Lucerna

System Operation Manual Model VDL980-1

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INTRODUCTION

The Viax Dental Lab Lucerna® model VDL980-1 diode laser is a surgical and therapeutic device at the cutting edge of technology; it is designed for a wide variety of oral soft tissue procedures, dental tooth whitening, and dental restorations requiring the photo-initiation (curing) of dental composite and adhesives.

The Viax Dental Lab Lucerna model VDL980-1 dental laser utilizes solid state laser diodes as a semiconductor source for invisible infrared radiation as well as visible spectrum blue energy for material curing. The energy is delivered to the treatmentsite via flexible fiber connected at one end to the laser source(s) and the other end to the Handpiece. Various types of single use, disposable tips are designed and optimized for different applications and procedures. The device is activated by means of a touch screen display and/or a footswitch.

Prescriptive Device Statement

This is a prescription device that is indicated for professional use only by licensed medical and dental practitioners.

Training

The use of this device requires proper clinical and technical training. Only licensed professionals who have reviewed and understood this User Manual should use this device. This manual provides instructions for those professionals that have completed the appropriate training for using a DENTAL laser. Training is provided by VIAX Dental Lab contact your local sales representative or go to www.viaxdental.com

VIAX Dental Lab assumes no responsibility for parameters, techniques, methods, or results. Clinicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, and other operating parameters.

SAFETY PRECAUTIONS

(Read first before proceeding.)

Warning

Before connecting and operating the Viax Dental Lab Lucerna model VDL980-1 dental laser, read all safety instructions. When used properly and with normal precautions, the Viax Dental Lab Lucerna model VDL980-1 is a safe and effective multi-purpose laser system. However, the Lucerna is a source of intense light, and infra-red energy. **This product must only be used as indicated in this manual.**

Before connecting the Viax Dental Lab Lucerna model VDL980-1 to the mains (the AC wall power adapter), verify that the voltage to be applied is within the range of that specified on the identification label on the backside of the instrument. If you have any questions concerning the proper voltage, call the factory for clarification.



LASER WARNING

Never point the laser at a person's eyes. All persons present in the operatory must wear protective eyewear when the laser is in operation

High-intensity light can be harmful to the eyes. When the system is in use, the patient, operator, and assistant(s) must wear protective eyewear.

Important Safety Precautions

- Do not start the light outside of the mouth
- Do not look directly into the end of the fiber optic cable or handpiece or directly into the light output on the front of the operating tip (even with protective eyewear)
- Do not use in the presence of flammable materials
- NEVER shine the light into the eyes
- The Viax Dental Lab Lucerna model VDL980-1 diode laser should not be used by operators or on patients who may be photo-sensitive
- When the Viax Dental Lab Lucerna model VDL980-1 diode laser is in use, all operatory entrances must be marked with an appropriate warning sign (one (1) included)





Only use the Fiber optics supplied with the Viax Dental Lab Lucerna model VDL980-1. Other fiber optic components may not be effective and may damage the laser(s) Do not cause excessive bending in the fiber optic cable. Do not drop the handpiece or tip. Do not autoclave the handpiece. Do not autoclave the fiber optic cable. Removable tip is single use disposable and is delivered as NON STERILE product. Do not use abrasives or liquid chemicals to clean the tip or the handpiece.



CAUTION

Do not cover or block ventilation channels. These channels provide an air-flow path to cool the unit.

The vents at the front of the laser provides cooling when the system is on. Obstructing the air flow will cause heat buildup and may damage the system.

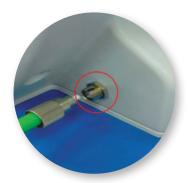
Disconnect the Lucerna battery and power cord from the power outlet and contact the factory for service instructions if the light has been exposed to liquid spills, dropped or otherwise damaged (including the power cord), or otherwise malfunctions.

IMPORTANT START-UP INSTRUCTIONS

Follow these instructions prior to using the system



- The Viax Dental Lab Lucerna model VDL980-1 comes with a safety feature that allows you to lock the unit from unauthorized use. The display screen supplies a dialogue for entering your unique PIN. This must be initialized from the set-up dialogue screen. Your PIN must be entered prior to use.
- 2. Your new system will be delivered with a default passcode of "456". Enter it by using the keypad to get into the operational screen. You can change the passcode by entering the menu screen and selecting the passcode option.
- Make sure the fiber optic cable is firmly inserted all the way into the rear panel receptacle before turning on the power. If the light guide is not completely inserted, the laser may not work properly and the light intensity may be reduced.





CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.



LASER WARNING: Never operate the laser without a fiber tip attached

| SYMBOLS | DESCRIPTION |
|---|---|
| ## Control of the co | Product ID Label Location: Bottom of laser console |
| | Manufacturer |
| | Date of Manufacture |
| REF | Catalog/Part Number |
| SN | Product Serial Number |
| | Refer to User Manual |

SYMBOLS

∱

THIS PRODUCT COMPLIES WITH FDA PERFORMANCE STANDARDS FOR LASER PRODUCTS EXCEPT FOR DEVIATIONS PURSUANT TO LASER NOTICE NO. 50 DATED 24 JUNE 2007

P/N: 540034



NOTICE
This device compiles with Part 15 of FCC
Rules. Operation is subject to the following
two conditions: (1) this device may not
cause harmful interference, and (2) this
device must accept any interference
received, including interference that may
cause undesired to operation.





DESCRIPTION

Type B Applied Part:

The applied part is not conductive to the patient.

FDA Compliance Label:

Indicates the device complies with FDA laser standards.

Warning Label:

Indicates there is the risk of possible exposure to both infrared and visible laser radiation.

Location: Back of laser console

FCC Compliance Notice: The footswitch and laser console comply with Part 15 of FCC Rules regarding unlicensed transmissions.

Location: Bottom of Footswitch

Fiber Warning:

Indicates the laser aperture is at the end of the fiber.

Location: Back of Laser Console

DO NOT REUSE For single use only.

| SYMBOLS | DESCRIPTION |
|---|--|
| 5200612 REV. A | WEEE (Waste Electrical and Electronic) Recycle Lithium Ion battery as regulated. Do not throw in trash bin. |
| Rx Only 4400417 Rev C | Prescription Statement: Federal Law restricts this device to sale by or on the order of a dentist or physician or other licensed medical practitioner. |
| 50 kPa ATMOSPHERIC PRESSURE | Atmospheric Pressure Limitations |
| FRAGILE | Fragile: Handle with care |
| KEEP DRY | Keep Dry |
| 10%———————————————————————————————————— | Humidity Limitations |
| 10%——90% NON - CONDENSING | |

| SYMBOLS | DESCRIPTION |
|----------------------|--|
| -20°C TEMPERATURE | Temperature Limitations |
| THIS END UP | This End UP |
| | Laser Warning: Indicates the system contains a laser. Location: Back of Laser Console |
| IPX6 | Ingress Protection Code: The footswitch is water-resistant, protected against splashes of water. |
| | |

BASIC SYSTEM CONTENTS

- (1) Viax Dental Lab Lucerna Model VDL980-1
- (1) VDL980-1 laser Handpiece (Non Sterile)
- (1) Viax Laser Accessory Kit (Country Specific)
- (1) Fiber Optic Patch Cord (Whitening)
- (1) Viax Dental Lab Lucerna Model VDL 980-1 Owner's Manual
- (1) Viax Dental Lab Lucerna Model VDL980-1 Instructions for Use (IFU)
- (1) Quick Start Guide
- (1) Laser Safety Sign
- (1) Warranty Information

GENERAL DESCRIPTION

The Lucerna Model VDL980-1 is a high-intensity multi- purpose laser system used for:

- Excision and incision biopsies
- · Hemostatic assistance
- Treatment of apthous ulcers
- Frenectomy
- Frenotomy
- · Gingival incision and excision
- Gingivectom
- Gingivoplasty
- Incising and draining abscesses

- Operculectomy
- Oral papillectomy
- · Removal of fibromas
- Soft tissue crown lengthening
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for impression
- Photo initiation of gingival barriers and dams
- Laser-assisted bleaching/whitening of teeth

Specially designed lasers provide peak performance for each use.



WARNING: No modification of this equipment is allowed.

QUICK SETUP INSTRUCTIONS

- Select the handpiece assembly from the package. (Fig.2)
- Insert the proximal end of the handpiece's fiber optic cable into the Rear panel receptacle until it stops. Screw retaining cap clockwise until it stops.
- Insert Battery into battery compartment (if not pre-installed).
- Plug the AC adapter into an AC outlet to charge/re-charge battery (Note: this may take up to 4 hrs).
- Turn the power switch (located on the back panel) to the ON (I) position.
- The display on the front panel will light up, indicating that system power is available.

CONTROLS AND FUNCTIONS

1. Viax Dental Lab Lucerna Model VDL980-1 Dental Laser Controls

- 1- Battery
- 2- Charging Jack
- 3- Interlock/Footswitch Jack
- 4- Power On/Off Switch
- 5- Fiber Optic Port Connector
- 6- Fiber Optic Cable (not shown)
- 7- Emergency Stop
- 8- LCD Display (GUI)

2. Viax Dental Lab Lucerna LCD Display:

Includes control and display user interface, mode indicator, display windows, and Laser Indication, System Status, and Entry Screen



3. Lucerna Display Windows:

- Entry Screen
- PIN security screen
- Procedure Menu
- Mode menu
- Digital display of the pre-set time, curing mode, and Laser Output Power and mode.

4. Control/Emergency Stop Button:

- · Laser Emergency stop
- Blue LED indicator
- 5. Fiber Optic Cable: Flexible optical device for delivery of light to handpiece and tip(s).

6. Lucerna Laser Handpiece:

- Removable Laser Tip(s)
- Disposable single use component
- Interchangeable Curing Tip
- Couples Fiber Optic Cable to Tip

7. Removable Disposable Tip(s):

Single use Optical device for exact placement of energy.

8. Entry Screen:

Safety feature to prevent unauthorized use, Iconic PIN for entry.

NOTE: Wireless Foot Switch (not shown) may be utilized for the unit, which allows the operator to initiate Lasing and Curing Procedures

9. Power Switch:

Turns power ON (I) and OFF (O). Note: Located on back panel



ACCESSORIES

Eyewear

The protective eyewear provided with the Viax Dental Lab Lucerna Model VDL980-1 must be worn by the operator, assistants, and patient when the system is in use. Additional eyewear is available through Viax Dental Technologies. Contact your sales representative for ordering information.



WARNING: All persons present in the operatory must wear protective eyewear when the laser is in use.

Fiber Optic Cable and Handpiece

The fiber optic cable is detachable from the console. The Handpiece is a Re-usable accessory and will require cleaning and High Level Disinfection prior to each patient treatment. Tips are intended for single-use only and must be disposed of after each patient use. Proper tip disposal in a biohazard medical waste. Tips are delivered Non Sterile and must be sterilized prior to use. For instructions on cleaning and High Level Disinfection of the handpiece refer to page 21.

Manual Footswitch

A wired manual footswitch is provided for use; available as an option is a wireless footswitch.

Remote Door Interlock

A remote door interlock is available from Viax that will allow the practitioner to disable the laser when the operatory door is opened.



SETUP AND OPERATION INSTRUCTIONS

- 1. Remove the Viax Dental Lab Lucerna Model VDL980-1 from shipping container and verify that all materials are present and that there is no physical damage to unit.
- 2. Set laser on a clean workspace and install handpiece/Fiber optic cable to connector on rear of housing.

CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off

4. Install Battery into battery well on rear of unit. Make sure that battery is firmly seated in well. Place cap over battery. Plug in wall mounted power adapter and connect to jack on rear panel of unit. Initially charge battery for 4 hrs. to insure a complete charge. hen fully charged, the battery will display 5 bars. When the battery reaches 2 bars, the Viax Dental Lab Lucerna Model VDL980-1 will emit a chirp indicating batteries are low. Recharge batteries for around 4 hours. During this time, you will not be able to utilize the Viax Dental Lab Lucerna Model VDL980-1.

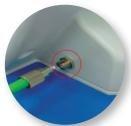
Note: Viax Dental Lab Lucerna Model VDL980-1 batteries can only be charged when the instrument is turned on (I).

Note: Battery condition/charge level is displayed on User Interface.

- 5. Remove footswitch from packaging and place in a convenient location for operation.
- 6. Laser is now ready for operation. Turn on Power Switch on rear of unit, LCD screen will illuminate with boot icon. Follow menu instructions; you will be prompted to enter your user name; Select 3 numbers for personal identification (PIN) for use of the Viax Dental Lab Lucerna Model VDL980-1; Preferential language choice (English, Spanish, or Portuguese).

Note: Default language is pre-set based on region. Exit configuration mode when prompted. Viax Dental Lab Lucerna Model VDL980-1 splash screen will appear.

- 7. Enter PIN number. Mode selection menu will appear on Display, select (1) Soft Tissue Management (Procedure) mode or (2) Curing mode or (3) Whitening Mode. Operational procedure will appear on display and the unit will be ready to operate and automatically placed in standby mode for the selected procedure.
- 8. Lasing, Curing, or Whitening modes may be initiated either from the Display (GUI) by touching the Lase icon on the display, or by depressing the footswitch. An audio tone will indicate initiation of action.







SURGICAL LASER MODE SETTINGS

NOTE:

For complete information on using the Viax Dental Lab Lucerna Model VDL 980-1 Laser mode and performing soft tissue Laser procedures, refer to the Viax Dental Lab Lucerna Model VDL980-1 Laser Instructions for Use (IFU) documentation.

The Laser mode offers two operational modes: CW (CONTINUOUS WAVE) and PULSE (10Hz). The following instructions will describe how to control both.

The Viax Dental Lab Lucerna Model VDL980-1 Laser defaults to the CW mode and the indicator icon on the display will turn on. The power setting will defaults to 1.0 Watts, or the last setting that was used and will be displayed in the LASER POWER screen.

Power can be adjusted by using the scrolling slider bar on the display GUI to increase (up) or decrease (down) the power setting.

Use the Pulse icon on the display to toggle between the CW (CONTINUOUS WAVE) AND PULSE modes. Press the READY/SELECT icon in either mode to prepare the unit for Laser activation. A GREEN indicator will glow next to the icon identifying the "READY" status. Changing the mode or power level releases the unit from "READY" status requiring the user to "SELECT" the new setting by pressing the READY/SELECT button again. Setting may not be changed when the laser is activated.

The Laser can be activated using either the touch screen display or footswitch, but not both at the same time.

The Laser unit may be deactivated at any time by pressing the Emergency "STOP" button on the Laser front panel. This action deactivates the unit function in any mode, at any power setting and whether the Laser power is activated or not.



Tip Initiation

Parameters and Method (Not required if using 200um or pre-initiated tips).

Most soft tissue surgical procedures require initiation of the fiber tip. If tip initiation is recommended attach the selected tip to the handpiece and set the power setting to 1.4 W (continuous mode) and aim the tip at a carbon sheet (occlusal paper) and fire the laser momentarily to initiate the tip.

CURING MODE

Timers and Control Panel Operation

There are three operator-selectable curing timers available on the display. Each timer is pre- set at 1, 3, and 5 seconds. It is recommended that multiple 5-second exposures are used for resins that need a little more time.

Whenever the curing handpiece tip is attached, manually select the curing mode on the Viax Dental Lab Lucerna Model VDL980-1. The display GUI for the CURING mode will appear. The factory preset time for composite curing is 3 seconds, however this can be manually changed to the desired setting by touching the time icon(s) on the touch screen display. Curing may be activated by touching the lase icon on the touch screen display or depressing the footswitch.

An audio signal will emit a chirp when curing cycle starts and when cycle is complete.

When the timer setting is selected, it will stay at that setting until the next time it is changed, even when the system power is turned off. This allows the operator to use favorite settings without having to reset before each usage.



WARNING: All persons present in the operatory must wear protective eyewear when the curing laser is in use.

The ACTIVATOR button on the display GUI and/or the footswitch will activate and deactivate the lamp. The TIMER SELECT button on the display GUI will set the curing time.



ATTENTION: DO NOT HOLD DOWN THE START/STOP ICON OR FOOTSWITCH. - Just press and release

CURING INSTRUCTIONS

NOTE: Clean the tip prior to use for maximum light output.



ATTENTION: Do not touch the angled tip of the light guide handle to the restorative material.

Hold the tip approximately 2 mm above the material to be cured!

It is recommended that you test all restorative materials for the time required for complete curing prior to use. Fill a 2mm wide x 2mm deep test fixture with the restorative to be used. Set timer to 5 seconds. Position the angled tip of the handpiece approximately 2 mm from the composite and start the curing cycle. After the timing cycle is completed and the light turns off, test the bottom surface for hardness using a dental probe. If the material is not completely cured, restart the system again for another 5-second exposure. Test, and repeat again, if necessary. This will give you an indication of the optimum timing increment for the specific restorative to be used. Select a new timer increment which is close to the total time it took to cure the material. Repeat the test and verify that complete curing has occurred. If curing time is longer than 5 seconds, it is recommended that you repeat an additional 5-second exposure. It is important that you maintain a log of composite materials, shades, and associated curing times. This log can also be used to monitor system performance.

If the cavity preparation is deep, an incremental filling technique is recommended and each increment should be cured following the manufacturer's guidelines or your own experience with the restorative being used.



CAUTION: Do not direct the light to unprotected gingiva or skin.

NOTE: For replacement or additional protective laser eyewear, please contact Viax Dental Lab or visit our website at www.viaxdental.com



CAUTION: Periodically inspect laser eyewear for pitting and cracking



WARNING: Do not use this unit if you suspect it of functioning improperly or other than described herein

Curing Safety

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at a person's eyes.
- Always place the system into STANDBY mode (by pressing the Control Button while in READY mode) before exchanging Handpieces or disposable tips.
- Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving unit unattended for extended periods of time or removing from the operatory.



LASER WARNING: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect and create a potential hazard

WHITENING MODE



The Whitening mode is pre-programmed to deliver 2 x 15 minute whitening sessions. The whitening mode emits 450nm pulsed laser light output. Note: Laser Safety goggles must be worn by all personnel in operatory.

Whitening Set up:

- 1. Remove laser handpiece and disconnect fiber optic cable from rear of unit
- 2. Connect 'Whitening' Fiber optic cable to fiber optic port on rear of unit
- 3. Select whitening mode from Menu option of GUI and initiate from GUI Icon Note: Footswitch is not used for whitening application

Set Up instructions for Lucerna Whitening Mode

1. After installation of the Whitening tip and Fiberoptic cable, turn the Viax Dental Lab Lucerna VDL980-1 on and enter whitening mode on the Menu. The Whitening screen will appear and a 15 minute timer will be ready to activate the 450nm laser in a pulsed mode. The whitening procedure may be activated by touching the Lase Icon on the screen. The laser will turn for a 15 minute cycle (Note: The whitening procedure takes 2 x 15 minute cycles). The Laser will return to standby mode upon completion of the cycle.

CONTRAINDICATIONS

All clinical procedures performed with Viax Dental Lab Lucerna VDL980-1 must be subjected to the same clinical judgment and care used with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease (including pacemakers), lung disease, bleeding disorders, sleep apnea or an immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

DAILY MAINTENANCE

Use the peel-off clear covers for the laser console supplied with the system. Use disinfectant to wipe down the front panel and handpiece system after each procedure. **Do not use bleach or abrasive cleansers.**

CLEANING, STERILIZATION, SANITIZING & HIGH LEVEL DISINFECTION (HLD)

The contamination control suggested for the Viax Dental Lab Lucerna VDL980-1 Handpiece is HLD and steam Sterilization for the Tips. However, before HLD, the Viax Dental Lab Lucerna VDL980-1 reusable Handpiece should be carefully cleaned per the following procedure and tips steam sterilized per the following procedure:





Tips are single-use only to avoid cross-contamination and are designed to withstand a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container. Handpieces are reusable and must be cleaned and High Level Disinfected between patient use.

Steam Sterilization for Surgical, Curing and Whitening Single Use Tips

The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

NOTE: Always perform the procedure prior to use and only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray.

- Place the tips in separate single-wrap, self-seal autoclave pouches.
- Place on an autoclave tray; do not stack other instruments on top of the pouches.
- Place the tray inside the autoclave chamber and set the appropriate cycle as recommended in Figure xx.1.

| Type of Sterilizer | Temperature | Min Time | Drying Time |
|----------------------------------|----------------------------------|--------------------------|-----------------|
| Gravity Displacement | 121°C (250°F) 132°C (270°F) | 30 minutes 15 minutes | 15 - 30 minutes |
| Dynamic-Air-Removal (Pre-Vacuum) | 132°C (270°F) 134°C (EU only) | 4 minutes | 20 - 30 minutes |

• Once the cycle is completed, remove the tray and let each sterilized item cool and dry. The tips must remain in the sterilization pouches until used in order to maintain sterility.

NOTE: The Handpiece and clear protective shield are not autoclavable. The clear protective shields are intended for one-time use only and should never be reused to prevent cross- contamination.

The Viax Dental Lab Lucerna VDL980-1 Handpiece should be used with a FDA cleared barrier or sleeve. Viax Dental Lab recommends use of a barrier shield or sleeve in addition to the HLD procedure listed below.

Cleaning and Disinfecting Instructions-Surgical Handpiece, Reusable Fiber Optic Cable

The cleaning process is intended to remove blood, protein and other potential contaminants from the surfaces and crevices of reusable accessories. This process may also reduce the quantity of particles, microorganisms and pathogens present. Cleaning must be performed prior to High Level Disinfection and must be conducted only by qualified office personnel trained to perform the procedure and handle the Viax Dental Lab Lucerna VDL980 fiber optic delivery system.

Wear protective latex gloves when handling the contaminated delivery system.

To disinfect the fiber cable, wipe the entire cable, including the shaft, with an appropriate disinfecting solution, such as CaviCide™ or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. Avoid getting any liquid or debris near the distal end of the fiber cable.

Manual Cleaning of the Surgical Handpiece

Cleaning must be performed within a maximum of 1 hour after the procedure and always prior to HLD disinfection.

- 1. After use, carefully remove the tip from the handpiece and dispose of in a biohazard medical waste container.
- 2. Carefully remove the handpiece and the fiber optic cable
- 3. Prepare any commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol® or similar enzymatic presoak and cleaner, per the manufacturer's instructions. (Follow the manufacturer's instructions for disposal of used solution.)

- 4. Rinse the Handpiece under running lukewarm tap water (22 43°C) for a minimum of 10 seconds to remove gross soil.
- 5. Wrap the handpiece in a piece of gauze that has been soaked in the cleaning solution; leave it wrapped in the gauze for a minimum of 10 minutes.
- 6. Unwrap the handpiece from the gauze and use a soft-bristled brush dipped in the cleaning solution to gently scrub it for at least 15 seconds.
- 7. Rinse the handpiece under running lukewarm tap water (22-43°C) for a minimum of 10 seconds and then dry with a lint-free cloth.
- 8. Visually inspect the handpiece for any residual soil. If necessary, repeat steps 5 7 until all residual soil is removed.

High Level Disinfection (HLD) of the Surgical Handpiece

Immerse device completely, filling all lumens and eliminating air pockets, in CIDEX® OPA Solution for a minimum of 12 minutes at 20°C or higher to achieve high level disinfection. As with all high-level disinfectants, it is critical that temperature is monitored when using CIDEX® OPA Solution.

Rinsing Procedure for HLD of the Surgical Handpiece

- 1. Following removal from CIDEX® OPA Solution, thoroughly rinse the handpiece by immersing it completely in a large volume (e.g., two gallons) of water. Use sterile water unless potable water is acceptable.
- 2. Keep the handpiece totally immersed for a minimum of one minute in duration,
- 3. Manually flush all lumens with large volumes (not less than 100 mL) of rinse water
- 4. Remove the handpiece and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- 5. Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEX® OPA Solution residues. Residues may cause serious side effects.

 Note: THREE (3) SEPARATE, LARGE-VOLUME WATER IMMERSION RINSES ARE REQUIRED.

Cleaning The Viax Dental Lab Lucerna Model VDL980-1 System

NOTE: unplug the power adapter cord prior to cleaning with any liquid. Allow the system to cool prior to cleaning. Avoid spilling any liquid on the system. Do not use flammable liquids to clean the main system or Fiber Optic Cable. If the internal electronics are exposed to any liquid, disconnect the Battery and power adapter cable (and/or any other electrical cables to unit). Do not attempt to start the system. Contact Viax Dental Lab for instructions at www.viaxdental.com or customer support.

Clean the main system by using a mild, non-abrasive disinfectant. Do not saturate the control panel with liquid. Wipe with a damp towel and dry completely.

Replacement Parts

Additional tips, shields, and curing rings, light guides and lamp modules are available from Viax Dental Lab. See www.viaxdental.com for ordering information.

SERVICE

Minor problems can be quickly identified and resolved. These are usually related to the electrical power connection or light guide connection. All other malfunctions must be diagnosed and repaired by Viax Dental Lab.Contact Viax Dental Lab for technical support at www.viaxdental.com.



CAUTION: Orange safety glasses must be worn during testing.

TROUBLESHOOTING

Problem

The control panel and LCD display does not light up. Button does not respond.

Corrective action

Check the battery and insure that it is seated firmly in the well. Check indicator on the battery to verify that at least 3 bars are present. Verify that the power switch is in the ON (1) position.

Problem

The control panel LCD display lights up but the Laser does not start when the Footswitch is depressed.

Corrective action

Being careful not to look directly at the distal end of the light guide, press the Lase icon on the display. If the Laser does not come on, move to the next step. If the Laser comes on, recheck the wireless footswitch.

Problem

Light output is low or curing of the composite is slow.

Corrective action

Verify the light guide is plugged all the way into the receptacle on the back of the unit. Check the curing tip for contamination, scratches, or breaks. Clean the tip with composite solvent. Check the light guide for damage.

If corrective action does not resolve the problem, contact Viax Dental Lab for technical support at 1-844-842-9522 or visit www.viaxdental.com. This includes possible lamp replacement or return of the system for repair.

TRANSPORTATION

When transporting the Viax Dental Lab Lucerna VDL980-1, remove the power adapter, the battery, and the light guide from the Viax Dental Lab Lucerna VDL980-1 light source. Hold the handle or carry it with both hands, one hand underneath the unit to insure safety.

To prevent damage to the Viax Dental Lab Lucerna VDL980-1 during transportation, it is highly recommended that the unit be wrapped with bubble wrap and/or placed in the original shipping box or similar packing materials.

The Viax Dental Labs Lucerna is susceptible to damage if not handled properly. The unit should ALWAYS be handled carefully and never be banged, dropped, or knocked.

STORAGE

Store the Viax Dental Lab Lucerna VDL980-1 and accessories in a clean area and maintain the room temperature as follows:

Storage Environment (Operating): Ambient Temperature 6° C to 45° C

Transportation & Storage Environment (Non-operating): Ambient Temperature -20° C to +60° C Relative Humidity 10% to 90%.

DO NOT bend the power adapter cord severely, apply excessive force, pull, twist, or squeeze the power cable. **DO NOT** bend the Fiber Optic cable severely, apply excessive force, pull, twist, or squeeze the Fiber Optic Cable. **DO NOT** subject the Lucerna to excess impact during transportation; this may cause the unit to malfunction. **AVOID** placing the Lucerna in direct sunlight or high temperature environment.



CAUTION: Remove the batteries from the Viax Dental Lab Lucerna VDL980-1 Laser and from the wireless footswitch if the Viax Dental Lab Lucerna VDL980-1 Laser is not likely to be used for extended periods of time (exceeding 6 months)

The Viax Dental Lab Lucerna VDL980-1 dental Laser is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

CALIBRATION

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Bi-annual calibrations can be performed at a certified depot repair facility or by authorized service rep (on site). Call VIAX Service or your Authorized Service Representative to schedule an appointment.

When USING the Li BATTERY



WARNING

- Misusing the battery may cause the battery to get hot, rupture, or ignite and cause serious injury. Be sure to follow the safety rules listed below:
 - Do not place the battery in fire or heat the battery.
 - Do not install the battery backwards so that the polarity is reversed.
 - Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as a wire).
 - Do not carry or store the batteries together with necklaces, hairpins, or other metal objects.
 - Do not pierce the battery with nails, strike the battery with a hammer, step on the battery, or otherwise subject it to strong impacts or shocks.
 - Do not solder directly onto the battery.
 - Do not expose the battery to water or salt water, or allow the battery to get wet.
- Do not disassemble or modify the battery. The battery contains safety and protection devices that, if damaged, may cause the battery to generate heat, rupture, or ignite.
- 3. Do not place the battery on or near fires, stoves, or other high-temperature locations. Do not place the battery in direct sunshine or use or store the battery inside cards in hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may also result in a loss of performance and a shortened life expectancy.

When USING the Li BATTERY



CAUTION

- If the device is to be used by small children, the caregiver should explain the contents of the user's manual to the children. The caregiver should provide adequate supervision to ensure that the device is being used as explained in the user's manual.
- 2. When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.
- 3. Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location or Viax Dental Lab if any of these problems are observed.
- 4. Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
- 5. In the event the battery leaks and the fluid gets into one's eye(s), do not rub the eye(s). Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.

When CHARGING the Battery



WARNING

- 1. Be sure to follow the rules listed below while charging the battery. Failure to do so may cause the battery to become hot, rupture, or ignite and cause serious injury.
 - When charging the battery, either use a specified battery charger or otherwise ensure that the battery charging conditions specified are met.
 - Do not attach the batteries to a power supply plug or directly to a car's cigarette lighter.
 - Do not place the batteries in or near fire, or into direct sunlight. When the battery becomes hot, the built-in safety equipment is activated; preventing the battery from charging further, and heating the battery can destroy the safety equipment and can cause additional heating, breaking, or ignition of the battery.
- 2. Do not continue charging the battery if it does not recharge within the specified charging time. Doing so may cause the battery to become hot, rupture, or ignite.

 The temperature range over which the battery can be charged is 0°C to 45°C. Charging the battery at temperatures outside of this range may cause the battery to become hot or break.

 Charging the battery outside of this temperature range may also harm the performance of the battery or reduce the battery's life expectancy.

When DISCHARGING the Battery



WARNING

Do not discharge the battery using any device except for the specified device. When the battery is used in devices aside from the specified device it may damage the performance of the battery or reduce its life expectancy, and if the device causes an abnormal current to flow, it may cause the battery to become hot, rupture, or ignite and cause serious injury.



CAUTION

The temperature range over which the battery can be discharged is -20°C to 60°C. Use of the battery outside of this temperature range may damage the performance of the battery or may reduce its life expectancy.

THE VIAX DENTAL LAB LUCERNA MODEL VDL980-1 SYSTEM SPECIFICATIONS

1. SAFETY CLASSIFICATION

The following safety classifications are applicable to the device:

- Laser Radiation Class 4
- Aiming Beam Class 2
- Type of protections against electrical shock Class 2
- Degree of protection against electrical shock Type B Applied Part
- Not protected against water ingress Ordinary Equipment (IPX0)
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode Continuous Wave and Pulse Mode
- Wireless Footswitch IPX6

System Specifications

General

| Dimensions | 197mm x 178mm x 153mm |
|------------|-----------------------|
| Weight | 1 kg |

Electrical

| Operating Voltage (Power Adapter) | . 100V - 240V ~ at 1.5-0.7A |
|-----------------------------------|--|
| Frequency (Power Adapter) | . 47/63Hz |
| External Fuses | . N/A |
| Main Power Control | . Power Switch (Back of Unit) |
| Remote Interruption | . Remote Interlock |
| Laser Disable Control | . Emergency Stop Button |
| Battery | . Lithium Ion Rechargeable, 7.2V, 6.8 Ah |
| DC Power Supply Module | . 12V DC, 5A |

System Specifications (continued)

LASER (Surgical)

| Laser Classification | IV (4) |
|-----------------------|------------------------------|
| Medium | InGaAsP Semi-conductor diode |
| Wavelength | 980 ± 10nms |
| Max Power Output | 3W (CW) / 6W (P) |
| Power Accuracy | ± 20% |
| Power Modes | Continuous, Pulse Modulation |
| Pulse Duration | 20ms |
| Pulse Interval | 30ms |
| Pulse Repetition Rate | 20 Hz |

LASER (Curing/Aiming):

| Laser Classification | IV (4) / II (2) |
|----------------------|------------------------------|
| Medium | InGaAsP Semi-conductor diode |
| Wavelength | 457nm ± 10nm |
| Max Power Output | 1.25 W / 1mW |
| Power Accuracy | ± 20% |
| Power Modes | Continuous |

OPTICS

| Standard Fiber Cable | . 200um/300um |
|-----------------------------|------------------------------|
| Standard Fiber Cable Length | . 1M |
| NOHD | . 4.77 meters |
| Beam Divergence | . 8 - 22° per side angle |
| Fiber Tips Diameter | . 100um, 200um, 300um, 400um |
| Curing Tip Diameter | . 1mm, 8mm |

SYSTEM WARRANTY

The Viax Dental Lab Lucerna VDL980-1 system (main system and Fiber Optic Cable/Handpiece base) is warranted to be free of defects in workmanship, materials, and malfunctions for one year from the date of original shipment when used under normal operating conditions as described in this manual. The warranty applies to the original purchaser only and does not apply to or cover any third party buyer or user. The warranty does not cover any damage that may have occurred as a result of misuse, improper operation, alteration, adjustments, or neglect.

Within the one-year warranty period, if service is required, the system must be returned to Viax Dental Lab for diagnostics and repair. Contact the factory to receive Return Authorization prior to shipping. The Return Authorization will include a pick-up notice (Call Tag) for a common carrier to return the merchandise to Viax Dental Lab. Freight charges for returns within the warranty period will be paid by Viax Dental Lab pending the results of evaluation of cause of the failure or damage. Freight charges for returns outside of the warranty period will be paid by the customer. The outside shipping container and any accompanying documents must be clearly marked "Repair Return." Use only the original shipping container or other adequate shipping materials to protect the system in transit. All returns will be evaluated for the cause and extent of failure or damage by Viax Dental Lab Service Representatives. Subject to the results of this evaluation, Viax Dental Lab will authorize warranty repair or will contact the customer with a price quotation for the cost of repairs for failures and damages occurring as a result of misuse, improper operation, or for merchandise outside of the warranty period.

This is a limited warranty and the liability of Viax Dental Lab to repair or replace the system. Viax Dental Lab has no liability to refund any part of the purchase price and no liability for consequential damages, loss of profits, and damages to person or injury by reasons of any defects in said system from any cause whatsoever.

Any buyer who purchases said system acknowledges their familiarity with the terms, conditions, and provisions of this limited warranty and purchases said system agreeing to such terms, conditions, and provisions.

Buyer purchases the Viax Dental Lab Lucerna system from Viax Dental Lab on the terms, conditions, and provisions of this limited warranty and waives all other rights and claims against Viax Dental Lab for any damages or remedies exceeding said limited warranty. Contact information is found in the warranty card sent with the unit.

