DIOMED 15PLUS DIOMED 30PLUS

DIODE LASER

Operator Manual

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DIOMED

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[Not all products in this manual are available in all countries.]

Manufactured in the United Kingdom by DIOMED Limited

PRODUCT INFORMATION

Laser Serial Number _____

Software Version

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

Date Installed _____

Installed by

Signed _____

Print Name _____

Organization _____

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

CONTENTS

1. *SYMBOLS USED IN THIS MANUAL*

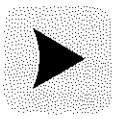
This symbol indicates caution should be taken, as there may be a potentially hazardous situation that could result in injury to personnel or damage to the equipment.

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.

2. *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.

The DIOMED 15/30*PLUS* must be stored at temperatures between 32°F and 140°F (0°C - 60°C). If stored at temperatures below 59°F (15°C) for a period of time, the laser requires up to 12 hours to acclimatize, prior to operation.

Failure to observe this could result in invalidation of the guarantee.

The laser will not operate at temperatures below 59°F (15°C).

EMC Warning

The **DIOMED 15/30*PLUS*** complies fully with North American and European requirements for EMC (Electro Magnetic Compatibility); however, this instrument may still be susceptible to electromagnetic interference from such equipment as microwave emitters, mobile phones, electro-surgical units or other high frequency generators. Do not use the instrument within the vicinity of such equipment.

3. *INTRODUCTION*

This manual describes the operation of the **DIOMED 15*PLUS*** and the **DIOMED 30*PLUS***, (referred to as **DIOMED 15/30*PLUS*** 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 Requirements, Operating Instructions and Clinical Instructions outlined in this manual.

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

The DIOMED 15*PLUS*

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

The **DIOMED 15*PLUS*** incorporates Class IV GaAlAs (Gallium Aluminum Arsenide) diode lasers with a wavelength of 810nm (± 20nm).

The **DIOMED 15*PLUS*** incorporates a visible Class IIIa diode laser aiming beam with a wavelength of 635-655nm and a maximum power output of 5mW.

The DIOMED 30*PLUS*

The **DIOMED 30*PLUS*** is a diode laser capable of delivering up to 400J/cm² of pulsed radiation via a fiber optic handpiece, or 30W of continuous wave radiation via an optical fiber coupled to the laser aperture.

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

The **DIOMED 30*PLUS*** incorporates a visible Class IIIa diode laser aiming beam with a wavelength of 635-655nm and a maximum power output of 5mW.

4. TECHNICAL SPECIFICATIONS - DIOMED 15PLUS

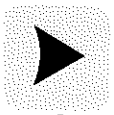
Laser Type	GaAlAs Laser Diode	
Wavelength	810nm ± 20nm	
Power	15W at the laser output port	
Output	Optical SMA-905 type connector, 400μm, 0.37 NA	
Treatment Modes	Spot Handpiece mode:	
	Spot Size	∅ 2mm
	Single / Repeat Pulse	50ms – 250ms
	Pulse Interval	100ms – 1000ms
	Fluence	Up to 119J/cm^2
	Fiber mode:	
	Single Pulse	100ms – 9900ms
	Repeat Pulse	100ms – 1000ms
	Pulse Interval	100ms – 1000ms
	Continuous Wave	0.5W – 15W
	Countdown	10-3200 seconds
Fibers	Contact and non-contact fibers, 400μm, 600μm and 1000μm	
Calibration	Internal photodiode power meter for handpiece or fiber calibration	
Aiming Beam	InGaAlP visible laser diode, Class IIIa 635-655nm 5mW (max)	
Cooling	Air cooled with inlet at rear	
Power Supply	110V, 130V, 230V or 250V AC ± 10% or 100V, 120V, 220V, 240V AC ± 10% 125VA + 10%, 50/60Hz ± 5%	
Dimensions (h x w x d)	6.7" x 15.75" x 15.75" (± 0.2") (170mm x 400mm x 400mm (± 5mm))	
Weight	26.5 lb. (12kg) max	
Lifetime	System 5 years	
Safety Standards	EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1 21 CFR 1040.10, 1040.11, UL 2601	

5. TECHNICAL SPECIFICATIONS - DIOMED 30PLUS

Laser Type	GaAlAs Laser Diode	
Wavelength	810nm ± 20nm	
Power	30W at the laser output port	
Output	Optical SMA-905 type connector, 400μm, 0.37 NA	
Treatment Modes	Spot Handpiece mode:	
	Spot Size	∅ 2mm, ∅ 4mm
	Single / Repeat Pulse	50ms – 950ms
	Pulse Interval	100ms – 1000ms
	Fluence	Up to 400J/cm^2
	Fiber mode:	
	Single Pulse	100ms – 9900ms
	Repeat Pulse	100ms – 1000ms
	Pulse Interval	100ms – 1000ms
	Continuous Wave	0.5W - 30W
	Countdown	10-3200 seconds
Fibers	Contact and non-contact fibers, 400μm, 600μm and 1000μm	
Calibration	Internal photodiode power meter for handpiece or fiber calibration	
Aiming Beam	InGaAlP visible laser diode, Class IIIa 635-655nm 5mW (max)	
Cooling	Air cooled with inlet at rear	
Power Supply	110V, 130V, 230V or 250V AC ± 10% or 100V, 120V, 220V, 240V AC ± 10% 220VA + 10%, 50/60Hz ± 5%	
Dimensions (h x w x d)	6.7" x 15.75" x 15.75" (± 0.2") (170mm x 400mm x 400mm (± 5mm))	
Weight	26.5 lb. (12kg)	
Lifetime	System 5 years	
Safety Standards	EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1 21 CFR 1040.10, 1040.11, UL 2601	

6. *SAFETY*

The **DIOMED 15/30*PLUS*** diode laser is classified as a Class IV laser product in compliance with EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1, FDA 21 CFR 1040.10, and FDA 21 CFR 1040.11.



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 (see sections 7-11) in areas where the laser is being used.

All personnel must wear approved protective glasses appropriate to the wavelength of the DIOMED 15/30*PLUS* 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.

The DIOMED 15/30*PLUS* Laser is a portable laser weighing 26.5 lb. (12kg). All standard safety procedures for lifting should be applied when moving the instrument.

There are no user serviceable parts in the DIOMED 15/30*PLUS* Laser. The exterior cover should only be removed by trained and authorized laser service technicians.

7. *EYE INJURY*

Extreme caution should be taken when operating the DIOMED 15/30*PLUS* near the eyes.

Near infrared light (810nm) from the **DIOMED 15/30*PLUS*** 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 anaesthetized. If the patient is anaesthetized, 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 recommendation 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 4" (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'

26.25 feet (8 meters) (**DIOMED 15*PLUS***)

68.9 feet (21 meters) (**DIOMED 30*PLUS***)

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.

8. *BURNS*

Irradiation of any substance or material other than the target tissue may result in a laser burn.

9. *REFLECTION WARNING*

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

10. *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.

11. *VAPOR PLUME*

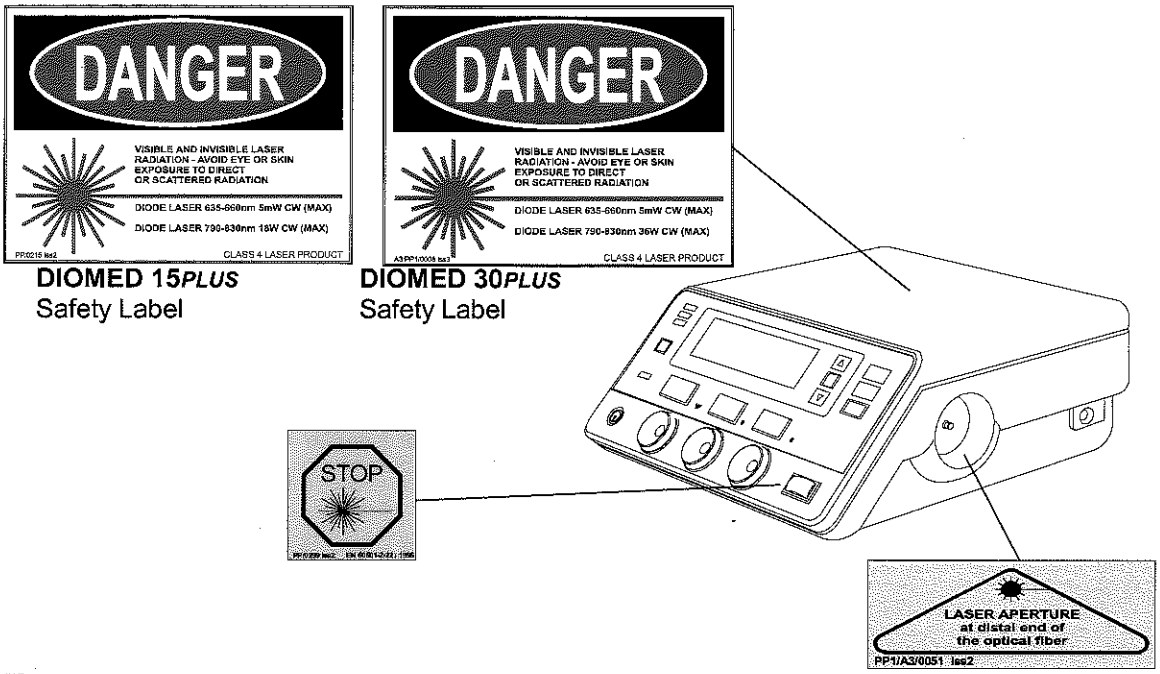
DIOMED recommends that a smoke evacuator or in-line filter be used when lazing.

Caution - Laser Plume may contain viable tissue particulates.

12. *SAFETY LABELING FOR THE DIOMED 15/30PLUS*

Figure 1 Location of Safety Labeling

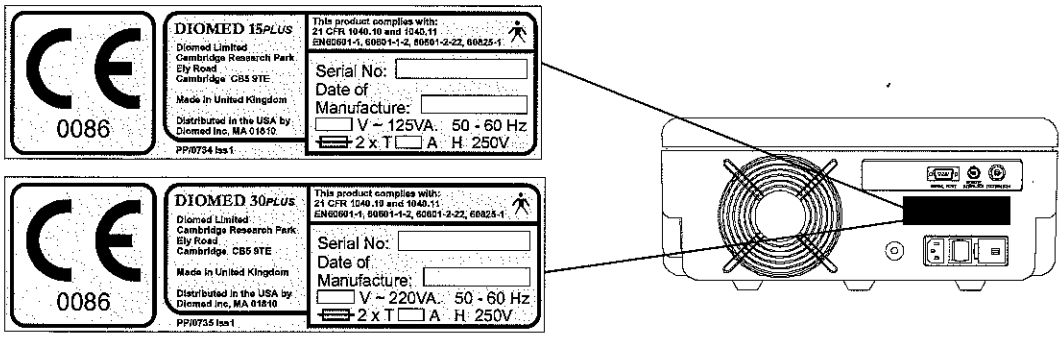
DIOMED 15/30*PLUS* safety labels are positioned as indicated.



DIOMED 15*PLUS*
Safety Label

DIOMED 30*PLUS*
Safety Label

Figure 2 Identification Labels



DIOMED 15/30*PLUS* Identification Labels

The identification label is located on the rear of the **DIOMED 15/30*PLUS*** laser.

13. SAFETY FEATURES OF THE DIOMED 15/30PLUS

The **DIOMED 15/30*PLUS*** includes a number of safety features, which are provided in accordance with the requirements of the appropriate standards. The **DIOMED 15/30*PLUS*** is built in compliance with:

European Harmonized Standards: EN 60601-1, EN 60601-1-2, EN 60601-2-22, EN 60825-1

USA Standards: FDA 21 CFR 1040.10, 1040.11

The **DIOMED 15/30*PLUS*** has the following safety features required to comply with these standards:

- protective housing
- remote interlock bypass
- key switch
- laser radiation emission indicator, visible (READY lights up) and audible (beep)
- **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
- calibration procedure for power measurement
- aiming beam

The **DIOMED 15/30*PLUS*** is equipped with the following additional safety features:

- self test
- time out (automatic return to **STANDBY** mode)
- laser condition monitoring
- pulse duration monitoring
- power diodes watch-dog
- microprocessor watch-dog
- mains power fail protection
- power supply monitor
- temperature monitors

14. *DESCRIPTION OF THE DIOMED 15/30PLUS*

Components

The **DIOMED 15/30*PLUS*** 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 radiation when in **READY** mode
- The handpiece or fiber for delivering the laser radiation to the tissue

15. *LOCATION OF CONTROLS*

Figure 3 Front and Side Panels

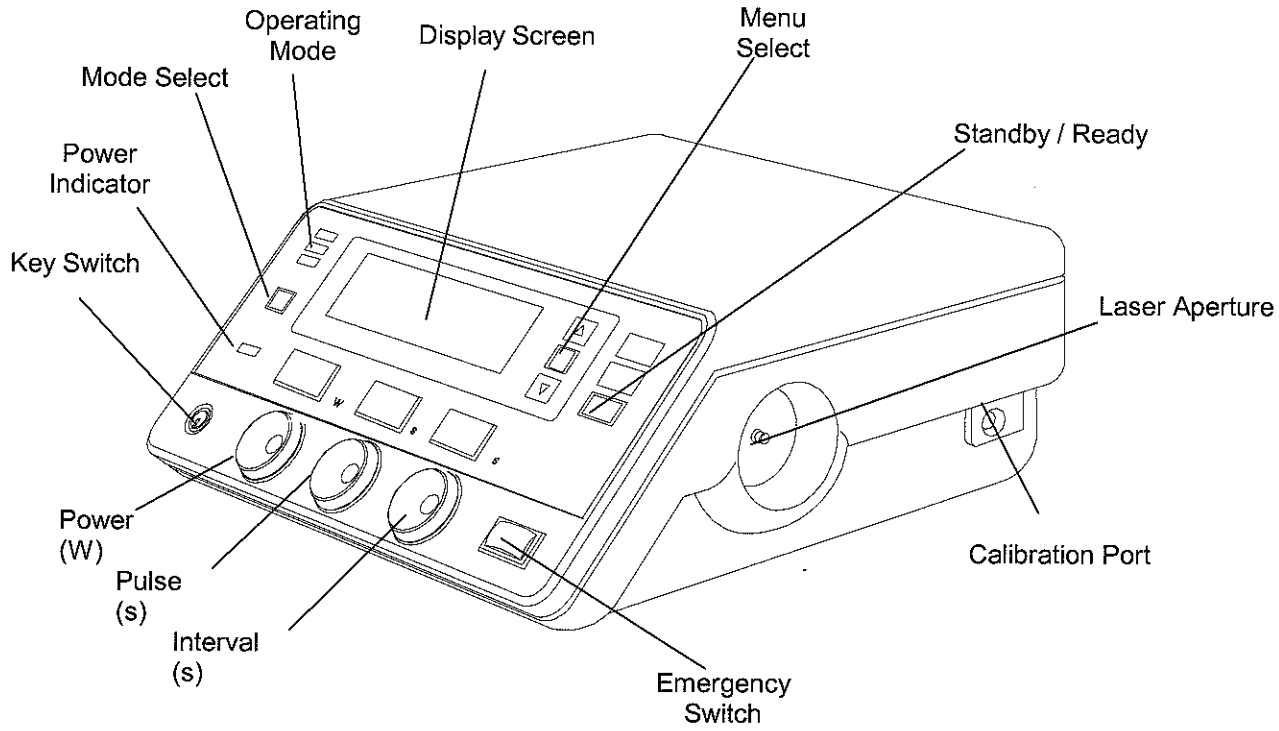
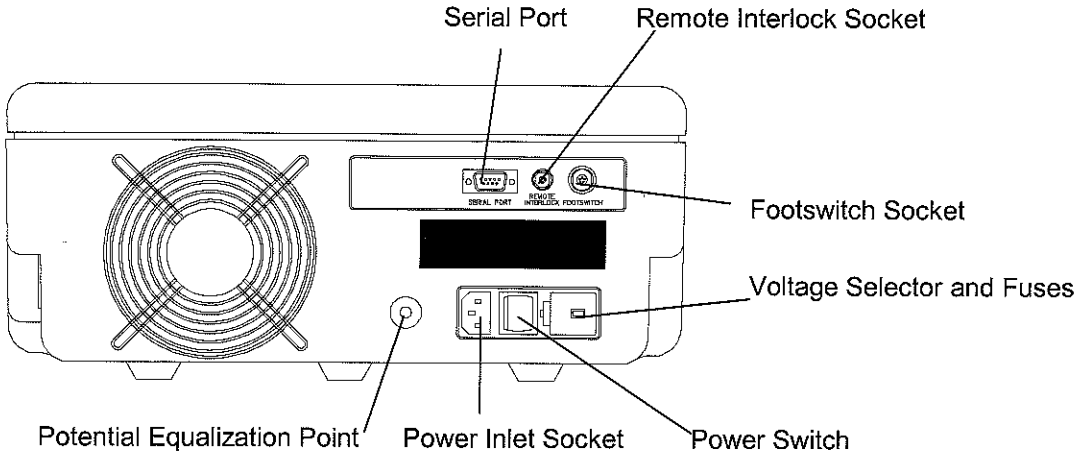


Figure 4 Rear Panel



16. *FRONT PANEL CONTROLS*

The main operating controls for the **DIOMED 15/30*PLUS*** diode laser are located on the front panel of the main enclosure. Figure 3 illustrates the control locations.

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 (emission indicator) starts flashing before the system enters **READY** mode. Flashing lasts two seconds. By pressing the button a second time, the system will return to **STANDBY** mode.

If the footswitch is pressed when **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.

Menu Select

To enable selection of Menu commands. Use the up (▲) and down (▼) keys to move between commands.

Display Screen

This displays all menu options and information.

Mode Select

To select the operating mode. Available modes are

- Continuous (not Spot Handpiece Mode)
- Pulse
- Repeat Pulse

The appropriate Operating Mode light will light up to indicate the mode selected.

Power Indicator

When the main power switch is ON, the Power Indicator light will be on, and power is being provided to the system.

Key Switch

The key switch is used to start the **DIOMED 15/30*PLUS*** 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. The key switch activates the self-test program.

DIOMED recommends that the keys are assigned to one or two key-holders, who should make the keys available for scheduled procedures only, thus preventing unauthorized use of the system.

Power (W)

Rotate the knob to increase or decrease the output power in all operating

Fiber Mode
0.5W to 5W in 0.5W increments
5W to maximum W in 1W increments
Spot Handpiece Mode
0.5W to maximum W in 0.1W increments

Pulse Duration (s)

Rotate the knob to increase or decrease the pulse duration in pulse and repeat pulse modes:

Fiber Mode
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 Mode
50 to 250 ms in 10 ms increments in single or repeat pulse mode (**DIOMED 15*PLUS***)
50 to 950 ms in 10 ms increments in single or repeat pulse mode (**DIOMED 30*PLUS***)

Interval (s)

Rotate the knob to increase or decrease the interval between the pulses in the repeat pulse mode:

Fiber Mode
0.1 to 1.0 seconds in 0.1 second increments
Spot Handpiece Mode
0.1 to 1.0 seconds in 0.1 second increments

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 emergency switch activation, the key switch must be used to restart the system.

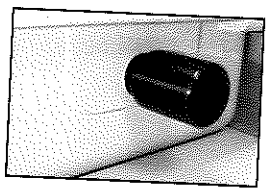
17. *SIDE PANEL CONNECTIONS*

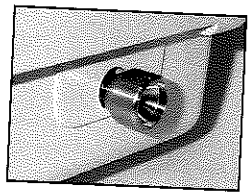
Laser Aperture

For the connection of the spot handpiece (Spot Handpiece Mode) or optical fiber (Fiber Mode) via an SMA-905 connector. Use only DIOMED approved or DIOMED labeled optical fibers. Damage caused by use of unapproved handpieces or fibers may invalidate the guarantee.

Calibration Port

A calibration port with adapter is provided on the side panel to calibrate the fixed focus spot handpieces. A separate adapter is provided to calibrate optical fibers.





18. *REAR PANEL CONTROLS*

Power Switch

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

Power Inlet Socket

To connect an IEC power cord.

Remote Interlock Socket

To connect the remote interlock cable connector. This will automatically turn the system to **STANDBY** mode in the event of the door being opened during the procedure.

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

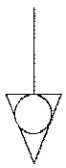
DIOMED supplies two remote interlock bypasses for facilities without or not wishing to use the door switch option. The **DIOMED 15/30*PLUS*** will not operate without the remote interlock bypass being inserted into the remote interlock socket on the rear of the laser.

Serial Port

To connect a remote terminal for use in Engineer Mode.

Potential Equalization Point

To connect possible potential equalization line, for common grounding between equipment(s), if needed.



Footswitch Socket

To connect the footswitch to the **DIOMED 15/30*PLUS***.

Voltage Selector

To select appropriate international main power voltages.

Fuses

2 x T4A H 250V.

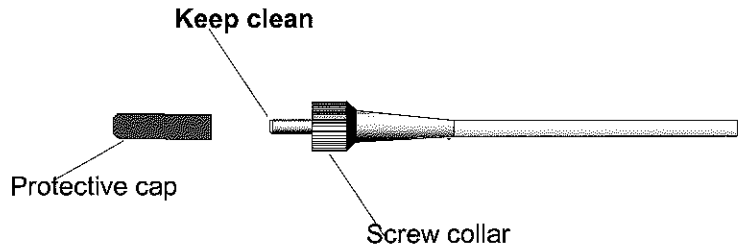
19. *LASER APERTURE FOR THE SPOT HANDPIECE OR OPTICAL FIBER*

Laser energy is delivered to the spot handpiece or optical fiber via the laser aperture located on the side panel of the **DIOMED 15/30*PLUS*** (Figure 3). The handpiece or fiber is connected to the laser aperture by means of an SMA-905 type optical fiber connector.

20. *OPTICAL FIBER CONNECTOR*

Inserting the Optical Fiber Connector

To insert the optical fiber connector, remove the protective cap from the end of the optical fiber, insert the optical fiber connector into the laser aperture on the **DIOMED 15/30*PLUS*** and rotate the screw collar until secured in place (finger tight only).



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

Removing the Optical Fiber Connector

To remove the optical fiber connector, rotate the screw collar of the connector until unscrewed fully and disconnect from the laser aperture. Immediately fit a protective cap over the end of the optical fiber to protect the optical surface from contamination.

21. *INSTALLATION*

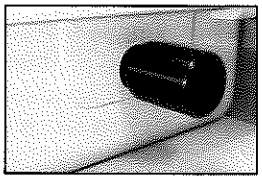
Installation of the **DIOMED 15/30*PLUS*** can be carried out by the end user.

Inspection

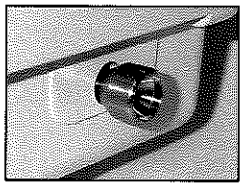
Inspect the **DIOMED 15/30*PLUS*** and contents for signs of damage. If the unit is damaged **DO NOT USE**; contact DIOMED or your local DIOMED distributor. If there are no signs of damage and all components are present, assemble the **DIOMED 15/30*PLUS***.

Components

- **DIOMED 15/30*PLUS*** Laser unit
- Footswitch
- IEC Power cable
- Fixed Focus Spot Handpiece Calibration Port Adapter



- Optical Fiber Calibration Port Adapter



- 2 x Remote Interlock bypass connectors

- 2 x Keys
- 10 x T4A fuses
- Operator Manual

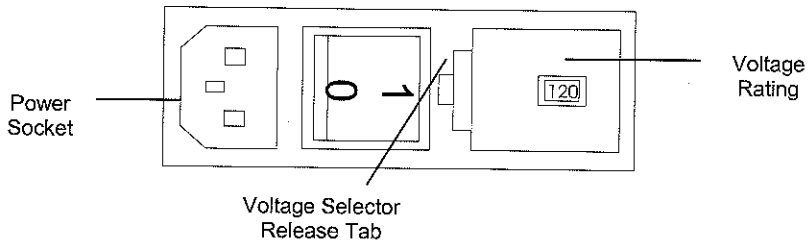
Optional extras

- ∅ 2mm fixed focus Spot Handpiece
- ∅ 4mm fixed focus Spot Handpiece (**DIOMED 30*PLUS*** only)

Installing the DIOMED 15/30*PLUS*

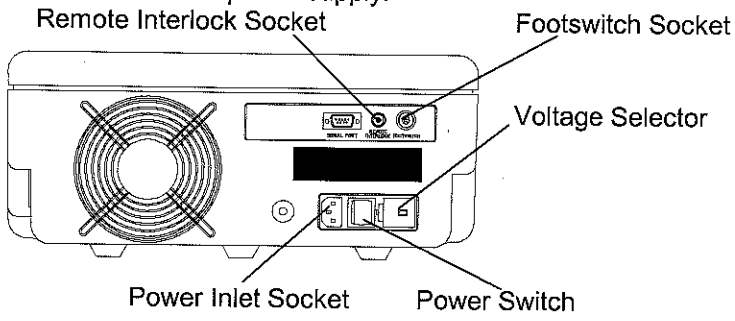
Before connecting the unit to the main power outlet, ensure that the voltage selector at the rear of the unit is set to the correct voltage for the USA (120V).

Ensure the voltage selector is set correctly.



a) Insert a small flat-headed screwdriver into voltage selector release tab and pry the assembly out.
b) This assembly contains two fuses. These should be rated 4A for the USA.
c) Pry out the inner right side assembly.
d) Rotate the assembly such that the voltage rating facing towards the user reads 120 for the USA.
e) Replace the assembly in this position.
f) Replace the fuse assembly.
g) The unit is now set for use in the USA.

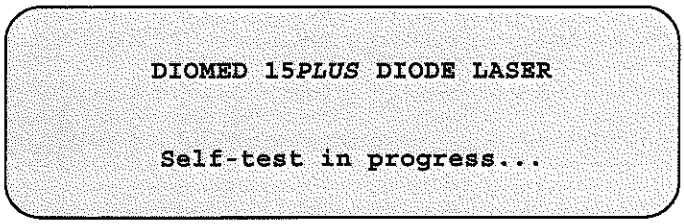
1. Connect the footswitch to the footswitch socket (line up red dots and insert).
2. Connect a remote interlock bypass connector to the remote interlock socket (line up red dots and insert).
3. Connect the ∅ 2mm Spot Handpiece or the optical fiber to the laser aperture using the optical fiber connector. **The ∅ 4mm Spot Handpiece may be used with the DIOMED 30*PLUS* laser only.**
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 15/30*PLUS*** is now installed and ready for use.

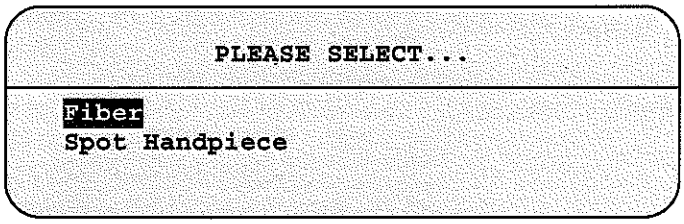
22. *START-UP AND SELF TEST*

When the **DIOMED 15/30*PLUS*** is turned ON with the key switch, the system performs a self-test function to ensure that **DIOMED 15/30*PLUS*** is connected and operating correctly. The display will show a screen similar to the following:

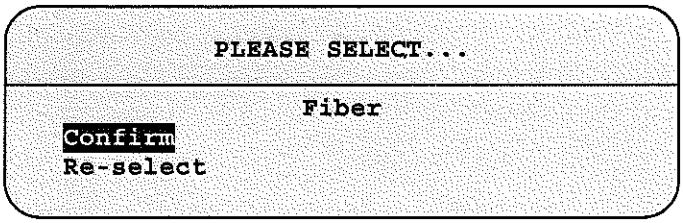


Whilst the self-test program is running, ensure that all the LED segments for Power, Pulse and Interval are illuminated.

After successful completion of the self-test, or when a fiber or handpiece is disconnected and reconnected, the following screen will be displayed:



Use the ▲ and ▼ keys to select 'Fiber' or 'Spot Handpiece' as required, and press **SELECT**. The following screen will be displayed:



Highlight 'Confirm' and press **SELECT** to confirm the selection or highlight 'Re-select' and press **SELECT** to return to the previous screen.

If an Optical Fiber is to be used, refer to Section 23.

If a Spot Handpiece is to be used, refer to Section 25.

23. *FIBER MODE*

Section 23 relates to the Fiber Mode. If using a Spot Handpiece, disconnect and re-connect a Spot Handpiece, and select and confirm 'Spot Handpiece' when prompted by the display. Refer to section 25 for instructions on using Spot Handpiece Mode.

Menus

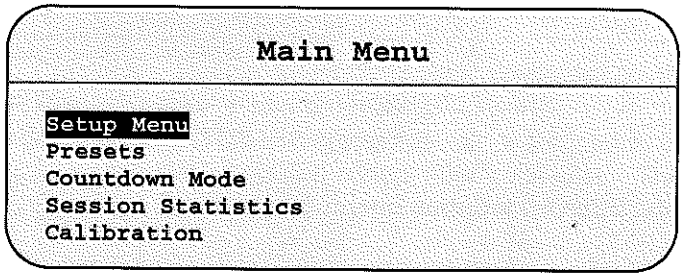
The Menu selection on the Liquid Crystal Display (LCD) panel is used to select, adjust and display different operating functions of the system. Functions are selected and/or adjusted from the display menu using the three keys (**▲/SELECT/▼**) shown in Figure 2, located on the right hand side of the display.

The required function can be highlighted by using the ▲ and ▼ keys and then activated by pressing the **SELECT** key. By pressing **SELECT** again the previous menu will be displayed. Normally the clock will be displayed and the display, by default, automatically returns to the clock mode after one minute without use (except in the Countdown and Engineer Modes and when displaying Statistics).

The display provides all the information needed to make the selections or adjustments. This display also provides the user with all the information on the system faults.

Main Menu (Default Menu)

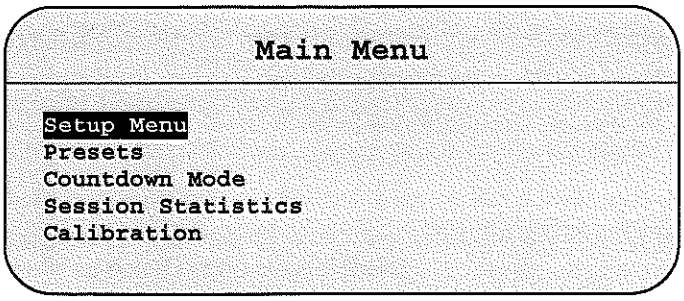
Press **SELECT** from the clock display to access the Main Menu. The Main Menu provides access to all sub-menus.



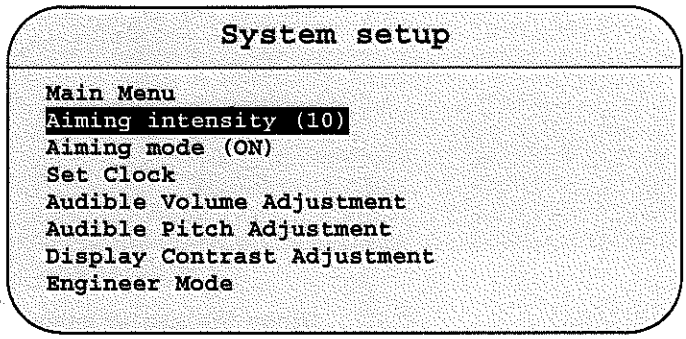
Fiber Mode

System Setup Menu

The System Setup Menu enables the user to adjust the settings of certain operating functions of the laser. To access this menu press ▲ or ▼ until 'Setup Menu' is highlighted in the Main Menu and then press **SELECT**.



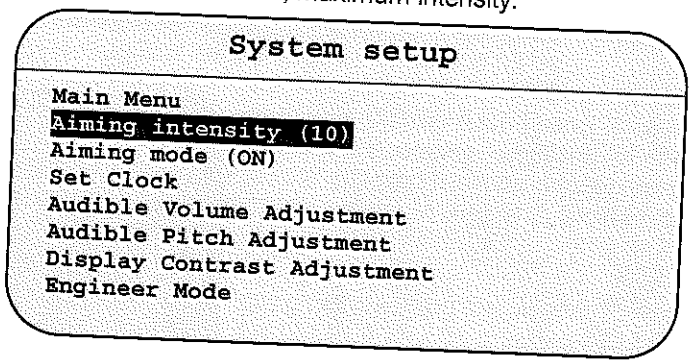
To access any of the functions within the System Setup press ▲ or ▼ until the function is highlighted and then press **SELECT**.



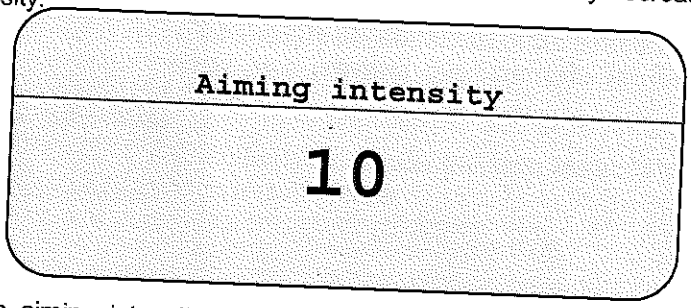
Fiber Mode

Aiming Intensity

This menu enables the user to set the aiming beam intensity in ten linear steps (1-10), where 10 is the maximum intensity. The system default for the Fiber mode is '10', maximum intensity.



Select this function by highlighting 'Aiming Intensity' and pressing **SELECT**. The ▲ key increases the intensity and the ▼ key decreases the intensity.



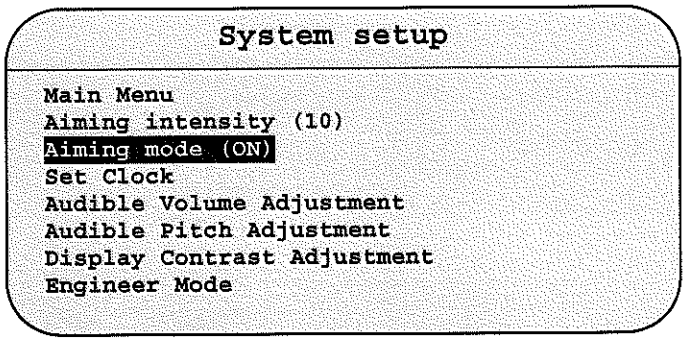
When the aiming intensity is at the desired level, press **SELECT** to return to the System Setup Menu.

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

To observe the intensity of the aiming beam, place the DIOMED 15/30PLUS 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.

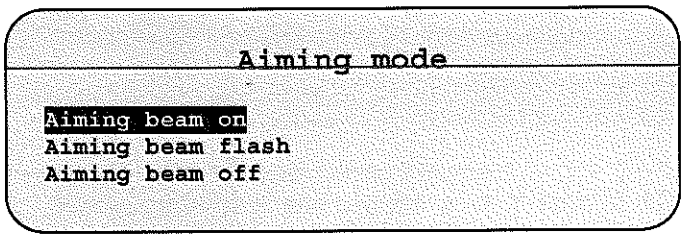
Fiber Mode

Aiming Mode



This menu enables the user to select the mode for the aiming beam. The currently selected option is highlighted.

Pressing ▲ or ▼ moves the highlight and **SELECT** activates the highlighted mode.

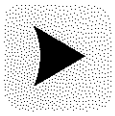


If **ON** (default) is selected, the aiming beam is on continuously when in **READY** Mode.

If **OFF** is selected, the aiming beam is turned off and the value of aiming beam intensity is ignored.

If **FLASH** is selected, the aiming beam will flash 0.25 second on, 0.25 second off when in **READY** Mode.

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.

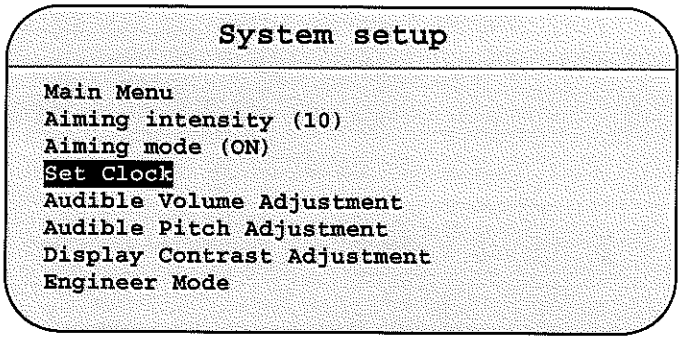


To observe the different modes of the aiming beam, place the DIOMED 15/30*PLUS* into READY mode by pressing the STANDBY/READY key. The aiming beam will be activated if ON or FLASH is selected. For safety, it is not possible to fire the laser in READY state at this menu.

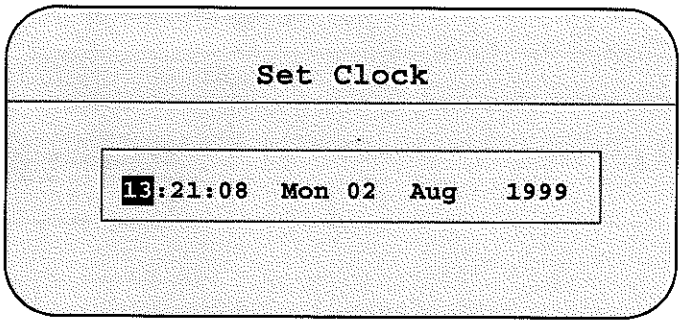
Fiber Mode

Set Clock

This menu is used to adjust and set the clock.



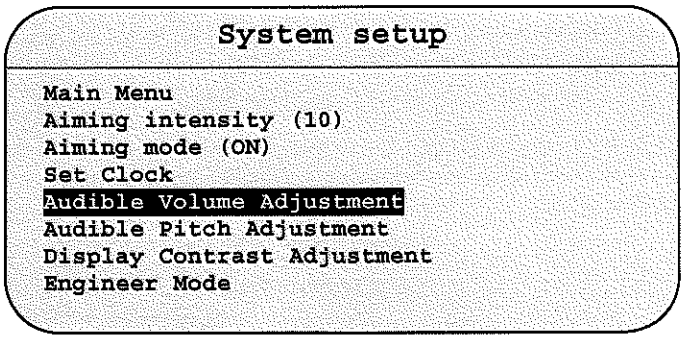
Select 'Set Clock' from the System Setup menu and the Set Clock function will be displayed. The hour text is highlighted.



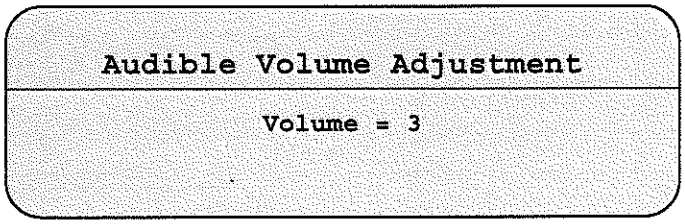
The ▲ and ▼ keys change the hour, and the **SELECT** key moves the highlight through the time and date configuration from minute to year allowing for timing adjustments to be implemented. When the highlight reaches the year option and the **SELECT** key is pressed, the unit will return to the System Setup menu.

Fiber Mode

Audible Volume Adjustment



This menu is used to adjust the audible volume of the buzzer heard when the laser is firing.

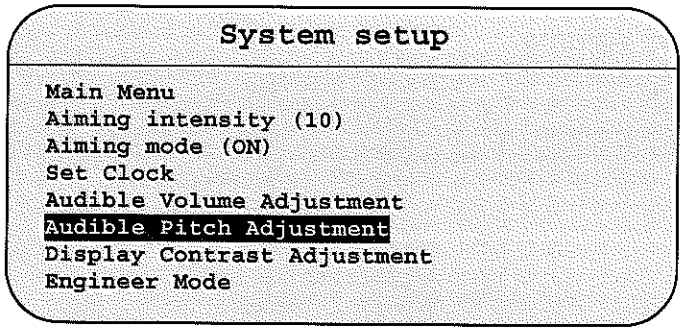


There are three volume adjustments: Volume 1 – 2 – 3. Select 'Audible Volume Adjustment' and use the ▲ or ▼ keys to adjust to the volume required. Once the volume required is selected, press the **SELECT** key to return to the System Setup menu.

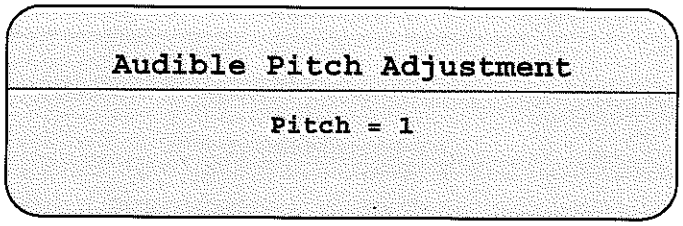
The volume setting will be demonstrated as the selection is made. The volume setting chosen is then stored in the memory and retained when the laser is switched off. The next time the laser is switched on, the audible volume will return to this setting. If a subsequent change in volume is required, this procedure must be repeated.

Fiber Mode

Audible Pitch Adjustment



This menu is used to adjust the audible pitch of the buzzer heard when the laser is firing.

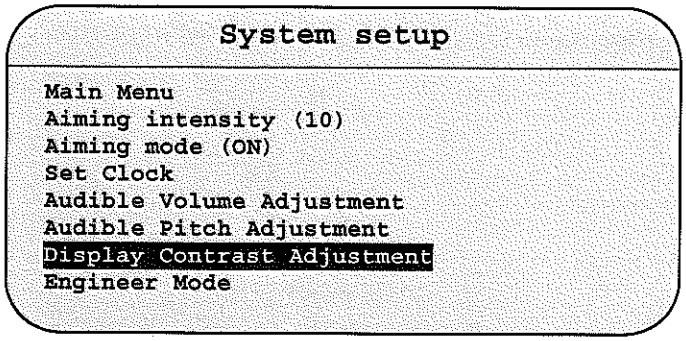


There are three pitch adjustments: Pitch 1 – 2 – 3. Select 'Audible Pitch Adjustment' and use the ▲ or ▼ keys to adjust to the pitch required.

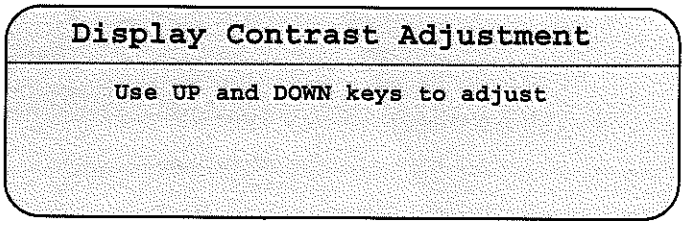
Once the pitch required is selected, press the **SELECT** key to return to the System Setup menu. The pitch setting will be demonstrated as the selection is made. The pitch chosen is then stored in the memory and retained when the laser is switched off. The next time the laser is switched on, the audible pitch will return to this setting. If a subsequent change in pitch is required, this procedure must be repeated.

Fiber Mode

Display Contrast Adjustment



This menu is used to adjust the contrast of the Liquid Crystal Display (LCD). Select 'Display Contrast Adjustment' and use the ▲ or ▼ keys to adjust the contrast of the display to the level required.

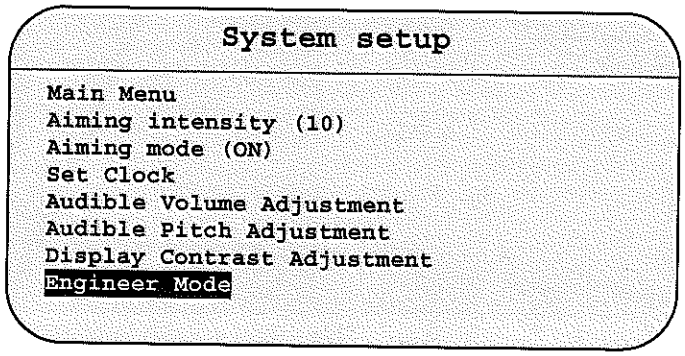


Once the contrast required is selected, press **SELECT** to return to the System Setup menu.

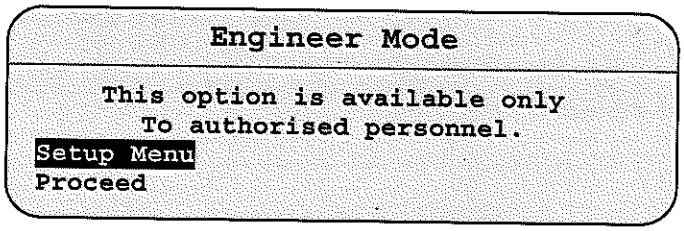
The contrast chosen is then stored in the memory and retained when the laser is switched off. The next time the laser is switched on the contrast will return to this setting. If a subsequent change in display contrast is required, this procedure must be repeated.

Fiber Mode

Engineer Mode



This menu gives access to the Engineer Interface, which is password-protected and available only to authorized personnel.



If the 'Setup Menu' option is selected, the unit returns to the System Setup Menu immediately.

Select 'Proceed' to enter a password on a remote terminal, to operate the engineer interface.

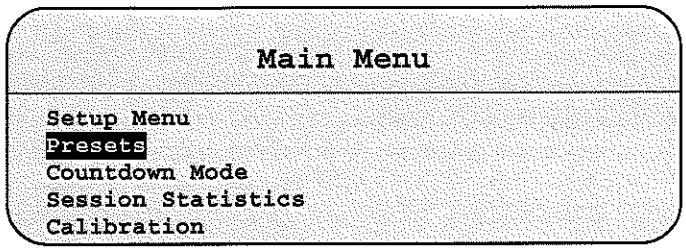
Passwords are only distributed to DIOMED authorized service personnel.

If 'Proceed' is selected and a password is not entered or entered incorrectly, the system will return to the System Setup menu.

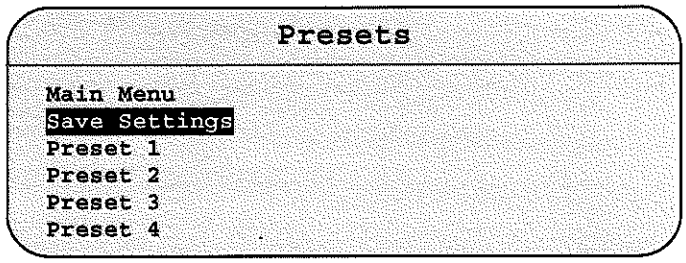
Fiber Mode

Presets

Select 'Presets' from the Main Menu by using the ▲ or ▼ keys and pressing **SELECT**.



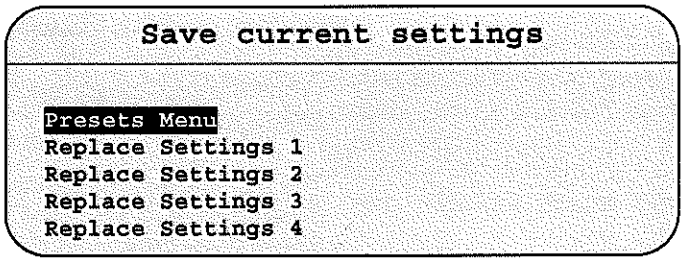
The Presets function is provided to enable the user to store up to 4 preferred or frequently used settings.

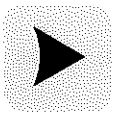


To view a Preset Setting use the ▲ or ▼ keys and the set values will be displayed. To use a Preset Setting, choose the Preset number required and press **SELECT**. The previously saved settings will be automatically set.

To store a Preset:

1. Adjust the power, pulse, interval, aiming mode and aiming intensity to the desired levels
2. Select 'Save Settings'
3. Save the parameters in Preset 1, 2, 3 or 4 by selecting 'Replace Settings'. This will overwrite any previously saved settings at that location.





Settings saved in Spot Handpiece mode and recalled in Fiber Mode will be coerced into the nearest compatible setting.

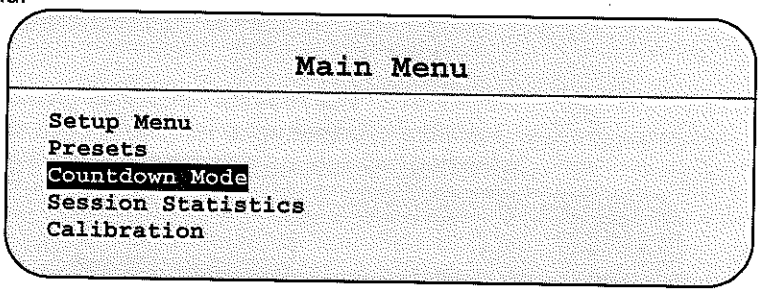
Fiber Mode

Countdown Mode

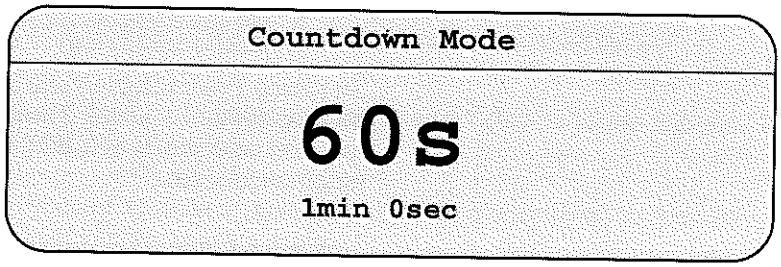
Countdown mode enables the user to select longer CW exposure times than the maximum 9.9 seconds allowed when using the pulse mode control.

The programmed default time is 60 seconds but the time can be adjusted between 10 seconds to 3200 seconds using ▲ and ▼ keys.

To activate Countdown Mode select 'Countdown Mode' from the Main Menu:



The following screen will be displayed:



To continue, press **STANDBY/READY** and when the laser enters **READY** mode, press the footswitch to start treatment.

The display counts down until zero is reached or the footswitch is released. To restart the countdown after the footswitch has been released press the footswitch and the countdown will resume.

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 Main Menu, by pressing **SELECT**, or the countdown time has been completed.

By returning to the Main Menu, any remaining countdown time will be lost.

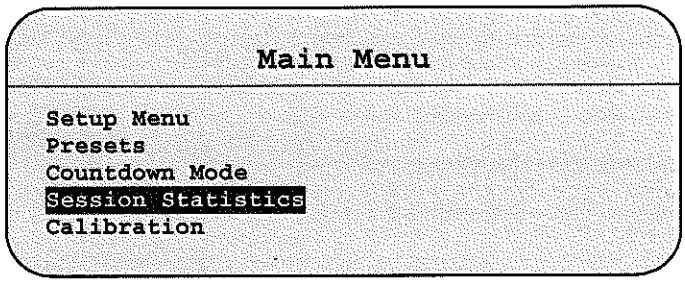
Fiber Mode

Session Statistics

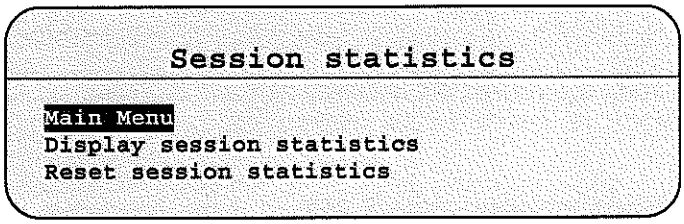
Statistics can be defined as a summary of the laser energy delivered and is recorded fully for the time that the **DIOMED 15/30*PLUS*** is switched on. Statistics will be displayed as the amount of joules of energy delivered.

Each time the treatment parameters are changed, the 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 not stored in the DIOMED 15/30*PLUS* memory and will be erased from the display when the DIOMED 15/30*PLUS* is switched OFF.



From the Main Menu, use the ▲ or ▼ keys to select 'Session Statistics' and press **SELECT**. The following screen will be displayed:



Use the ▲ or ▼ keys to select 'Display session statistics' and press **SELECT**. Details of the selected mode, exposure time, power and energy used will be shown on the display. Press **SELECT** again to return to the previous screen.

To reset the current session to zero, highlight 'Reset session statistics' and press **SELECT**.

To return to the Main Menu highlight 'Main Menu' and press **SELECT**.

Fiber Mode

Calibration

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

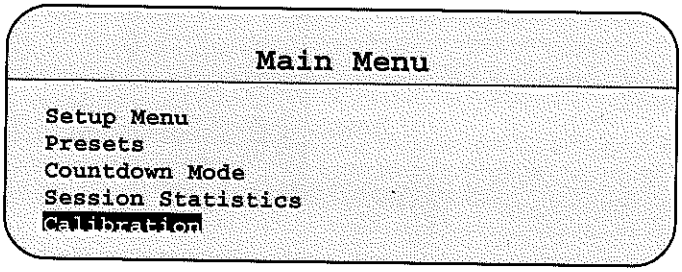
When calibration is carried out, the displayed power will be the power at the distal end of the fiber.

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

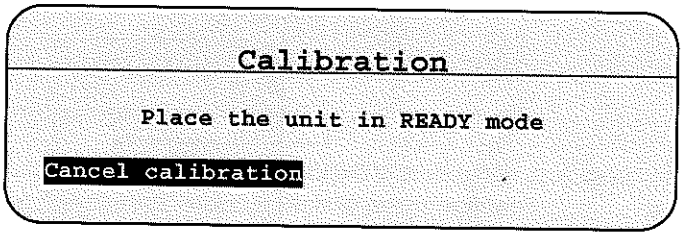
Ensure all personnel are wearing approved safety eyewear.

To calibrate

Use the ▲ or ▼ keys to select 'Calibration' from the Main Menu and press **SELECT**.

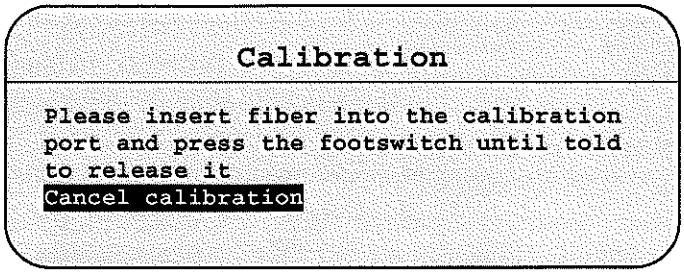


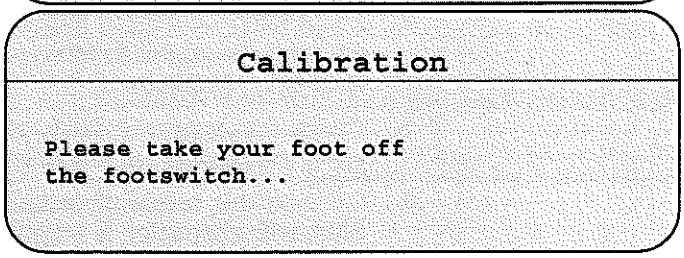
The following screen will be displayed:



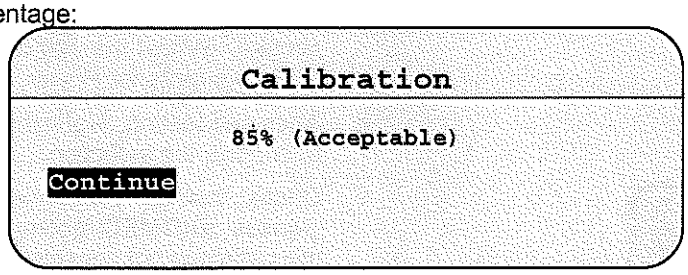
Selecting 'Cancel calibration' will return the user to the Main Menu leaving the fiber uncalibrated.

1. Screw in the optical fiber calibration port adapter. (The adapter should be sterilized to maintain fiber sterility).
2. Guide the fiber into the calibration port using the optical fiber calibration port adapter provided.
3. Place the **DIOMED 15/30*PLUS*** in **READY** mode.
4. Follow the instructions on screen.
5. Fire the **DIOMED 15/30*PLUS*** by pressing the footswitch until release is indicated on the display.





The screen will display the fiber acceptability and transmission percentage:



6. To proceed, highlight 'Continue' and press **SELECT** to return to the Main Menu.

Transmission Acceptability

The **DIOMED 15/30*PLUS*** will calculate the percentage transmission of the fiber system, and the results will be shown 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.

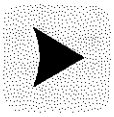
Calibration will be canceled if:

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

24. *OPERATING INSTRUCTIONS – FIBER MODE*

1. Place the **DIOMED 15/30*PLUS*** in a convenient position on an instrument table no farther than 6 feet (1.8 meters) from the patient. Ensure that all controls are within easy reach of the operator.
2. Connect the electrical power cord to the main power outlet.
3. Connect the footswitch and place in a convenient position for the operator.
4. 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 15/30*PLUS***.
5. Check that approved safety glasses are available and laser-warning signs are provided at entrances to the treatment room.
6. Connect the optical fiber to the laser aperture, ensuring that the SMA-905 connector is screwed 'finger tight'. Read instructions in Section 34 relating to pre-carbonization of fiber tips and application of fibers to tissue prior to commencing the operating procedure.
7. Turn on the power switch and key switch to activate the control circuits. Whilst the self-test program is running, ensure that all the LED segments for Power, Pulse and Interval are illuminated.
8. After self-testing, highlight 'Fiber', press **SELECT**. Press **SELECT** to confirm the selection.

9. Check that all personnel present are wearing approved safety glasses. DIOMED recommends that patient's eyes are taped shut, if the patient is not conscious.
10. The system will automatically go to **STANDBY** mode, with a default setting of continuous operating mode and 10W power.
11. If a non-contact fiber has been selected, select 'Calibration' from the Main Menu screen and follow the on-screen instructions to calibrate the fiber.



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

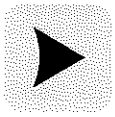
CONTACT FIBERS DO <u>NOT</u> REQUIRE CALIBRATING.

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.

12. After calibration has been carried out successfully, set the Operating Mode, Power, Pulse Length and Pulse Interval or Fluence as required for the particular treatment.
13. Guide the optical fiber to the operating field and check that the gas or fluid cooling is provided (if a gas/fluid assist fiber is being used).
14. To start treatment and delivery of laser energy, press **READY/STANDBY**, wait for the **DIOMED 15/30*PLUS*** to enter **READY** mode and depress the footswitch. An audible warning will be heard during laser irradiation.

NOTE: The **DIOMED 15/30*PLUS*** will automatically return to **STANDBY** if treatment is paused for 3 minutes.

15. To turn the **DIOMED 15/30*PLUS*** **OFF** turn the key switch and remove the key.



If an error message is displayed, refer to Section 27.

25. *SPOT HANDPIECE MODE*

Section 25 relates to the Spot Handpiece Mode. If using an Optical Fiber, disconnect and re-connect an optical fiber, and select and confirm 'Fiber' when prompted by the display. Refer to Section 23 for instructions on using Fiber Mode.

Fixed Focus Spot Handpiece

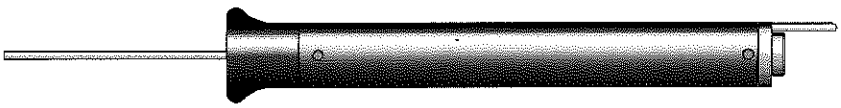
The handpiece delivery system consists of a sleeved optical fiber, with an optical fiber connector at one end and a handpiece at the other.

The handpiece has a user replaceable protective lens.

CAUTION

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.

A ∅ 2mm fixed focus Spot Handpiece is available separately for use with the **DIOMED 15/30*PLUS***.



∅ 2mm fixed focus Spot Handpiece, color-coded blue for identification, delivers a 2mm diameter beam of laser energy.

A ∅ 4mm fixed focus Spot Handpiece (not illustrated) is available separately for use with the **DIOMED 30*PLUS*** only. The ∅ 4mm fixed focus Spot Handpiece is color-coded yellow for identification, and delivers a 4mm diameter beam of laser energy.

New handpieces are supplied with the fiber fitted.

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.

WARNING

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).

CAUTION

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

Spot Handpiece Mode

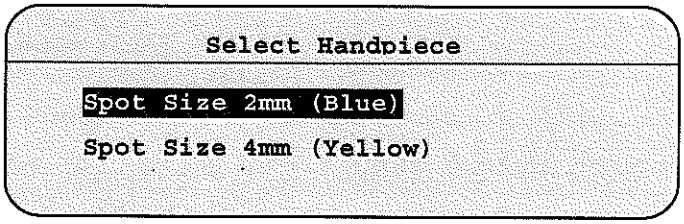
Handpiece Selection

After completion of the self-test function on the **DIOMED 15/30*PLUS***, select 'Spot Handpiece' and confirm the selection. The **DIOMED 15*PLUS*** will automatically select the ∅ 2mm fixed focus Spot Handpiece.

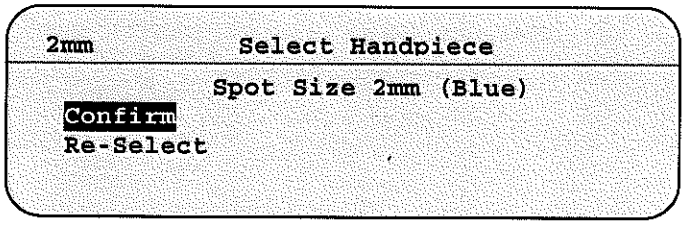
Handpiece Selection for the DIOMED 30*PLUS*

In order for the correct handpiece spot size to be made when using the **DIOMED 30*PLUS*** system, the user must select and confirm the handpiece in use before the **DIOMED 30*PLUS*** system will operate. Handpiece selection will need to be made each time the user switches on the **DIOMED 30*PLUS*** laser, when a handpiece is disconnected or after using the Engineering Interface.

It is essential that the correct spot size is selected. Failure to comply will result in incorrect Fluence levels.



Use the ▲ and ▼ keys to highlight the correct handpiece spot size and press **SELECT**. The following screen will be displayed:



To confirm selection press **SELECT**. To change the selection, use the ▼ key and press **SELECT**. This will display the previous menu. After confirmation the Main Menu screen will be displayed.

All subsequent screens will now display the spot size selected in the top left hand corner of the screen.

Spot Handpiece Mode

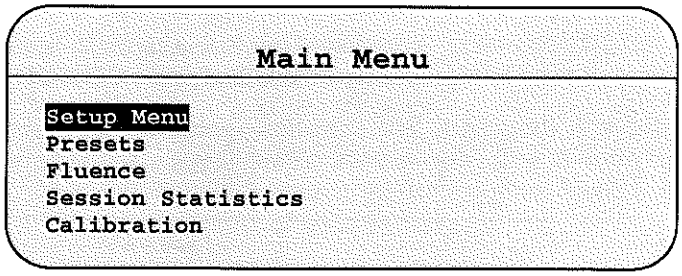
Menus

The Menu selection on the Liquid Crystal Display (LCD) panel is used to select, adjust and display different operating functions of the system. Functions are selected and/or adjusted from the display menu using the three keys (▲/**SELECT**/▼) (shown in Figure 2) located on the right hand side of the display.

The required function should be highlighted by using the ▲ and ▼ keys and then activated by pressing the **SELECT** key. Press **SELECT** again to display the previous menu. Normally the clock will be displayed, and the display, by default, automatically returns to the clock mode after one minute without use, except in the Engineer Mode, when displaying Statistics, when calibrating, selecting a handpiece or displaying Fluence. The display provides all the information needed to make the selections or adjustments. This display also provides the user with all the information on the system faults.

Main Menu (Default Menu)

Press **SELECT** from the clock display to access the Main Menu. The Main Menu provides access to all sub-menus.

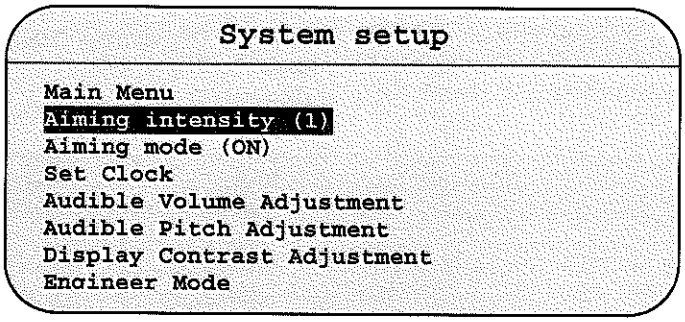


System Setup Menu

The System Setup Menu enables the user to adjust the settings of certain operating functions of the laser. To access this menu press ▲ or ▼ until 'Setup Menu' is highlighted in the Main Menu and press **SELECT**.

Spot Handpiece Mode

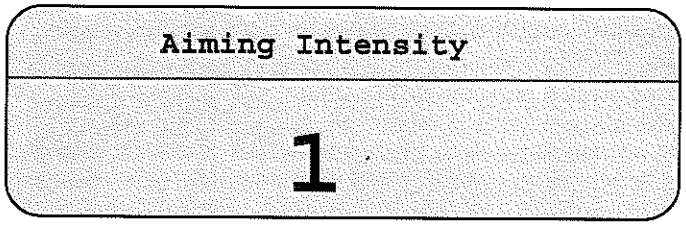
To access any of the functions within the Setup Menu, use the ▲ and ▼ keys to highlight the desired function. Press **SELECT**.

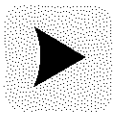


Aiming Intensity

This menu enables the user to set the aiming beam intensity in ten linear steps (1-10). Select this function by highlighting 'Aiming Intensity' and pressing **SELECT**.

The ▲ key increases the intensity and the ▼ key decreases the intensity. Press **SELECT** to return to the System Setup Menu. Note that the intensity adjustment will be ignored if the aiming mode is **OFF**. The system defaults to Aiming intensity '1', minimum intensity, in the Spot Handpiece mode.



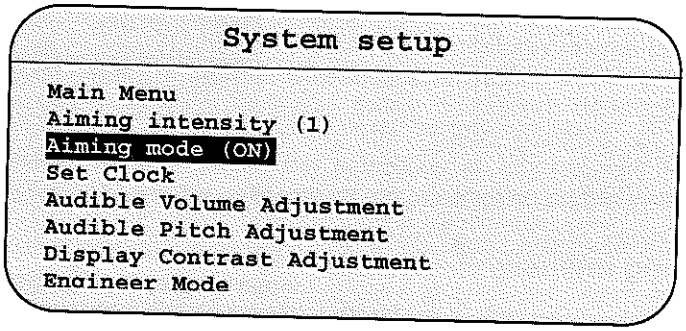


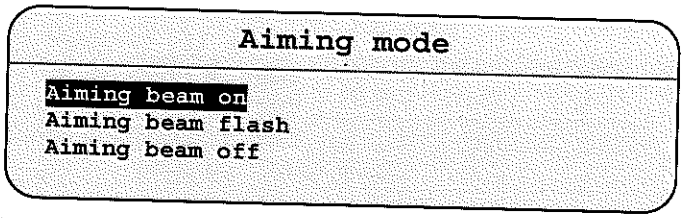
To observe the intensity of the aiming beam place the **DIOMED 15/30PLUS** into **READY** state by pressing the **STANDBY/READY** key. The aiming beam will be activated. **For safety it is not possible to fire the laser in READY state at this menu.**

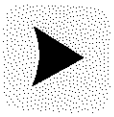
Spot Handpiece Mode

Aiming Mode

This menu enables the user to select the mode for the aiming beam. The currently selected option is highlighted. Use the ▲ and ▼ keys to highlight 'Aiming Mode' and press **SELECT**. If **ON** (default) is selected, the aiming beam is on continuously. If **OFF** is selected the aiming beam is turned off and the value of aiming beam intensity is ignored. If **FLASH** is selected, the aiming beam will flash 0.25 second on, 0.25 second off. The system default is 'Aiming beam on'.





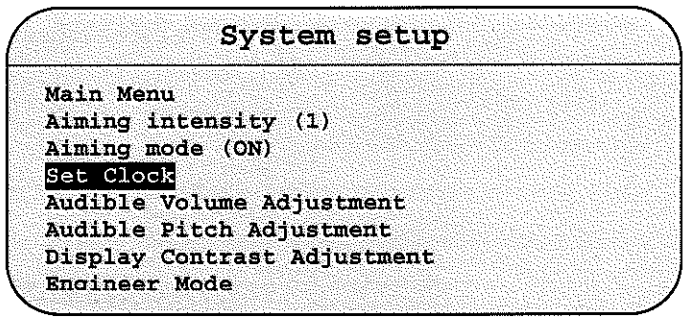


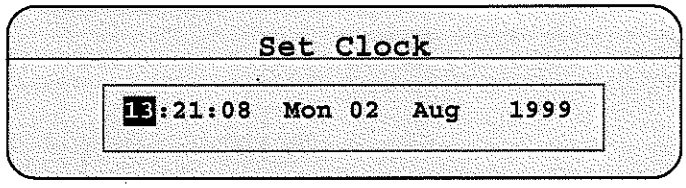
To observe the different modes of the aiming beam place the **DIOMED 15/30*PLUS*** into **READY** state by pressing the **STANDBY/READY** key. The aiming beam will be activated if **ON** or **FLASH** is selected. **For safety it is not possible to fire the laser in READY state at this menu.**

Spot Handpiece Mode

Set Clock

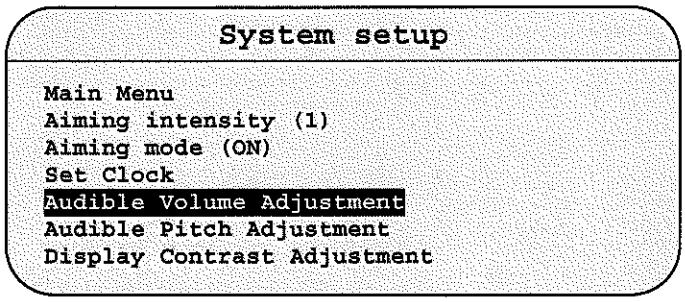
This menu is used to set the clock. When 'Set Clock' is selected, the highlight starts from the hour. The ▲ and ▼ keys change the hour, and the **SELECT** key moves the highlight through the date configuration from minute to year allowing for timing adjustments to be implemented. When the highlight reaches the year option and the **SELECT** key is pressed, the unit will return to the System Setup menu.

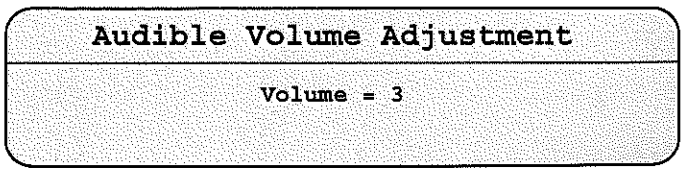




Audible Volume Adjustment

This menu is used to adjust the volume of the buzzer heard when the laser is firing. There are three volume adjustments: Volume 1 – 2 – 3. Select 'Audible Volume Adjustment' and use the ▲ or ▼ keys to adjust to the volume required. Press the **SELECT** key to return to the System Setup menu. The volume setting will be demonstrated as the selection is made. The volume setting chosen is then stored in the memory and retained when the laser is switched off. The next time the laser is switched on, the audible volume will return to this setting. If a subsequent change in volume is required, this procedure must be repeated.

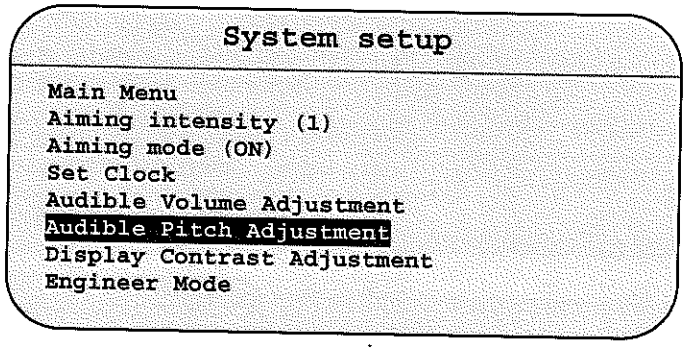


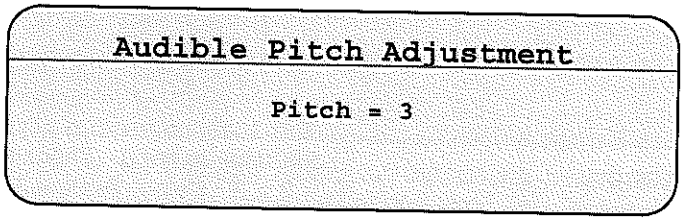


Spot Handpiece Mode

Audible Pitch Adjustment

This menu is used to adjust the audible pitch of the buzzer heard when the laser is firing. There are three pitch adjustments: Pitch 1 – 2 – 3. Select 'Audible Pitch Adjustment' and use the ▲ or ▼ keys to adjust to the pitch required. Press the **SELECT** key to return to the System Setup menu. The pitch setting will be demonstrated as the selection is made. The pitch chosen is then stored in the memory and retained when the laser is switched off. The next time the laser is switched on, the audible pitch will return to this setting. If a subsequent change in pitch is required, this procedure must be repeated.

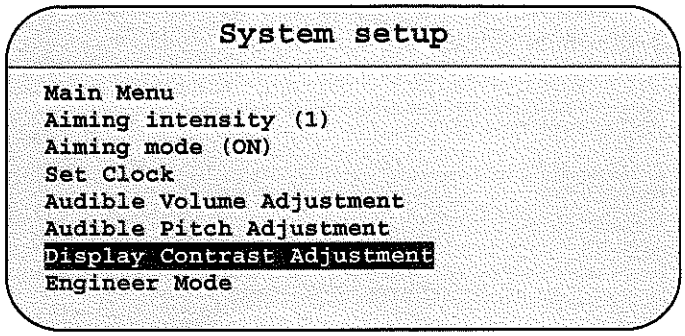


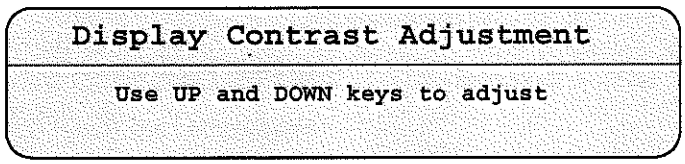


Spot Handpiece Mode

Display Contrast Adjustment

This menu is used to adjust the contrast of the Liquid Crystal Display (LCD). Select 'Display Contrast Adjustment' and use the ▲ or ▼ keys to adjust the contrast of the display to the level required. Press **SELECT** to return to the System Setup menu. The contrast chosen is stored in the memory and retained when the laser is switched off. The next time the laser is switched on the contrast will return to this setting. If a subsequent change in display contrast is required, this procedure must be repeated.

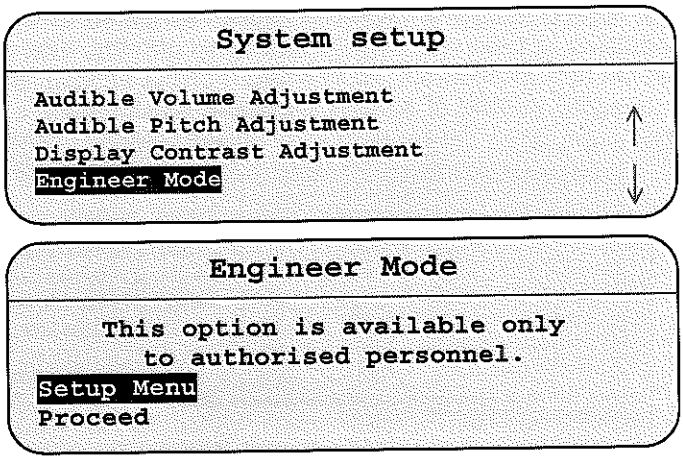




Spot Handpiece Mode

Engineer Mode

This menu gives access to the Engineer Interface, which is password-protected and available only to authorized personnel. If the 'Setup Menu' option is selected, the unit returns to the System Setup Menu immediately.



Select 'Proceed' to enter a password on a remote terminal, to operate the Engineer Interface.

Passwords are only distributed to DIOMED authorized service personnel.

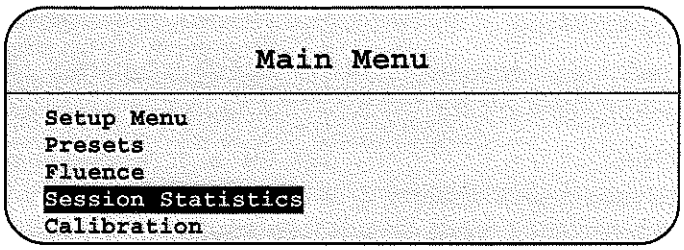
If 'Proceed' is selected and a password is not entered, or entered incorrectly, the system will return to the System Setup Menu.

Spot Handpiece Mode

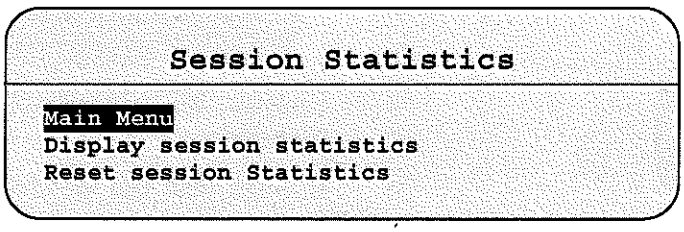
Statistics

Statistics can be defined as a summary of the laser energy delivered and is recorded fully for the time that the **DIOMED 15/30*PLUS*** is switched on. Statistics will be displayed as the amount of joules of energy delivered. Each time the treatment parameters are changed the 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 this screen.

Session statistics are not stored in the DIOMED 15/30*PLUS* memory and will be erased from the display when the DIOMED 15/30*PLUS* is switched OFF.



From the Main Menu, use the ▲ or ▼ keys to select 'Session Statistics' and press **SELECT**. The following screen will be displayed:



Use the ▲ or ▼ keys to select 'Display Session Statistics' and press **SELECT**. Details of the selected mode, exposure time, power and energy used will be shown on the display. Press **SELECT** to return to the previous screen.

To reset the current session to zero, select 'Reset Session Statistics' and press **SELECT**.

To return to the Main Menu, highlight 'Main Menu' and press **SELECT**.

Spot Handpiece Mode

Calibration

Calibration for the **DIOMED 15/30*PLUS*** 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.

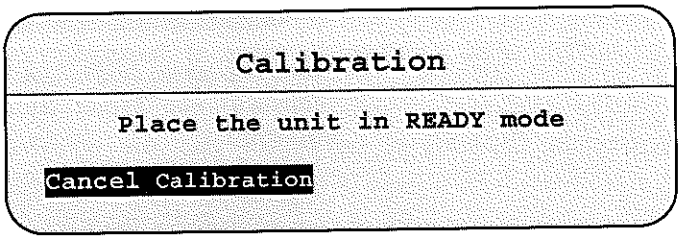
The DIOMED 15/30*PLUS* system will default to the Calibration Menu if the handpiece has not been calibrated.

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

To Calibrate

Use the ▲ or ▼ keys to select 'Calibration' from the Main Menu and press **SELECT**. The following screen will be displayed:



Ensure all personnel are wearing approved safety glasses.

Ensure that the window cell / treatment window of the handpiece to be calibrated is clean (see Fixed Focus Spot Handpiece Instructions for Use supplied with the handpiece).

If using the DIOMED 30*PLUS*, check that the handpiece selected on the screen corresponds to the handpiece in use.

Spot Handpiece Mode

1. Screw in the Spot Handpiece calibration port adapter.
2. Insert the Spot Handpiece into the calibration port adapter on the side of the **DIOMED 15/30*PLUS*** Laser.
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 15/30*PLUS*** in **READY** mode.
5. Follow instructions on screen.
6. Fire the **DIOMED 15/30*PLUS*** by pressing the footswitch until release is indicated on the display.

Transmission Acceptability

The **DIOMED 15/30*PLUS*** will calculate the percentage transmission of the handpiece system and the result 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).

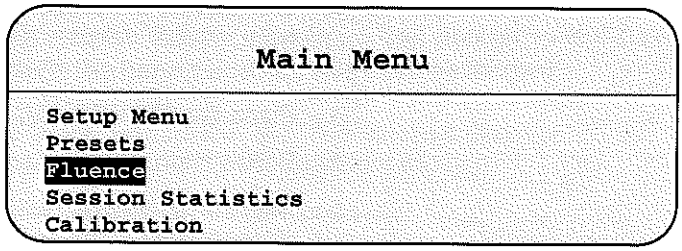
After carrying out the calibration procedure the **DIOMED 15/30*PLUS*** will display that the handpiece has been calibrated.

7. To proceed, highlight 'Continue' and press **SELECT** to return to the Main Menu.

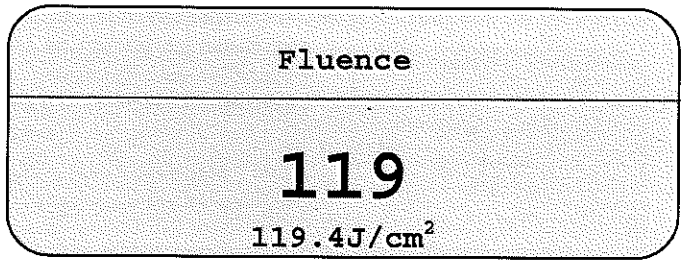
Spot Handpiece Mode

Fluence

Select 'Fluence' from the Main Menu by using the ▲ or ▼ keys and pressing **SELECT**.



The Fluence function automatically calculates and displays the laser energy delivered to the tip of the handpiece. 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:

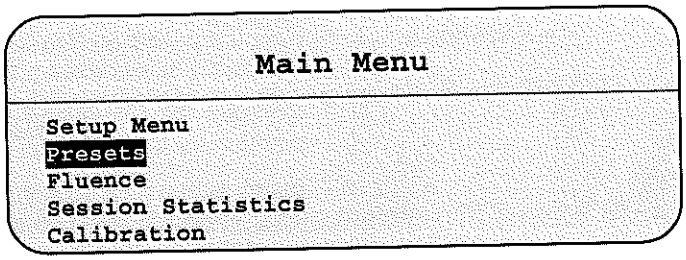
$$\text{Fluence} = \frac{\text{Power (W)} \times \text{Pulse Duration (s)}}{\pi \times (\text{Spot Radius})^2 \text{ (cm)}}$$

where radius = $\frac{\text{Diameter}}{2}$ ie 0.1 cm or 0.2 cm

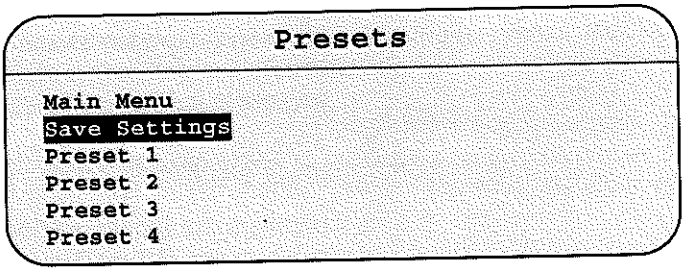
Spot Handpiece Mode

Presets

Select 'Presets' from the Main Menu by using the ▲ or ▼ keys and pressing **SELECT**.



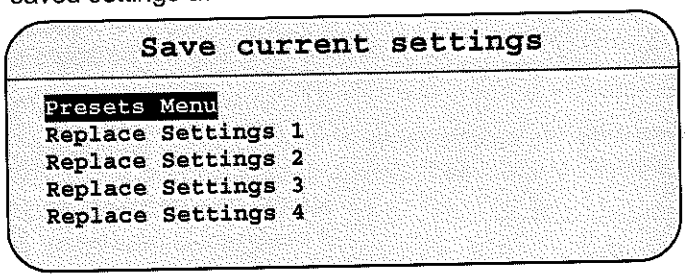
The Presets function is provided to enable the user to store up to 4 preferred or frequently used settings.

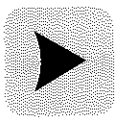


To view a Preset Setting use the ▲ or ▼ keys and the set values will be displayed. To use a Preset Setting, choose the Preset number required and press **SELECT**. The previously saved settings will be automatically set.

To store a Preset:

- Adjust the power, pulse, interval, aiming mode and aiming intensity to the desired levels
- Select 'Save Settings'
- Save the parameters in Preset 1, 2, 3 or 4 by selecting 'Replace Settings'. This will overwrite any previously saved settings at that location.





Settings saved in Fiber mode and recalled in Spot Handpiece mode will be coerced into the nearest compatible setting.

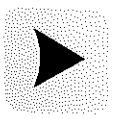
26. *OPERATING INSTRUCTIONS – SPOT HANDPIECE MODE*

1. Place the **DIOMED 15/30*PLUS*** in a convenient position on an instrument table no farther than 6 feet (1.8 meters) from the patient. Ensure that all controls are within easy reach of the operator.
2. Connect the electrical power cord to the main power outlet.
3. Connect the handpiece and footswitch and place in a convenient position for the operator.
4. 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 15/30*PLUS***.
5. Check that approved safety glasses are available and laser-warning signs are provided at entrances to the treatment room.
6. Turn on the power switch and key switch to activate the controls. Whilst the self-test program is running, ensure that all the LED segments for Power, Pulse and Interval are illuminated.
7. After self-testing, highlight 'Spot Handpiece' and press **SELECT**. Press **SELECT** to confirm the selection.
8. Highlight the required Spot Handpiece spot size (**DIOMED 30*PLUS*** only), press **SELECT** and the display will show the Main Menu screen.

9. Ensure the patient and all other personnel present are wearing approved safety eyewear. DIOMED recommends that the patient's eyes are taped shut if the patient is not conscious.
10. Select 'Calibration' mode from the Main Menu screen and follow the on-screen instructions.
11. After calibration has been carried out successfully, set the Operating Mode, Power, Pulse Length and Pulse Interval or Fluence as required for the particular treatment.
12. To start treatment and delivery of laser energy, press the **STANDBY/READY** button, wait for the **DIOMED 15/30*PLUS*** to enter **READY** mode and depress the footswitch. An audible warning will be heard during laser irradiation.
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**.

NOTE: The **DIOMED 15/30*PLUS*** will automatically return to **STANDBY** if treatment is paused for 3 minutes.

14. A summary of laser energy delivered may be reviewed if required by selecting 'Session Statistics'.
15. To turn the **DIOMED 15/30*PLUS*** **OFF** turn the key switch and remove the key.



If an error message is displayed, refer to Section 27.

27. *ERROR MESSAGES (FIBER MODE AND SPOT HANDPIECE MODE)*

All fault messages will be displayed on the lower part of the display screen. To clear the fault message, carry out the displayed instructions. Outlined below is a description of the error messages and appropriate action the user should undertake:

Aiming beam low	Check the intensity of the aiming beam. Press **SELECT** to clear this message.
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 15/30*PLUS*** distributor.
Diode switched off	The laser has been prevented from firing. Press **SELECT** and check the maximum power available.
Disconnect fiber	An attempt has been made to calibrate a non-contact fiber and the calibration has failed (below 75%). Replace the fiber and re-calibrate.
Electrical supply high	(Only shows in **READY** mode). The electrical supply has gone above its normal working level. The laser will still operate, and the message will clear automatically when supply returns to its normal level.
Electrical supply low	(Only shows in **READY** mode). The electricity supply has dropped to below its normal working level. The laser will still operate, and the message will clear automatically when full supply is restored.
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 not connected	The spot handpiece or optical fiber is disconnected from the laser. Press **SELECT** to acknowledge the fault. Reconnect a handpiece or fiber.
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.

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 15/30*PLUS*** distributor.
Footswitch not connected	The laser system will not go to **READY** mode unless the footswitch has been connected. Please connect the footswitch and ensure that it is correctly inserted into the footswitch socket.
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.
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.

28. *CLINICAL INSTRUCTIONS – FIBER MODE*

General Precautions


CAUTION

Only operators who have been trained in the use of lasers and are thoroughly familiar with this Operator Manual should use the **DIOMED 15/30*PLUS***. 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 15/30*PLUS*** 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 15/30*PLUS***. The exact effect depends upon the mode selected (Fiber), Power setting, Pulse Duration, Pulse Interval, and the tissue type being treated.

Precautions, such as careful assessment of the target tissue during treatment and the use of appropriate Power and Pulse Duration, should be taken. Use low Power 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, Pulse Duration or treatment time until the desired effect is obtained.

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

The diode laser may not be effective for coagulation for severe hemorrhages. The operator must be prepared to control hemorrhages with strident, alternative non-laser techniques. In contact surgery, the tissue interaction with the **DIOMED 15/30*PLUS*** 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.

29. *CLINICAL INSTRUCTIONS – SPOT HANDPIECE MODE*

General Precautions

CAUTION

Only operators who have been trained in the use of lasers and are thoroughly familiar with this Operator Manual should use the **DIOMED 15/30*PLUS***. 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 15/30*PLUS*** 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 15/30*PLUS***. The exact effect depends upon the mode selected (Spot Handpiece), Fluence/Power setting, Pulse Duration, Pulse Interval, Spot Size 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 Fluence/Power and Pulse Duration, should be taken. Use low 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 Fluence or Pulse Duration until the desired effect is obtained.

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

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

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

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

30. *CLINICAL WARNINGS*

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 15/30*PLUS* should be used only on tissue that is fully observable. Do not use the laser if the desired field is not visible.

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

Do not use the laser close to large blood vessels or in highly vascularized areas.

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.

31. *INDICATIONS AND CONTRAINDICATIONS*

Indications

The **DIOMED 15/30*PLUS*** is intended for the following contact or non-contact laser procedures: (with the exception of Endovenous Laser treatment – see separate section)

APPLICATION	SPECIALITY	**DIOMED 15*PLUS***	**DIOMED 30*PLUS***
Contact and non-contact use for incision, dissection, excision, resection, vaporization and coagulation.	General Surgery	B	B
Contact and non-contact use for incision, excision, vaporization and coagulation in both open and endoscopic procedures.	Urology	B	B
	Gastroenterology	B	B
	Gynecology	B	B
	Otorhinolaryngology	B	B
	Pulmonology/ Thoracic	B	B
	Dermatology/ Plastic Surgery	B	B
Non-contact use for coagulation only	Neurosurgery	N	N
Contact and non-contact use for incision, excision, vaporization and coagulation in non-intraocular procedures.	Ophthalmology/ Oculoplastics	B	B
Contact and non-contact use for incision, excision and coagulation.	Orthopedic	B	B

C = Contact Only N = Non-contact only B = Both

Contraindications

The **DIOMED 15/30*PLUS*** 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.

32. *COMPLICATIONS – FIBER MODE*

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.)

INDICATIONS

The 810nm Diomed Laser and EVLT Procedure Kit are intended for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

EVLT OPERATING PARAMETERS:

Fiber: 600µm EVLT bare tip fiber with distal markings

Power: 12W

Pulse Duration: 1s

Pulse Interval: 1s

Treatment Increments: 2-3mm

Contraindications

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

Potential Complications

The potential complications include, but are not limited to the following:

Vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, skin burns.

WARNING: TREATMENT OF A VEIN LOCATED CLOSE TO THE SKIN SURFACE MAY RESULT IN A SKIN BURN.

WARNING: PARESTHESIA MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT SENSORY NERVES.

WARNING: TISSUE NOT TARGETED FOR TREATMENT MUST BE PROTECTED FROM INJURY BY DIRECT AND REFLECTED LASER ENERGY WITH APPROPRIATE EYE AND PROTECTIVE WEAR FOR BOTH PATIENT AND OPERATING PERSONNEL.

PRECAUTION: PRIOR TO AND DURING USE, AVOID DAMAGING THE FIBER BY STRIKING, STRESSING OR EXCESSIVE BENDING OF THE FIBER. DO NOT COIL THE FIBER TIGHTER THAN A RADIUS OF 20mm.

PRECAUTION: THE POSITION OF THE MARKER BANDS ON THE EVLT FIBER HAVE BEEN MATCHED TO THE INTRODUCER SHEATH PROVIDED IN THE EVLT PROCEDURE KIT. ALTERNATIVE SHEATHS MUST NOT BE SUBSTITUTED.

PRECAUTION: PRIOR TO AND DURING USE, AVOID BENDING THE INTRODUCER SHEATH AS THIS CAN CAUSE KINKS AND DAMAGE.

PRECAUTION: THE ENTRY NEEDLE PROVIDED WITH THIS KIT IS MATCHED TO THE SIZE OF THE GUIDE WIRE AND SHOULD NOT BE SUBSTITUTED.

33. *COMPLICATIONS – SPOT HANDPIECE MODE*

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

Complications in extreme cases may include:

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

(This is not an exhaustive list.)

34. *ACCESSORIES – FIBER MODE*

Optical Fibers

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

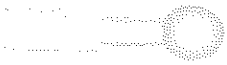
Contact Sculpted Tip Fibers

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 vaporizing 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 vaporization is required. Laser energy is displaced outwards from the forward curvature of the fiber, which gives the added advantage of vaporizing larger tissue surfaces. Heat delivered via the tip performs the cutting and extremely light pressure is all that is required for incising, excising and vaporizing 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 vaporization / coagulation.

Non-contact cooled fibers

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

Safety

Carefully read and follow the package insert instructions for use.

Handling

Leave the fiber tip protector in place during the uncoiling and hook-up process. When removing the protector, gently rotate the protector and pull straight off. 1000µm fibers are stiff and springy, requiring extra care in handling.

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-Carbonization 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 (●) 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-carbonized 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 23.

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.

35. *STERILIZATION OF OPTICAL FIBERS*

Optical fibers are provided sterile as a disposable, single-use product.

DO NOT RE-STERILIZE THE FIBERS.

DO NOT RE-USE THE FIBERS.

USE ONLY DIOMED OR FIBERSDIRECT.COM LABELED 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 labeled optical fibers have undergone stringent evaluation and testing to ensure that they are of the highest quality and that they operate safely, effectively and efficiently with 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 sterilized and used to locate the fiber in the calibration port.

Steam Sterilization

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

A validated cycle of ≥134°C (273°F) for ≥ 3 minutes sterilizing time should be used to give a sterility quality assurance level of 10^6.

Surgical Handpieces

Surgical handpieces with either rigid or malleable cannulae can be obtained from your DIOMED distributor. 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 distributor.

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 Sterilization

After use, remove the fiber from the handpiece, and wipe down the outside of the handpiece with alcohol. Insert a syringe full of water into the rear of the handpiece and depress the plunger to flush out any remaining debris. The handpiece can now be sterilized using a validated steam sterilization cycle.

Steam Sterilization

Reusable handpieces should be sterilized before use in accordance with ISO 11134 1993 'Sterilization of Healthcare Products, Requirement for Validation and Routine Control, Industrial Moist Heat Sterilization. A validated cycle of ≥134°C (273°F) for ≥ 3 minutes sterilizing time should be used to give a sterility quality assurance level of 10^6.

36. *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.

37. *LASER MAINTENANCE*

Cleaning the DIOMED 15/30*PLUS*

The **DIOMED 15/30*PLUS*** has been designed to operate reliably with minimal maintenance. The system enclosure may be wiped down periodically with a cloth dampened with a mild antiseptic solution.

There are no user serviceable parts in the **DIOMED 15/30*PLUS***, with the exception of a replaceable protective lens on the fixed focus Spot Handpiece and the optical fiber connected to it.

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

38. *DISPOSAL OF PRODUCT*

At the end of the life of the **DIOMED 15/30*PLUS***, it should be disposed of according to national environmental requirements or be returned to DIOMED.

39. 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 in Section 40.

40. LASER POWER OUTPUT

Measuring Laser Power Output

The LASER SAFETY OFFICER or suitably trained service personnel should check the output power of the **DIOMED 15/30PLUS** at least annually from the date of installation.

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

1. Calibrate the fiber.
2. Connect the fiber to the Laser unit output port and present the distal end of the fiber to the external power meter.
3. Record the Laser unit's actual and displayed outputs at various different power/energy settings e.g. 5W, 10W, 15W etc.
4. Calculate the percentage difference between the displayed and the actual power/energy output as taken from the external power meter.
5. If calculated disparity exceeds ± 20%, contact DIOMED Limited.

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 in Appendix B.

Please contact your DIOMED representative for further advice.

41. *GUARANTEE POLICY*

DIOMED guarantees the **DIOMED 15/30*PLUS*** against defects in materials and workmanship for a period of 12 months. The guarantee period begins on the date of installation.

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

The following items are expressly excluded from this Guarantee:

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


CAUTION

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

GUARANTEE CLAIMS

To make a guarantee 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: +1 978 475 7771
Fax: +1 978 475 8488
Email: diomed@diomed-lasers.com

DIOMED Limited
Cambridge Research Park
Ely Road
Cambridge CB5 9TE
United Kingdom

Tel: +44 1223 729300
Fax: +44 1223 729329
E-mail: service@diomed-lasers.com
http://www.diomed-lasers.com

42. APPENDIX A - CALIBRATING THE INTERNAL POWER METER

THE FOLLOWING INFORMATION IS PROVIDED FOR REGULATORY PURPOSES

INCORRECT CALIBRATION MAY CAUSE INJURY DURING TREATMENT.

THE ENGINEERS INTERFACE MAY BY-PASS MANY OF THE NORMAL SAFETY SYSTEMS.

DO NOT attempt the following procedures unless specifically authorized to do so by 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 AUTHORIZED BY DIOMED SHOULD PERFORM SERVICE AND MAINTENANCE.

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

Calibrating the internal power meter

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

Equipment required

- DIOMED diagnostic terminal / terminal software.
- Traceable power meter capable of recording a 3W, one second pulse of 810nm Infra Red laser light.
- 600µm reference fiber.
- Tool required to remove the top cover.

Procedure

a) Remove the top cover and place a link across the jumper JP1 of the main board. Replace cover without screws.

b) Establish access to the Engineers Interface at level 4. The terminal will present a display similar to the following:

```
Unit: 151684  S/W:  3406
Access level is 4
? for options
Top:
```

c) At the 'Top:' menu prompt type <B> to access the calibration menu. The terminal will display the following:

```
Calibration:
```

d) At the 'Calibration:' prompt type <T> to calibrate radiometer. The terminal will display the diode Set-Up parameters for the calibration pulse, and the following:

```
Put fiber in external meter. Press footswitch.
```

e) Press and then release the footswitch (minimum 20sec.) At the following prompt, enter the power measured in 100ths of a Watt:

```
Enter external meter reading (100ths W): [300]:
```

f) Repeat until the unit prompts:

```
*** POWER IS NOW OK ***  Put fiber in internal
meter.  Press footswitch.
```

g) Press and hold the footswitch. The unit will fire one-second pulses and write a line like the following for each pulse.

```
Average of 20 Samples = 160

Average of 20 Samples = 161
```

h) This will continue until the average is 167±1. At this point, the high, mean, and low values will be displayed. The following prompt will be displayed:

```
Set-Up complete? (Y/N):
```

i) Enter "Y" to complete and return to the "Calibration:" menu. Remove the link JP1 and replace and secure the top cover.

Alternative Method

At password level 0 and at step d), enter option <C> and return to user mode, the power meter function can be accessed from the engineer mode menu. This method works in the same way but instead of adjusting the EEPOT a software calibration factor is altered. This means that the JPI does not need to be linked and the cover of the laser does not need to be removed.

43. APPENDIX B – POWER OUTPUT ADJUSTMENTS

THE FOLLOWING INFORMATION IS PROVIDED FOR REGULATORY PURPOSES AND SHOULD ONLY BE UNDERTAKEN BY COMPETENT PERSONNEL AUTHORIZED BY DIOMED.

Diode Set Up

Null adjust the current probe and install it around the top loom (colored leads).

Ensure the current probe and power meter are switched on and connected correctly.

Set oscilloscope to the following settings:

- Channel 1 — 1V/div, DC coupled, Origin –2 div, Full B/W
- Channel 2 — 200mV/div, DC coupled, Origin –2div, Full B/W
- Time base — 5µsec/div, 50% trigger position
- Trigger — Ch 1, DC coupled, +ve slope, 0V level, Auto
- Cursors — Horizontal, Ch 2, Ref 1000mV, Var 600mV
- Acquire — Sample

Connect

- Channel 1 to the test point on U67 pin 1
- Channel 2 to the test point on U77 pin 6/7
- And the third test point as a common 0V for both probes.

Still in Control menu, fire the first channel by setting:

- i to 245
- m to 40
- f to 10
- c to 9
- a to 0
- d to 1

Check that the correct LED lights up on the test box when used then hold the footswitch down and type c return. The laser should now fire. Alternatively when not firing:

- Reduce m (small steps) until CH1 just exceeds 5V, by about 0.2V, AND diode current is still less than I_{op}.
- Turn the pot for this channel CW to reduce the drive voltage on Ch1 back to 5V. Ensure that diode current, which increases as pot is turned, does not exceed I_{op}.
- Repeat this iteration until the drive voltage on Ch1 is 5V and the diode current is at I_{op}. If, while following these iterations, the diode current reaches I_{op} while the drive voltage still exceeds 5V, reduce the value of the demand CH1 slightly. This simultaneously reduces the diode current and the drive voltage. This process is iterated until the diode current and drive voltage

converge to their respective targets simultaneously.

When these values have been set, move the lower cursor onto Ch2 and record this feedback voltage on the DIOMED diode set-up sheet. Also record the primary current, demand value used, m value used, and output laser power.

Now release the footswitch. Fire this diode a second time and check that the values that have been recorded above are repeatable.

Repeat this procedure for each diode. Having finished the first block, before removing the current probe from the loom, compare the power measured for each diode with that which was measured in the lab. If there are any diode power anomalies where the difference between lab and set-up powers contradict the trend, the diode channel concerned should be re-assessed. Otherwise, once set-up powers have been reconciled with those from the lab, set-up second block in the same way after moving current probe.

Identify the highest primary current, multiply by 1.25, and round up to the nearest tenth of a volt. This then gives the trip voltage that should be recorded on the diode set-up sheet. Using a DVM between 0V and VTrip, adjust RV1 to the correct trip voltage. VTrip can be found on the via between R414 and R416 (not fitted). The 60V must be present when the trip voltage is set up.

Disable all diodes and leave ready mode before switching off 60V. Switch off the unit, disconnect the test PSU loom (JIG 0104) and replace with the unit's own PSU loom. Remove scope probes from circuit.

Add up the feedback voltages and record on the diode set-up sheet (this should not exceed 10.2V). Do likewise with the $P_{ref.fib}$.

Now divide each $P_{ref.fib}$ by 0.89, having first multiplied by 100, and record in the column marked $P_{port.}$ Round this value to the nearest integer. Add up these P_{port}s and record at the bottom of the sheet. Multiply the sum of the P_{port}s by 0.89 and confirm that this is equal to the sum of the $P_{ref\ fib}$s. Photocopy the diode set-up sheet and mark the original as SET-UP and the copy as POST BURN-IN.

Enter Engineering mode and type 'd', then 'p'. Now enter the P_{port}s for each diode. Then type 'f' and enter the feedback values for each diode. Type 'k' to set the check sums and 'v' to view the details that have been entered. By checking the totals in the power and feedback column with those on the diode set-up sheet, all the values can be verified.

Exit Engineering mode. Reset the instrument in User mode to ensure correct operation and power is to specification.

12 MONTH MANUFACTURER'S GUARANTEE REGISTRATION CERTIFICATE

Product Type: Surgical / Aesthetic / PDT (delete as applicable) 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: _____

Organization: _____

Local DIOMED distributor details:

Distributor Signature: _____ Print Name: _____

- Registered User and Distributor 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 Ltd, Cambridge Research Park, Ely Road, Cambridge, CB5 9TE, United Kingdom, by post or fax (+44 1223 729329) within 28 days of date of Product installation. **Note: This Registered User information is essential in the event of a Guarantee Claim.**

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12 MONTH MANUFACTURER'S GUARANTEE REGISTRATION FORM

Product Type: Surgical / Aesthetic / PDT (delete as applicable) 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: _____

Organization: _____

Local DIOMED distributor details:

Distributor Signature: _____ Print Name: _____

- Registered User / Distributor to fully complete, detach and return this Registration form to DIOMED Ltd, Cambridge Research Park, Ely Road, Cambridge, CB5 9TE, United Kingdom, by post or fax (+44 1223 729329) within 28 days of date of laser installation. **Note: This Registered User information is essential in the event of a Guarantee Claim.**