

VELOPEX

Dental Diode laser system

User's Manual

Rev : 2

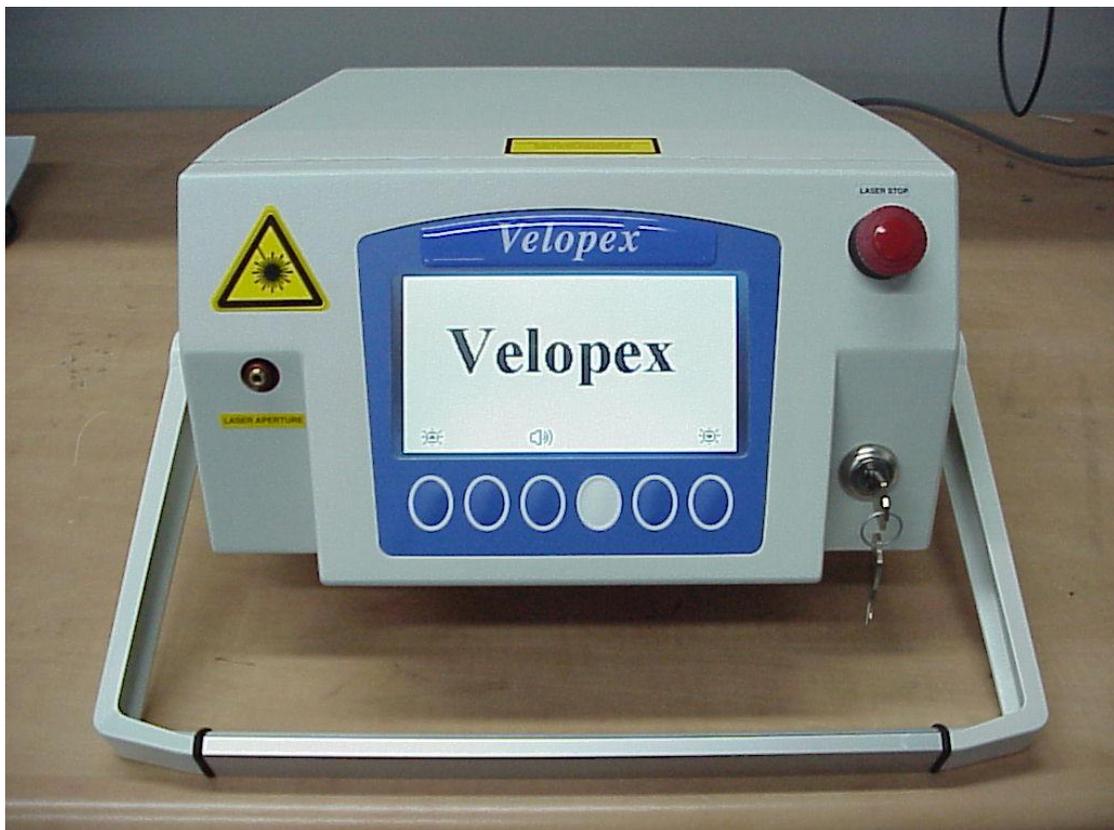


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Chapter 1 - Operating Safety Precautions

The VELOPEX diode laser system is designed to minimize accidental exposure to hazardous Radiation. 1.1 The laser beam is emitted only through the optical fiber and diverges in a wide angle ($> 20^{\circ}$). As a result, power density becomes virtually harmless a few centimeters from the fiber tip. However care should be taken to follow the instructions in the following sections.

Burn Hazard 1.2

The Dio Dent radiation has wavelength of 810 nm which is invisible to the human eye and can cause third degree burns.

Reflected and Direct Eye Exposure Hazards: 1.3

The laser beam emitted by the system is in the invisible part of the spectrum and can cause eye hazards to the human eye. As a precaution against accidental exposure to the output laser beam or its reflections, all personal must use appropriate safety eyewear.

Warning:

Do not stare into the diode laser beam or allow it to be reflected from any reflective Surface.

Do not stare directly into the aiming beam. Ensure that the aiming beam is not directed at anyone's eyes.

Be careful until operating with fiber optic hand piece. If any damage occurs – stop laser immediately and change damaged parts.

Safety Eyewear and Protective Clothing 1.4

The diode laser is hazardous to the human eye and skin. All personal must use safety eyewear and must ascertain that the eyewear provides adequate protection from 810 +/- 10 nm, radiation. Safety glasses and Goggles can be ordered from Medivance. All personal must use protective clothing worn should be made from a suitable flame and heat resisting material.

Explosion and Fire Hazard 1.5

The system is not suitable for use in the presence of flammable mixtures with air or oxygen. Do not operate in the presence of volatile solvents such as alcohol, gasoline or other. Before using system check atmospheric contamination.

Flammable materials must be kept away from the laser beam. Flame retardant materials and cloth are recommended during use of the system.

High voltage Hazard 1.6

The laser system utilizes 230 VAC. To avoid personal injury, do not operate the unit before ensuring that the casing is properly closed. Do not attempt to remove or disassemble the casing.

Only Medivance authorized technical personal are qualified to service and maintain the unit.

Using the proper power receptacle 1.7

Cable is not supplied with the unit. It is the user responsibility to use CE certified cable .

The VELOPEX unit requires 230 VAC 3 Amps, and can be connected to any standard single phase main power outlet

Grounding the unit 1.8

Proper grounding is essential for safe operation. The unit is ground through the grounding conductor in the power cord.

Fuse replacement 1.9

The system is surge protected by slow blow fuses. The fuse is housed in the cable inlet connector.

Personal Training and Medical Supervision 1.10

All persons that should be placed in control of this system must have received training to an appropriate level of laser safety. Training program must be in accordance with operation environment and national regulation acts. Personal medical supervision must be provided according to national regulation acts.

Warning, Certification and Identification labels: 1.11

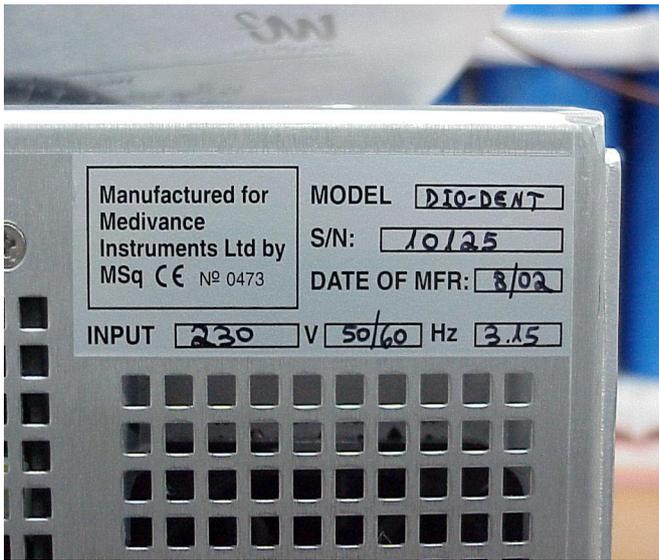
Fig 1 shows the location of the labels affixed to the unit.



B



A



C



D



E

FIG- 1 - LOCATION OF LABELS A , B: FRONT PANEL
D: BACK PANEL
C, E: TOP COVER

Chapter 2 – Installation

2.1 Unpacking and Inspection

The Dio Dent laser unit has passed quality assurance testing before shipment. Thus the unit should be operational upon delivery.

Note: Any damage to the packing or the unit found prior to opening the package, should be reported to Medivance

Equipment List:

The system includes the following:

- Velopex laser unit
- Set of keys
- Remote Interlock connector
- Foot switch + shroud
- One 400 um fiber optics
- One 320 um fiber optics for bleaching
- One hand piece for tooth bleaching
- 2 pairs of Protective glasses
- Operating Manual

Operating Configuration

The system should be placed on a table.

Line Power

The system is designed to operate on line voltage of 230VAT50/60 Hz. Voltage and frequency are marked clearly on the unit. A power plug compatible to the local electrical system is attached with the unit.

Remote interlock connection

To provide max safety the system is equipped with a remote interlock connection. The connection is suited on the rear panel (9 pin D type) (see chap 4). An external switch can be connected to this plug to create a remote interlock system. This switch should be mounted at the entrance door. If the door opens, the switch contacts also open and disable the laser Radiation.



FIG-3 REMOTE INTERLOCK

To connect the remote Interlock (Fig 3):

- Turn the system **off** .1
- Remove the D type connector from the rear of the system .2
- Open the plastic cover .3
- Solder the two wires from the Door switch to pins 5&9 .4
(shortened on delivery with white wire)
- Close the plastic cover of the D type connector .5
- Install to position .6
- Turn the system **On** .7

Connecting the Footswitch

The Footswitch supplied with the unit is an Air Activated footswitch for better safety. To connect the footswitch, plug the black tube coming from the footswitch to the inlet at the rear of the system.



FIG – 4 FOOT SWITCH CONNECTING

Connecting the Optical Fiber 2.7

An optical fiber is connected in the Fiber connection Port on the front of the unit (fig 4).



FIG 5 – FIBER PORT

The Fiber has a standard 905 SMA connector

The Port accept optical fibers of 200-600 μm .

To complete Hand Piece Assembly Procedure refer to APPENDIX 1

Chapter 3 – System Description

General Diode laser Theory

Laser is acronym for Light Amplification by Stimulated Emission of Radiation. The Diode laser is a solid state device made of GaAs/GaAl As as an active medium and rear and front mirror are deposited on the laser material and the pumping mechanism is high current flowing through the P/N junction of the device.

When the junction is forward biased, electrons and Holes are injected across the junction and population inversion is created in the active region. Light emission takes place at the junction. The emitted light is collected by a bundle of optical fibers to the working area.

General system description

The VELOPEX unit is a portable unit delivering up to 5 watts 810 nm at the fiber exit.

The system is intended for Dental soft tissue applications and Tooth Whitening.:

The main subassemblies of the unit are :

- Diode laser •
- Fiber relay optical system and optical path •
- Heat Exchanger and TEC elements •
- Diode laser driver •
- DC power supplies for the driver and the axillary units •
- PCU and control unit •
- Service (rear) panel •

3.1 Diode Laser

Fig 6 shows the diode laser with the fiber bundle, which combines the Red aiming beam with the fiber bundle.



FIG-6.1 – DIODE LASER ASSEMBLY

Aiming Diode 3.2

Fig 7 shows the Aiming Diode assembly. This assembly contain Class 1 Red laser diode, fiber optic coupler and driver plate.

AIMING DIODE Safety Warning: Aiming Diode laser radiation is safe for skin and other tissues. AVOID DIRECT EYE EXPOSITION.



FIG-6.2 – AIMING LASER DIODE ASSEMBLY

Fiber relay optical system and optical path 3.3

Fig 7 shows the optical coupler, which convert the fiber bundle and the Aiming fiber into a single 300-600 nm fiber optic. The fiber connection port accepts 300 micron fibers and incorporates a pair of microswitches for double safety, disabling laser emission when a fiber is inadequately connected or not connected at all.

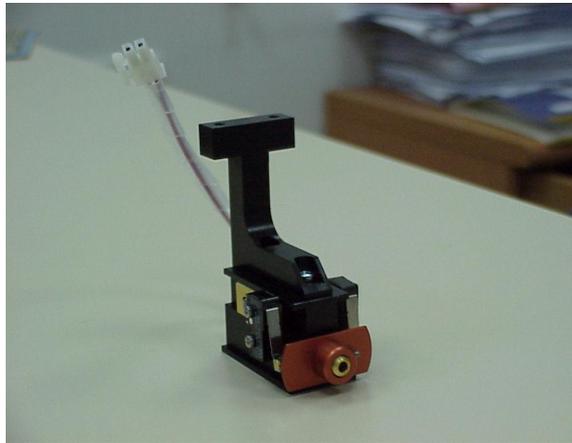


FIG -7 OPTICAL CONVERTER

Heat Exchanger and TEC elements 3.3

The diode is temperature control by a TEC. The TEC is mount on a heat exchanger.

The heat exchanger is responsible to remove heat from the hot side of the TEC.

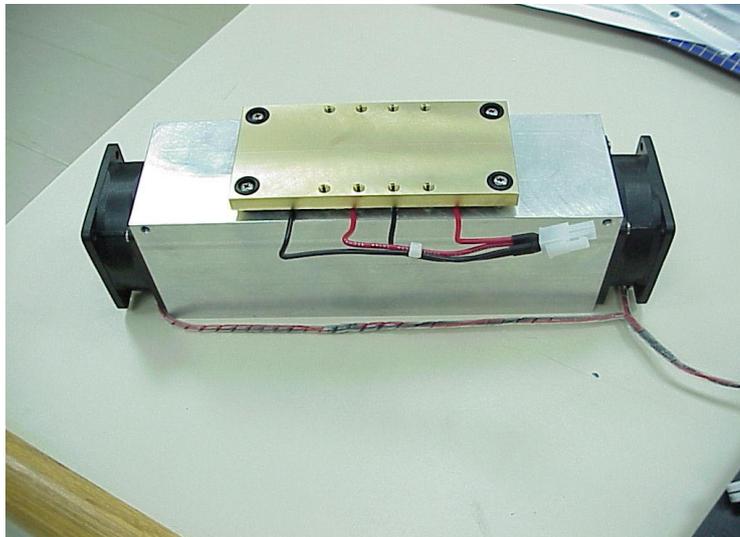


FIG - 8 HEAT EXCHANGER AND TEC

Diode laser driver (MEG –18) 3.4

The diode laser driver is responsible to drive current to the laser diode according to signals from the LCD. The drive is also monitor over voltage and over temperature on the diode.

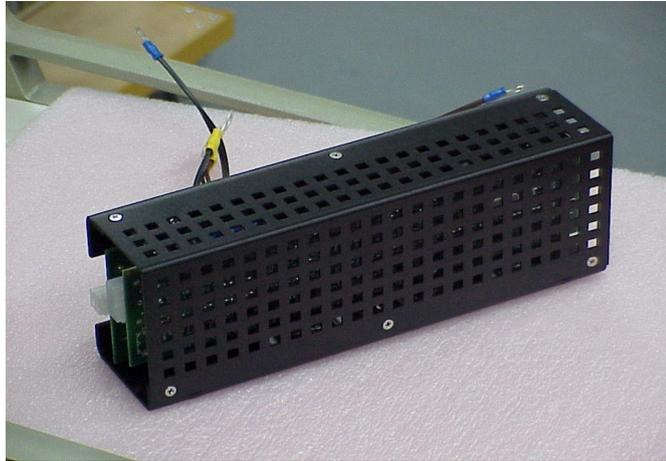


FIG - 9 DIODE LASER DRIVER

AC/DC power supplies for the driver and the control units 3.5

The power supply is 200 watts 90-264V 50/60Hz medical grade. It supplies 5V and +/-12V to the diode driver and to the LDC unit.



FIG – 10 AC/DC POWER SUPPLY

3.6 Control Panel

The controls and indicators required for system operation, are located on the front of the system.

The DIO DENT , incorporates fully micro controller based system with a Bakelite LCD display.

Control panel functions are described in chapter 4.

Main CPU Board Located together with the LCD in the Front panel

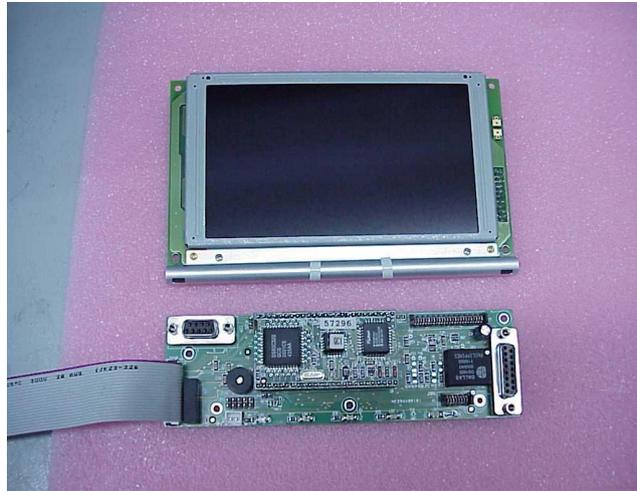


FIG -11 CPU and LCD

Service (rear) panel 3.7

The service panel is located at the back of the unit. It incorporates all the required connections to the unit.

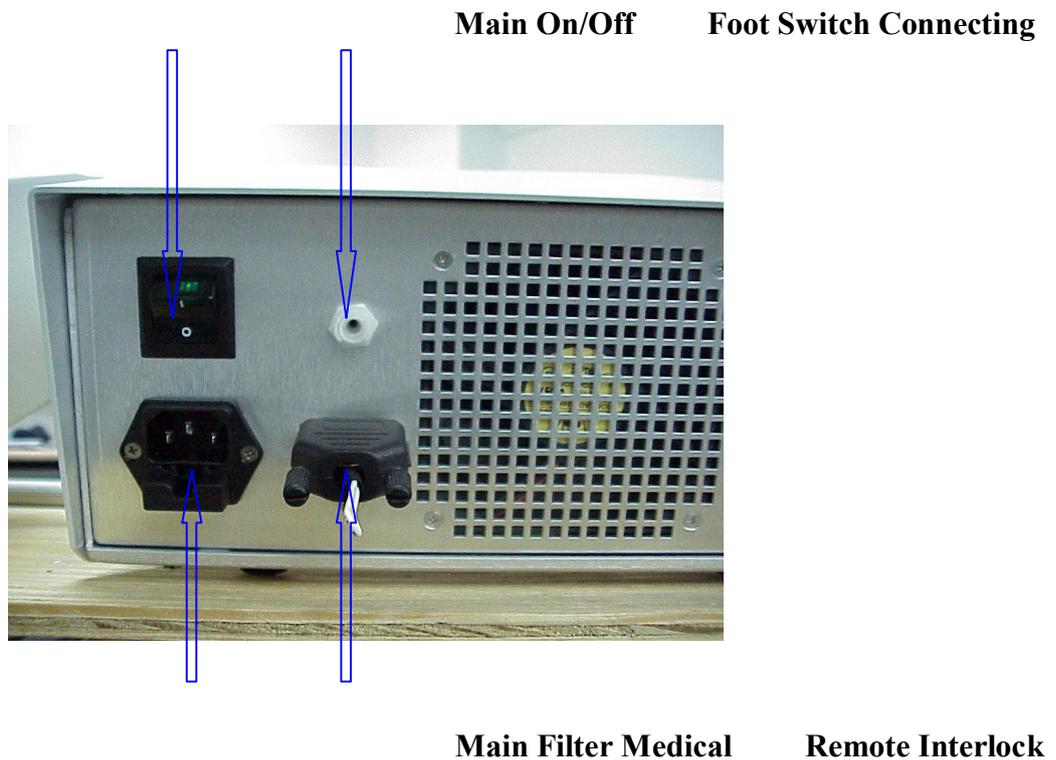


FIG - 12 SERVICE PANEL

Classification of the system according to IEC 60601-1. 3.1

According to the type of protection against electric shock the system is **CLASS 1** equipment. The hand piece is type **BF** applied part. According to the degree of protection against ingress of water the system is ordinary equipment. Equipment is not suitable for use in presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The system has continuous operating mode.

Chapter 4 – Controls and Indicators

Main switch 4.1

A Green switch Located on the rear of system.



FIG 13 – MAIN ON/OFF

Key switch 4.2

Located on the front panel. Is used to turn on the main operating manual.

Warning: Remove the key from the key switch when device is not used, this will prevent its unqualified use.



FIG 14 – KEY SWITCH

Control Panel and Display 4.3

The control panel is a backlit LCD graphic display, control keys, laser emission indicators (audio and visible)

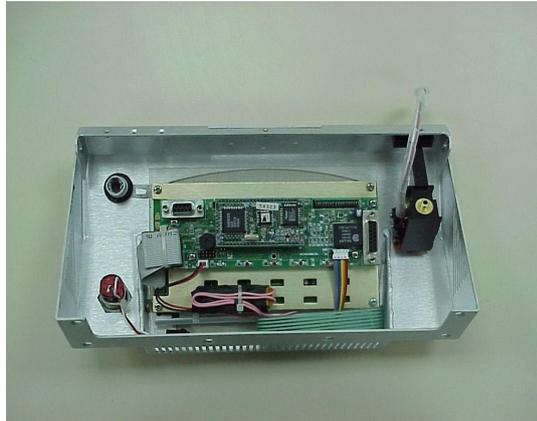


FIG 15 – INSIDE LCD PANEL

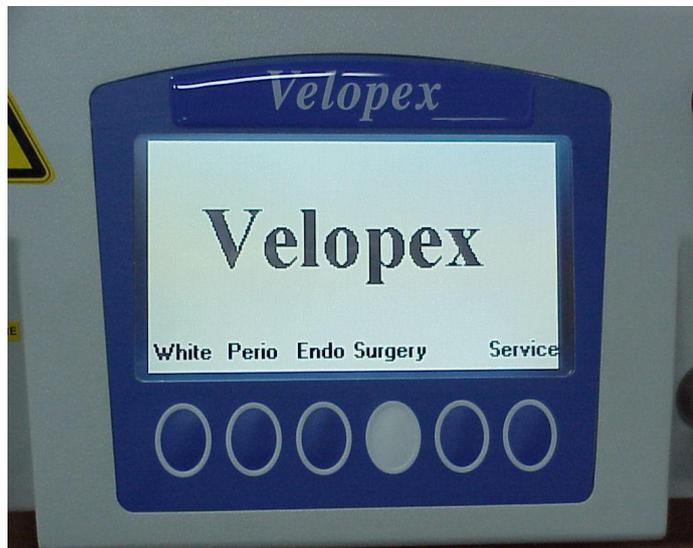


FIG -16 LCD AND CONTROL BUTTONS

Laser Emission Indicators

A red emission lamp (housed in the Panic Button), issue a red signal when the laser is On mode. Also an Audio signal is delivered when the laser is On. There is an option to silence the Audio signal on the main menu.

Fiber Connection Port 4.4

Both the diode laser beam and the red aiming beam are emitted from the laser aperture on the fiber connection port directly into the optical fiber.

The fiber connection port includes fiber presence detectors, which disable laser emission in case a fiber is improperly connected or not connected at all.

Refer to Chapter 2.7.



FIG – 17 FIBER CONNECTION PORT

Emergency Stop Switch 4.5

In case of an emergency, pressing the emergency switch shuts down the main Input Power immediately. To restart the laser, rotate the emergency switch up, turn the keyswitch off and on again.



FIG – 18 EMERGENCY STOP SWITCH

Chapter 5 – Operating Instructions

This system is type BF class 1, and as such have to be operated by M.D, according to the local laws in every country.

Introduction 5.1

The chapter describes in details the operating instruction of the system.

Turning on the system 5.2

- Plug the unit into main power outlet 1
- Connect foot switch 2
- Connect Fiber. Chose fiber :diameter (200,300,400,600 um) Fig-19 3
- Connect remote interlock 4
- Wear Safety Goggles 5
- Turn the Green Main power (on Rear panel) 6
- Turn key switch on 7
- Select fiber diameter 8
- Set Operating procedure 9

Selecting laser power and operating Modes 10

There are 4 operating programs :

Tooth whitening

Endo surgery

Perio surgery

General surgery

Each of them has factory recommended operation settings and recommended fiber diameter

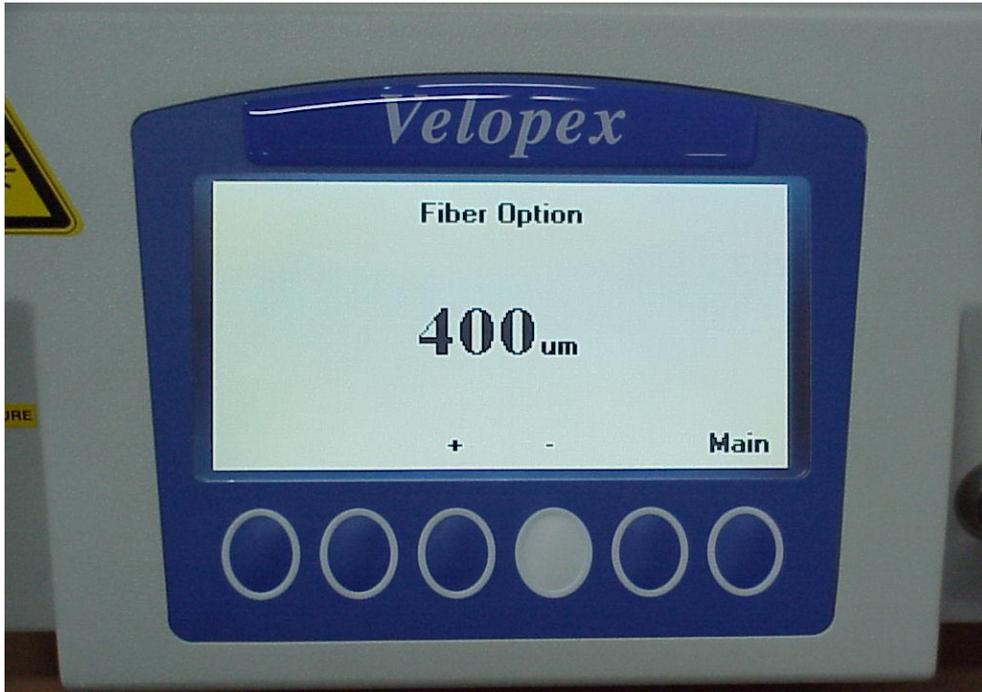


FIG - 19 SELECTION FIBERS

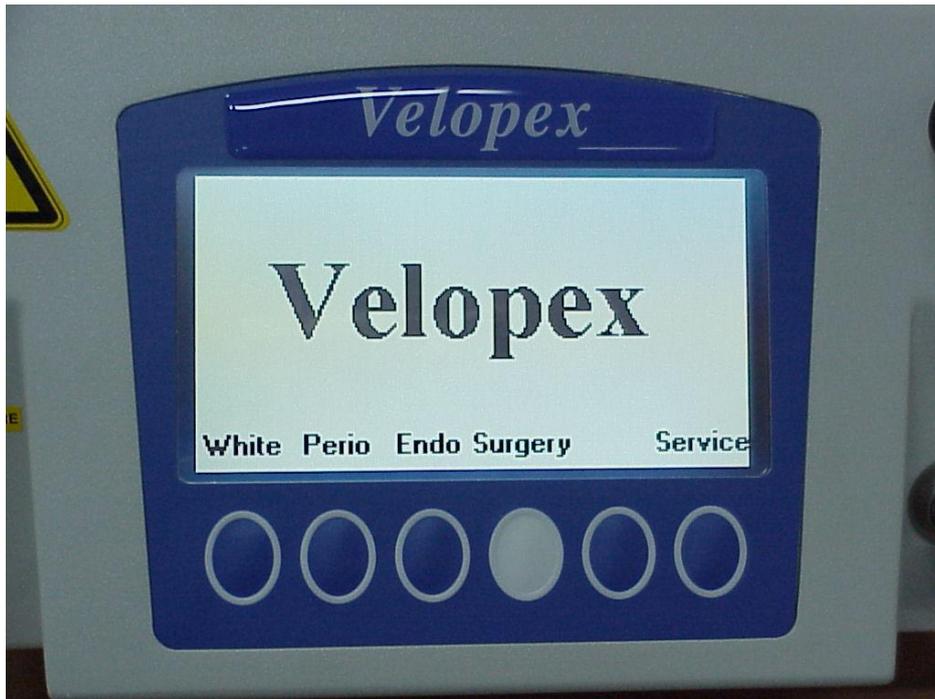


FIG - 19.1 OPERATING PROGRAMS

5.3.1 Surgery operating screen

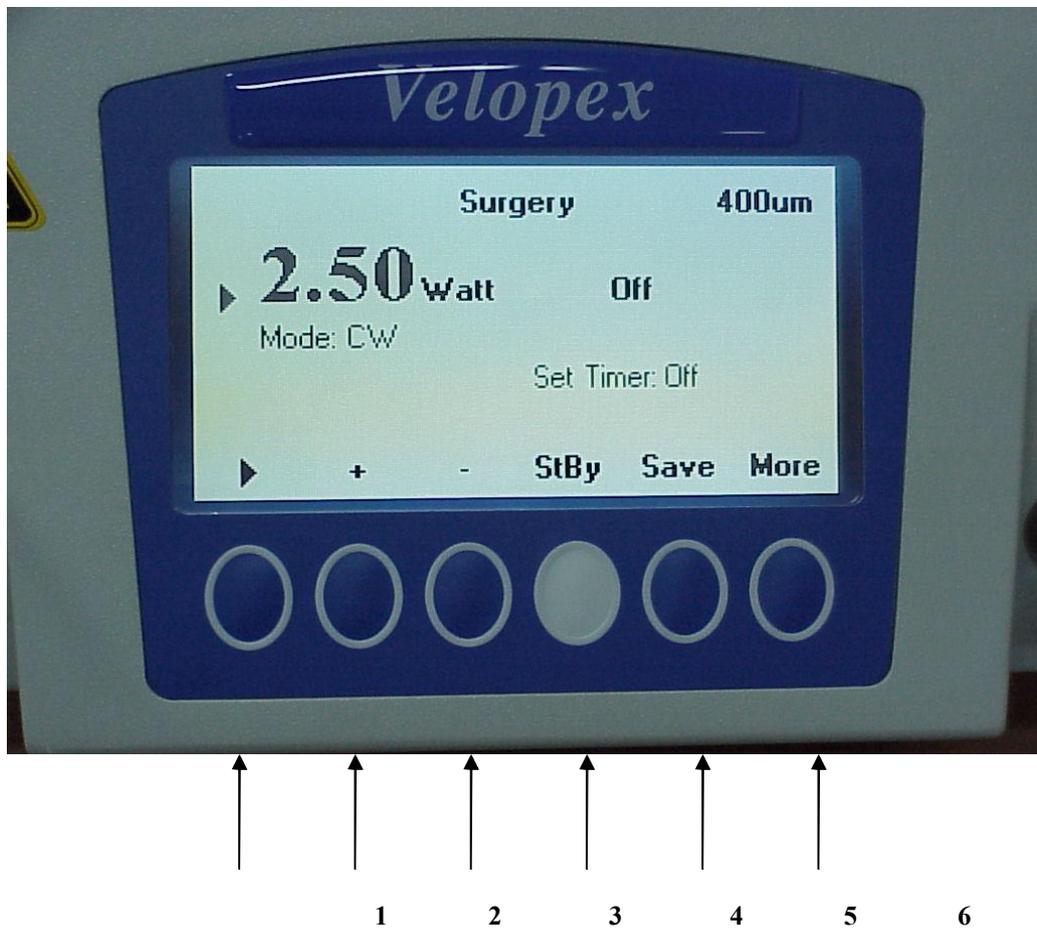


FIG – 20 SURGERY OPERATING SCREEN

Buttons description from left to right:

1. “▶” -Cursor that indicates the controlled parameters.
Pressing the cursor moves it in a cyclic way through the system parameters
 - “+” - increased the chosen parameter value .2
 - “-“ - decreases the chosen parameter value .3
 - “StBy / Ready” .4
 - “Save” - The operating setup is saved in the microprocessor. Once the system is .5
turned **Off** and **On** again –it will appear with the saved parameters.
 - “More” - Moving to the main manue screen that presents the 4 operating programs. .6

5.3.1.1 Operating Modes:

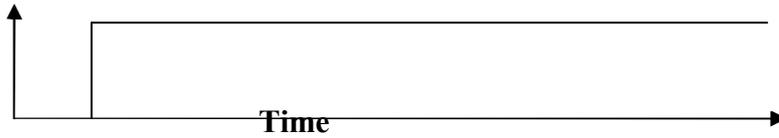
The VELOPEX unit has 3 Operating Modes:

- CW (continuous wave)
- Single pulse
- Repeat pulse

- **CW Mode:**

1. Put the “▶” on “Mode”.
2. Use the “+” to change into “Mode: CW”.
3. Press the “On” Button.

The DLD will work in “CW Mode”, after pressing the “On” Button.



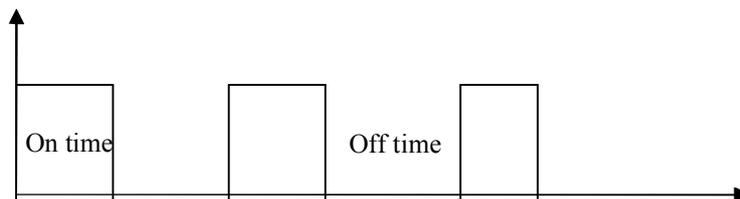
- **Single Pulse mode:**

1. Set the “▶” on “Mode” and use the “+” Button to change the mode into “Single Pulse”.
2. Move the “▶” to “On time” and use “+/-” to set the exposure time.



- **Repeat mode:**

1. Set the “▶” on “Mode”.
2. Use “+/-” to “Repeat” Mode.
3. Move the “▶” to “On Time” Mode.
4. Set “On time” with “+/-” Buttons.
5. Set “▶” to “Off Time”.
6. Use “+/-” to set “Off time”.



Signal to the Pin 6 I the 9 pin D type (Rear Panel)- to set the pulse width and frequency.

5.3.1.2 Last Setup Selection

The operator can save all operating parameters.

The procedure is the following :

Set the system to “Standby” Mode. .One

Press “Save” Button. .Two

Parameters are saved. These parameters are the new default operating parameters, every time the system is turned on.

5.3.2 Whiting operating screen

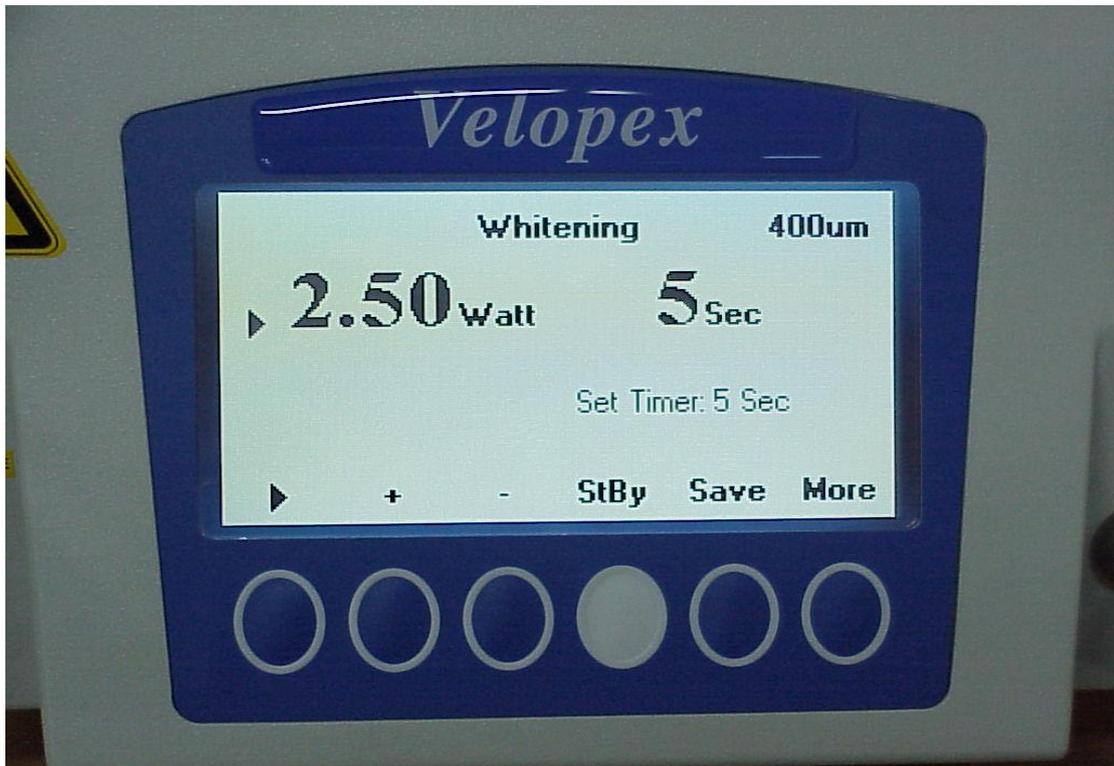


FIG – 21 WHITING OPERATING SCREEN

Operating Modes: 5.3.2.1

Set the operating program to whitening the recommended parameters are saved.

5.3.2.2 Power setting:

- Place **cursor** (button no. 1) to power.
- Use + / - (button no. 2,3) to set designed power.
- Set **cursor** (button no. 1) to timer.
- Use + / - (button no. 2,3) to set designed exposure time.
- If you want to program press **save**.
- To operate press **stby** (button no. 4)
- Press footswitch to operate.

System Turn Off 5.4

To turn off the system :

- Change to “**Standby**” Mode. .1
- Turn “**Key Switch**” - “**Off**”. .2
- Turn “**Main Power**” - “**Off**”. .3
- Disconnect the “**Hand Piece**” from the “**Optical Fiber**”. .4
- Disconnect the “**Optical Fiber**” and store it. .5
- Disconnect the “**System**” from the “**Power inlet**”. .6

Chapter 6 – Laser Surgical Accessories

6.1 Dental suitcase:

Dental suitcase is supplied as a standard accessory with Velopex system and

Includes the following:

Hand piece black / blue .1

Ceramic scissors .2

Fiber stripper .3

Intra oral tips .4



HAND PIECE BLACK /HAND PIECE BLUE

CERAMIC SCISSORS

FIBER STRIPPER

INTRA ORAL TIPS

FIG –22 DENTAL SUITCASE ACCESSORIES

6.2 Optical delivery fibers:

Two types of optical delivery fibers are necessary to operate the two hand pieces.

The two fibers are:

Fiber model HWF 300T, metal coated fiber. .1

Fiber model WF GE 400, orange flex fiber. .2

The first fiber is designed for use with the tooth whitening hand piece blue (see picture no.23.1). It is comprised of a Jacketed 300 micron optical fiber, a proximal SMA connector and a SMA connector at the distal end that attaches to the tooth whitening hand piece.



FIG- 23 METAL COATED FIBER



FIG- 23.1 WHITENING HAND PIECE BLUE

The second fiber is designed for use with the blue/black hand piece that operating these programs: endo surgery, perio surgery and general surgery. It is comprised of a bare, reusable 400 micron fiber with a proximal free standing SMA connector.



FIG – 24 ORANGE FLEX FIBER

6.3 Protective glasses:

Protective safety glasses provide ample protection from laser radiation at the 810nm wavelength, it is available for use with the Velopex, and have $ND > 6$ at 810 nm.

6.4 Footswitch pedal:

The footswitch supplied with the unit is a foldable, watertight device that controls laser emission. The footswitch cord is 2 meters long. To connected the footswitch, place it on the floor and plug its cord into the footswitch connection located on the service panel at the back of the unit (see fig no.11). Screw the cord's threaded cap onto the connection terminal securely.



FIG -25 FOOTSWITCH PEDAL

Chapter 7 – Maintenance

7.1 Introduction

This chapter contains the maintenance instruction for the VELOPEX unit. Operators may perform routine maintenance.

Other maintenance procedures that are not in this chapter are freeform only by qualified technicians.

Note : Calibration procedure is done only by Medivance qualified service personal.

Service Information 7.2

In communication with Medivance Service personnel, always include the model and S.N of the unit

No internal maintenance or user-performed adjustments are required for this self-contained system. All of the alignments or adjustable parameters are rigidly set at the factory.

Unauthorized servicing or modification of this system, not described in this manual, may expose the operator / patient to potential electrical energy and laser radiation hazards.

Improper use or adjustment of this system may invalidate the service warranty agreement.

7.3 Maintenance

Cleaning and desinfection

The VELOPEX unit should be kept clean at all times. Use vacuum cleaner once a week to clean the air ways of the unit (front and rear).

Hand piece and optical fibers should be cleaned immediately after use, to prevent stains from drying on the accessories. The hand piece and outer surface of the unit may be wiped clean with a soft cotton swab in 70 % alcohol.

Disinfecting of hand piece and fiber optic cable shall be performed by clearing with a soft cotton swab in 70% alcohol after treatment of patient.

7.4 Power meter calibration check

Power meter calibration is done annually by Medivance Service Personnel. Power meter must have measurement range up to 10W CW

Chapter 8 - Troubleshooting

Introduction

The VELOPEX laser system is equipped with self-check in routine that continuously monitors system operation.

In case there is a problem a fault message will appear on the LCD display and audible beep signal is provided.

Faults are divided into two:

Fatal Message, .1

Warning Message, .2

Fatal Message - will block the system to the operator and the operator should turn the system “**Off**” by the Main Switch.

Warning Message - will direct the operator to fix the problem, to press the “**OK Button**” and to continue.

If the Diode Laser System malfunctions, a message will appear on the LDC. With this message consult the following **Troubleshooting Guide**. Carefully follow the instruction.

If the problem persists, please call Medivance Service.

Barretts Green Road, London, NW10 7AP Tel 020 9865 2913

Troubleshooting Guide

Fault Message	Probable Cause	Action
Warning Fiber not connected	No optical fiber is connected to the fiber connection port	Connect Fiber to port
Warning Connect footswitch or interlock	Footswitch cable or interlock Disconnected or improperly connected	Check footswitch or interlock connection

ANY FATAL ERROR CALL SERVICE

Symptom	Probable Cause	Action
Display does not illuminate when keyswitch is turn on	<ul style="list-style-type: none"> • Emergency stop switch is engaged • No power from wall Outlet • Burnt fuse • Burnt display lamp 	<ul style="list-style-type: none"> • Turn off keyswitch, pull emergency stop switch out and restart system • Check if mains power is available and the power cable is properly plugged into wall outlet • Call service • Call service
Laser emission does not occur when footswitch is pressed	Footswitch cable or interlock disconnected or improperly connected	Check footswitch or interlock connection
Laser emission indicator does not illuminate in Ready mode	Burn indicator lamp	Call service
Aiming beam is not available	Aiming beam system malfunction	Call service

TABLE – 1 FAULT MASSEAGE AND SYMPTOM

Chapter 9 - Specifications

The next table summarized “System Specs”

Output Current		General	
Output power	0.3 - 5W	Display	
Wavelength	830+/- 10 nm	Graphic LCD (Dots)	128X240
Internal TEC cooling			
Fiber Output Port	SMA	Measurement Display	
Optical Fibers	300, 320 micron	Output Power	
NA	0.37	Operating mode	
Application Modes		Laser on –off	
Tooth whitening			
Endo surgery			
Perio surgery		Input	
General surgery		Power Requirement	200 W 90-264V
		Max Input Current (Amps)	
		AC 3.15 A SB	
Modulation		Input frequency (Hz)	50/60
Internal Frequency Modulation		Size	28.5 W X 39 D X 16 H mm.
On time : 0-1000 msec		Weight	10 kg
Off time : 0-1000 msec		Laser Safety Features:	
		Key switch	
		Remote Interlock	
Aiming Beam	650 nm 2 mw	Emergency Pushbutton	
	On / off	Footswitch	
		Classification	
		Class	1
		Type	BF

TABLE – 2 DIO DENT SPECIFICATIONS

Appendix: 1 Stripping , cleaving of the fiber optics and introducing into the Hand piece

Follow the following steps :

1. Open the accessory box and pick: fiber stripper, hand piece, fiber cleaver and a fiber optics (200, 300, 400 or 600 um)

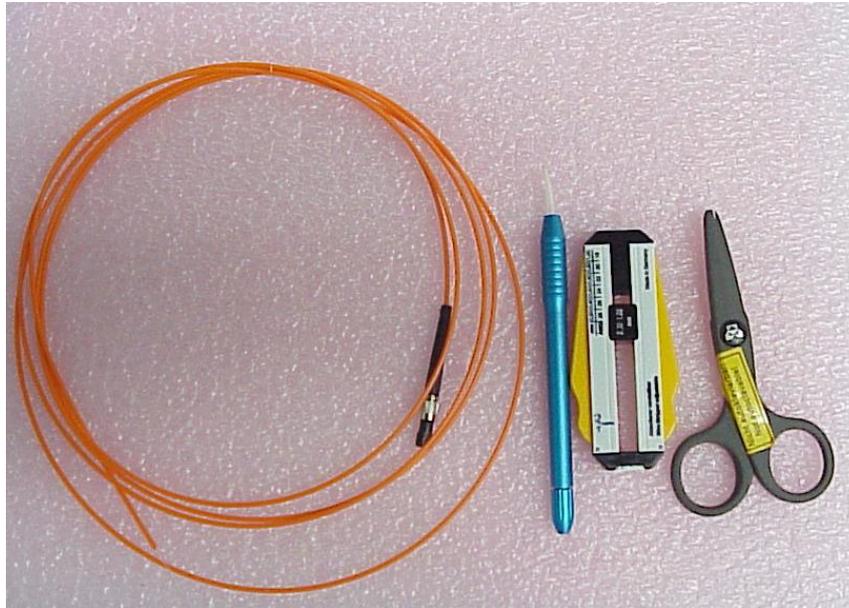


FIG 26 - ACCESSORIES

- .2 Take the selected fiber (example : 400 um orange color) and strip the orange coating using the fiber stripper (set at # 10) for length of 5 cm.

Set the stripper on # 10 which is the size of the blade for stripping the coating ♦



FIG 26.1 – STRIPPER TOOL SETTING

Remove the Orange coating for length of 5 cm ♦

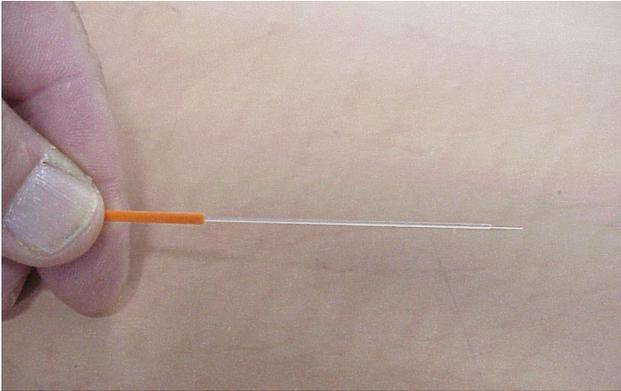


FIG 26.2 – FIBER AFTER STRIPPING PROTECTIVE COATING
Set the Stripper blade on # 4 (for 400 um fiber or # 3 for 300 um fiber etc..) ♦



FIG 26.3 – STRIPPER TOOL SETTING

Remove the plastic cladding for length of 1 cm ♦



FIG 26.4 - FIBER AFTER STRIPPING PLASTIC CLADDING

Insert The stripped fiber into the hand piece ♦



FIG 26.5- INSERT STRIPPED FIBER INTO HAND PIECE



FIG 26.6 – OUTLET FIBER FROM ORAL TIPS

Appendix: 2. Environmental condition for transportation and storage

Transportation and storage of this equipment should be done providing the following conditions:

An ambient temperature range of +10°C to +40°C ● One

A relative humidity range 30% to 75% ● Two

An atmospheric pressure range of 700 Hpa to 1060 HPa ● Three

These conditions shall be marked on the system packaging.