits, fibers and accessories for your **DIOMED DELTA 15/30**.

Description	DIOMED or fibersdirect.com part number
EVLT Procedure Kit	EVLT/PK-02
EVLT Procedure Kit – Extra Length	EVLT/PK-02-EL
Micro-Introducer Kit	EVLT/PK/MIK
2mm Spot Handpiece replacement fiber only	AS/0618
4mm Spot Handpiece replacement fiber only	AS/0619
Manual Adapter	AS/0686
Test fiber	AS/0604
Emergency Override Reset Device	AS/0598
MMC Multimedia Memory Card	S10/06/0086
USB MMC Card Reader/Writer	S10/06/0087
DIOMED Key Fob / MMC Card Holder	AS/0685

This list was correct at the time of publication but new procedure kits, fibers and accessories may be added at any time. Please check with your local DIOMED representative for the latest information.

EVLT

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

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

EVLT Continuous

The laser output power is fixed at a continuous 14 W. No adjustments can be made.

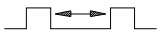
EVLT Pulsed

The laser output power is fixed at 12 W with a 1 second pulse and 1 second interval. No adjustments can be made.

EVLT Manual

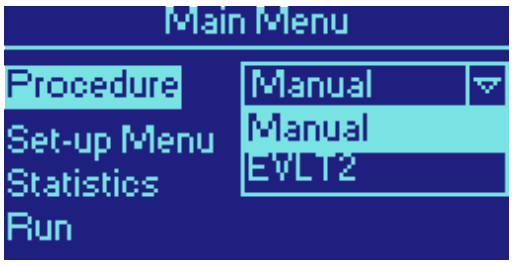
The laser output power may be varied between 5 W and 15 W. The mode may be switched between continuous output and 1 second pulses with 1 second interval.

These three procedures are summarised in the following table:

	EVLT Continuous	**EVLT Pulsed**	**EVLT Manual**
Power (W) 	14 W	12 W	5 W to 15 W
Pulse Duration (s) 	Continuous	1 second	Continuous or 1 second Pulse / 1 second Interval
Interval (s) 		1 second	

Selecting the Procedure

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



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

Adjusting an EVLT procedure

The EVLT Continuous and EVLT Pulsed procedures use preset parameters and cannot be adjusted. The EVLT Manual procedure allows the power to be adjusted between 5 W and 15 W and the mode

may be switched between Continuous and Pulsed. The pulse duration and interval are preset to 1 second.

Instructions on how to select mode and adjust power are included in section 3 – Operating Instructions.

SPOT HANDPIECES

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

BARE-ENDED FIBER

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

MANUAL ADAPTER

If you wish to use a fiber not supplied by DIOMED then, in certain circumstances, it is possible to use a special adapter to enable the fiber to be accepted by the Fiber Recognition System. The **DIOMED DELTA 15/30** will then be enabled for Manual operation.

For details of this adapter please contact your DIOMED representative.

TEST FIBER

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

EMERGENCY OVERRIDE RESET DEVICE

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

SECTION 5 TECHNICAL INFORMATION

The **DIOMED DELTA 15/30** has been designed to operate reliably with minimal maintenance and there are no user serviceable parts.

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

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

CONTENTS

SPECIFICATIONS

	DIOMED DELTA 15	DIOMED 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	0.5 W to the laser output port	
Set power accuracy	Better than ± 10% of displayed power	
Output power stability	± 5% maximum	
Aiming beam	Red Class 3a diode laser, ≤ 5 mW at port, wavelength 635-655 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 **DIOMED DELTA 15**)	
Spot Handpiece Mode	Spot handpiece mode is available on the **DIOMED DELTA 30** and on the **DIOMED DELTA 15** when fitted with the optional calibration meter	
Spot size	Ø 2mm	Ø 2mm , Ø 4mm
Single/Repeat Pulse	50ms – 250ms	50ms – 950ms
Pulse Interval	100ms – 1000ms	100ms – 1000ms
Fluence	Up to 119J/cm^2	Up to 400J/cm^2
Fiber Recognition System	**(FRS)**	
Operating Frequency	125 kHz ± 1 kHz	
Operating Range	Maximum of 40 mm 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 mm x 370 mm x 325 mm (± 5 mm)	
Weight	12 kg max.	
Operating Temperature	+10ºC to +40ºC	Up to 15W CW +10ºC to +40ºC
		Over 15W CW +10ºC to +30ºC
Operating Humidity	Up to 75% relative humidity, non-condensing	
Operating Pressure	Normal atmospheric pressure	
Storage Temperature	0ºC to +55ºC	
Storage Humidity	Up to 90% relative humidity, including condensing	
Storage Pressure	500 hPa to 1014 hPa	
Safety Standards	EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1, 21 CFR 1040.10, 1040.11	

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 DIOMED DELTA 15/30

The **DIOMED DELTA 15/30** has been designed to operate reliably with minimal maintenance. There are no user-serviceable parts in the **DIOMED DELTA 15/30**. Any attempts to repair, adjust or modify the system beyond the procedures allowed in this Operator Manual, by any person not authorised by DIOMED, will invalidate the guarantee.

The system enclosure may be wiped down periodically with a cloth dampened with a mild antiseptic solution. Before cleaning always disconnect the **DIOMED 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.

Pre-Carbonisation of sculpted tip (contact) fibers

Prior to use on the patient, an enhanced tissue effect can be achieved by establishing a plane of microcarbon on the face (end) of the contact tip. A plane of carbon traps the laser energy within the fiber tip, resulting in increased efficiency at lower powers.

1. Using sterile technique, darken a small area (`l`) on a wooden tongue depressor/spatula with a surgical marker.
2. Pass the fiber into surgical field.
3. Set the laser power at 10 Watts continuous.
4. Observing the safety procedures described in this Operator Manual, gently touch tip of the fiber to the darkened area on the tongue depressor and operate laser only until a small plume of smoke appears.
5. The fiber has now been pre-carbonised and is ready for clinical use.
6. Reset the laser to the correct power setting and duration for desired procedure.

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. Haemostasis 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 **DIOMED DELTA 15/30** is continuously monitoring its operation and performance. Should it detect a problem it will display a short message on the screen. To clear a message, carry out the instructions on the display. Outlined below are some common messages and the appropriate action that the user should undertake.

Remote interlock

The remote interlock has been violated. Close the entry door or insert the remote interlock bypass into the remote interlock bypass socket on the rear of the unit.

Footswitch not connected

The laser system will not go to **READY** mode unless the footswitch has been connected. Connect the footswitch and ensure that it is correctly inserted into the footswitch socket.

Fiber not connected

The optical fiber or spot handpiece is disconnected from the laser. Connect a handpiece or fiber to the laser output port.

Emergency switch pressed. Use key switch to reset	The emergency switch has been pressed. Switch the laser OFF and ON using the key switch. The laser will carry out a self-test and the message will clear automatically.
Fiber calibration failed	An attempt has been made to calibrate a non-contact fiber and the calibration has failed (below 75%). Replace the fiber and re-calibrate.
Setting Wavelength	This message will occur when the temperature of the laser diode is outside of its specified operating range for the correct diode wavelength. Leave the laser on to allow the temperature to stabilise. This may take a few minutes.
Ambient temperature out of range	The laser is being operated outside of its specified ambient temperature range. Switch it off at the mains inlet and allow it to stabilise at room temperature.
Temperature high	The laser is overheating. Switch it off at the mains inlet and allow it to cool.
Footswitch held down	There is a two-second safety delay when the laser is placed from STANDBY to READY. Ensure that the footswitch is not held down until after the two-second delay and the audible beep is heard. The message will clear when the footswitch is released.
Diode switched off	The laser has been prevented from firing. Press **SELECT** and check the maximum power available.
Software loading unsuccessful	A problem was detected when loading new software. Switch the laser OFF and then ON at the key switch and repeat the software load process. If the problem is repeated, call for support from your DIOMED representative.
Footswitch invalid	The laser has detected a problem with the footswitch. Check that the footswitch has been connected correctly. If the message does not clear, switch the laser OFF and then ON at the key switch. If this does not clear the problem, call for support from your DIOMED representative.
Panel switch stuck	A switch on the front panel has stuck during switch-on, and the laser will not be able to go into the READY mode. Switch the laser OFF and ON using the key switch. If this does not clear the message, call for a service engineer.
Call service engineer	If this message appears, switch the laser OFF at the key switch and then ON. If the message does not disappear, call service support from your DIOMED representative.

FRS Error Messages

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

FRS Error	The laser has detected a problem with the FRS system for identifying fibers. Try removing and replacing the fiber connector or connecting a new fiber. If the message does not clear, switch the laser OFF and then ON at the key switch. If this does not clear the problem, call for support from your DIOMED representative.
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	DIOMED 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 **DIOMED DELTA 15/30** is either not recognised 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 DIOMED FRS system has been extensively tested. In the unlikely event of a problem being experienced please perform the following checks before contacting your local DIOMED 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 **DIOMED DELTA 15/30**. This will cause the unit to try and read the fiber's data again. (2) Ensure that the **DIOMED 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	Some versions of the **DIOMED DELTA 15/30** can also operate with non-DIOMED fibers, as long as they are fitted with a special DIOMED adapter at the laser end of the fiber. This adapter is available as an accessory from your DIOMED representative and it will allow the **DIOMED DELTA 15/30** to be used in Manual mode only. See your DIOMED representative for further information.
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 DIOMED 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 **DIOMED DELTA 15/30** is set correctly. The procedure for setting the clock is described in Section 3 - Operator Instructions.

ACCESSORIES

Optical Fibers

The **DIOMED DELTA 15/30** has an output connector for optical fibers with standard SMA-905 connector. Only DIOMED or fibersdirect.com labelled fibers should be used. A list of fibers available for use with the **DIOMED DELTA 15/30** can be obtained from your DIOMED representative.

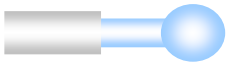
Contact Sculpted Tip Fibers

Used in contact with the tissue for incision/excision.

Conical Tip Fibers

DIOMED conical tip fibers have a tip size of 300µm and should be selected where a narrow or precise incision/excision is required. Laser energy is delivered from the end of the sculpted tip with minimal tissue effect from the side of the tip. Heat delivered via the tip performs the cutting and extremely light pressure is all that is required for incising, excising and vaporising and coagulating soft tissue. Haemostasis occurs as the tissue is incised.

Orb Tip Fibers



DIOMED orb tip fibers are available with tip sizes of 800µm, 1200µm and 3000µm and should be selected where a wider incision or tissue vaporisation is required. Laser energy is displaced outwards from the forward curvature of the fiber which gives the added advantage of vaporising larger tissue surfaces. Heat delivered via the tip performs the cutting and extremely light pressure is all that is required for incising, excising and vaporising and coagulating soft tissue. Haemostasis occurs as the tissue is incised.

Bare/Flat end fibers

Used in contact with the tissue for incision/ excision and in non-contact with tissue at low power for vaporisation / coagulation.

Non-contact cooled fibers

Held at a distance from the tissue for vaporisation / coagulation.

STERILISATION OF OPTICAL FIBERS

Optical fibers are provided sterile as a disposable, single-use product.
DO NOT RE-STERILISE THE FIBERS.
DO NOT RE-USE THE FIBERS.
USE ONLY DIOMED OR FIBERSDIRECT.COM LABELLED OR DIOMED APPROVED FIBERS.
Failure to observe this could invalidate the Laser Guarantee.

Intra-operative cleaning

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

Fiber Disposal

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

DIOMED and fibersdirect.com labelled 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 DIOMED 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.

Calibration Port Adapter

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

Steam Sterilisation

The calibration port adapter should be sterilised before use in accordance with ISO 11134 1993 ‘Sterilisation of Healthcare Products, Requirement for Validation and Routine Control, Industrial Moist Heat Sterilisation.

A validated cycle of ≥134°C (273°F) for ≥ 3 minutes sterilising 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 DIOMED 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 DIOMED representative.

Guildelines

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.

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 Sterilisation

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 sterilised using a validated steam sterilisation cycle.

Steam Sterilisation

Reusable handpieces should be sterilised before use in accordance with ISO 11134 1993 'Sterilisation of Healthcare Products, Requirement for Validation and Routine Control, Industrial Moist Heat Sterilisation. A validated cycle of ≥134°C (273°F) for ≥ 3 minutes sterilising 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 mains fuses are supplied with the **DIOMED DELTA 15/30**. Further spares can be obtained from DIOMED. They can be replaced as follows:

1. Use a small flat-bladed screwdriver to release the fuse compartment from the mains inlet on the rear panel.
2. 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 **DIOMED DELTA 15/30** should be disposed of according to national environmental requirements or be returned to DIOMED

SOFTWARE UPDATES

From time to time DIOMED may issue new procedures, upgrades and feature enhancements for the **DIOMED DELTA 15/30**. As a registered owner you will be notified of these when they become available.

CALIBRATION

Checking the Calibration of the Internal Power Meter

To ensure accurate calibration of the delivery fiber, the internal power meter should be checked at least annually. The LASER SAFETY OFFICER or suitably trained service personnel should carry out this procedure.

The method for carrying out this procedure is described below.

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 authorised to do so by DIOMED. 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 guarantee cover.
ONLY TRAINED LASER SERVICE PERSONNEL AUTHORISED BY DIOMED SHOULD PERFORM SERVICE AND MAINTENANCE.
DIOMED will not accept liability for the use of this equipment when calibrated by unauthorised 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

- DIOMED 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 DIOMED 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 **DIOMED DELTA 15/30** at least annually from the date of installation, by following the procedure described below.

Equipment Required	• A sampling power meter or an independent energy (integrated power) meter of known calibration • A bare ended optical fiber • Laser unit to be tested
Procedure	Calibrate the fiber. Connect the fiber to the Laser unit output port and present the distal end of the fiber to the external power meter. 1. Record the Laser unit's actual and displayed outputs at various different power/energy settings e.g. 5W, 10W, 15W etc. Calculate the percentage difference between the displayed and the actual power/energy output as taken from the external power meter. 2. If calculated disparity exceeds ± 20%, contact DIOMED.
Adjusting Laser Power Output	Power output adjustments can only be made by suitably trained DIOMED service personnel. For regulatory purposes, the method for carrying out these adjustments is described below. Please contact your DIOMED representative for further advice.

Adjusting the Laser Power Output

THE FOLLOWING INFORMATION IS PROVIDED FOR REGULATORY PURPOSES

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

Equipment Required	• A sampling power meter or an independent energy (integrated power) meter of known calibration • A calibrated bare ended optical fiber • Laser unit to be tested
Procedure	Connect the laser to a PC via a null-modem serial cable between the port on the rear panel and a serial port on the PC. Connect the calibrated fiber from the laser unit output port to the external power meter. Turn on the laser. Load and run the DIOMED Engineer Interface program on the PC. From the `Connection` menu, select `Connect to Laser`, choose the appropriate Comms Port and press `Connect`. From the `Connection` menu select `Enter EI` and enter the password. Select the `Non-volatile` data tab Diode calibration is stored in both the Monitor MCU and in the laser

module itself. The values in these locations are shown on the screen – if there are any discrepancies then an error message is displayed.
The laser is calibrated at three different power settings: 2W, 5W and 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` together, 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 DIOMED **Delta 15** and **Delta 30** lasers contain no user-serviceable components. In the event that repair or service is required please contact your local DIOMED representative. More detailed service instructions, including schematic diagrams, are available only to suitably-qualified technical personnel.

The DIOMED **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 mains power supply, laser driver and TEC driver are contained in their own enclosure. The power supply accepts a mains 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 along a dedicated RS232 serial interface.

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

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

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

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

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

User Interface PCA

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

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

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

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 MultiMedia Card interface allows a MMC 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
I^2C	Inter-Integrated Circuit
I/O	Input/Output
Kb	kilobits
LED	Light Emitting Diode
MCU	Microprocessor Control Unit
ms	milliseconds
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
SFC	Single Fault Condition
SPI	Serial Peripheral Interface
TTL	Transistor-Transistor Logic
TEC	Thermo Electric Cooling
UART	Universal Asynchronous Receiver/Transmitter
V	Volts
VFD	Vacuum Fluorescent Display

SECTION 6 WARRANTY

MANUFACTURER'S WARRANTY POLICY

DIOMED guarantees the **DIOMED DELTA 15/30** against defects in materials and workmanship for a period of 24 months. The warranty period begins on the date of installation.

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

The following items are expressly excluded from this Warranty:

- Safety Eyewear
- All optical fibers, handpieces and accessories
- Maintenance Instruments
- Footswitch and electrical cables
- All other accessories supplied by DIOMED Limited

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

WARRANTY CLAIMS

To make a warranty claim the purchaser shall, promptly following discovery of the basis of claim, contact your DIOMED distributor in the first instance or DIOMED Ltd. in writing, by telephone, fax or Email at the following address:

DIOMED

DIOMED Inc
One Dundee Park
Andover, MA 01810
USA

Tel: +1 866 883 8820
Fax: +1 978 475 8488
Email: service@diomedinc.com

DIOMED Limited
Building 2000
Beach Drive
Cambridge Research Park
Waterbeach
Cambridge CB5 9TE
United Kingdom

Tel: +44 1223 729372
Fax: +44 1223 729320
E-mail: service@diomedinc.com
http://www.diomedinc.com

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WARRANTY REGISTRATION CERTIFICATE

Product Type: **DIOMED DELTA 15/30** Product Serial No: _____

Registered User Information:
Institution: _____

Specialist: Name: _____ Speciality: _____

Address: Street: _____

City: _____ Zip / Post Code: _____

Country: _____

Telephone: _____ Fax: _____

Email: _____

Installation:

Date Installed: _____

Installed by: Signed: _____ Print Name: _____

Organisation: _____

DIOMED Sales Consultant details:

Distributor Signature: _____ Print Name: _____

- Registered User and Consultant to fully complete this Certificate.
- Registered User must keep this certificate in a safe place for reference.
- The accompanying Registration Form must be completed and sent to DIOMED Inc, One Dundee Park, PO Box 97, Andover, MA 01810, USA, by mail or fax (978) 475 8488 within 28 days of date of Product installation. **This Registered User information is essential in the event of a Guarantee Claim.**

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WARRANTY REGISTRATION FORM

Product Type: **DIOMED DELTA 15/30** Product Serial No: _____

Registered User Information:

Institution: _____

Specialist: Name: _____ Speciality: _____

Address: Street: _____

City: _____ Zip / Post Code: _____

Country: _____

Telephone: _____ Fax: _____

Email: _____

Installation:

Date Installed: _____

Installed by: Signed: _____ Print Name: _____

Organisation: _____

DIOMED Sales Consultant details:

Distributor Signature: _____ Print Name: _____

- Registered User / Consultant to fully complete, detach and return this Registration form to DIOMED Inc, One Dundee Park, PO Box 97, Andover, MA 01810, USA, by mail or fax (978) 475 8488) within 28 days of date of laser installation. **This Registered User information is essential in the event of a Guarantee Claim.**