

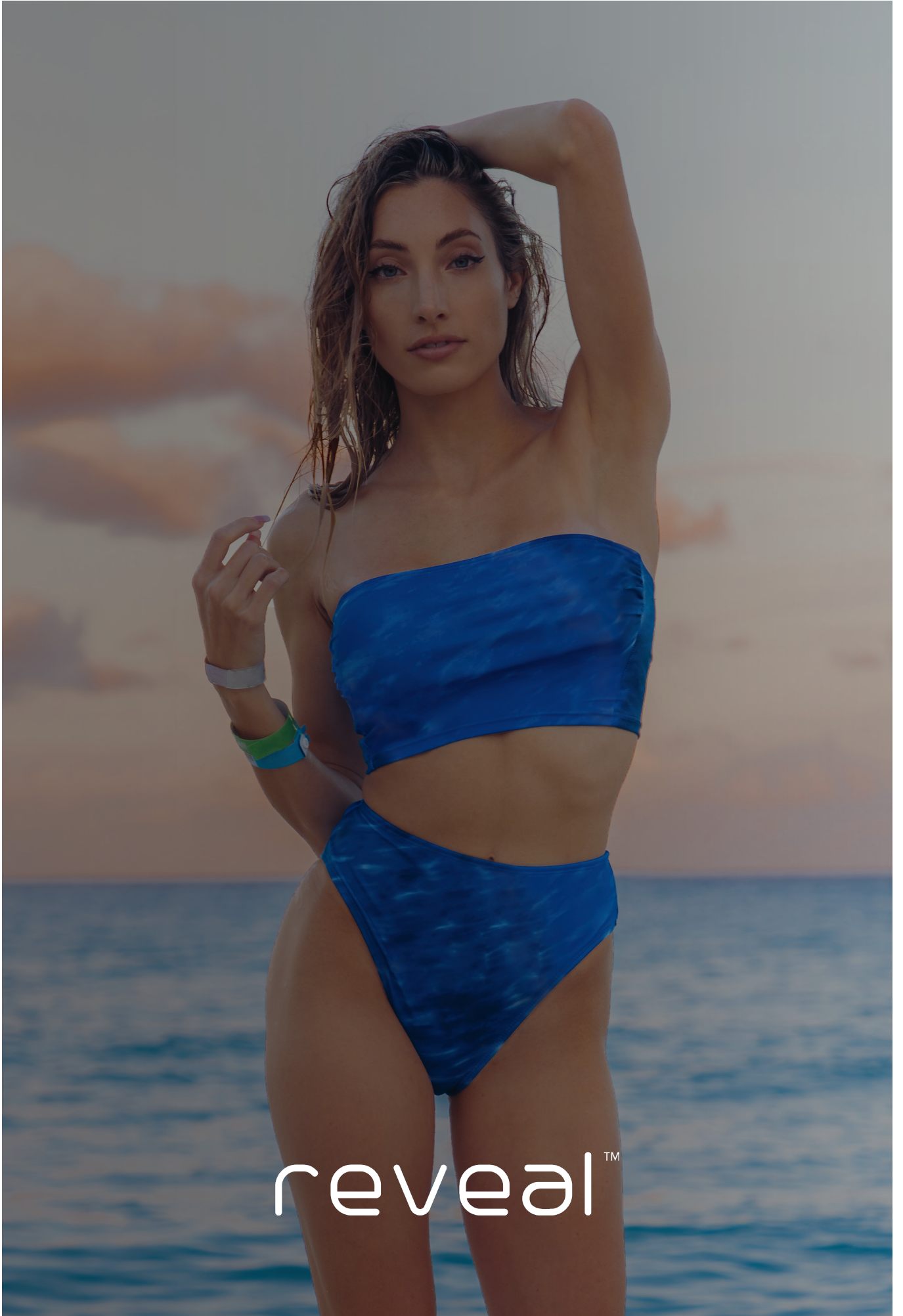
reveal™

VEGALUX™

HAIR REMOVAL - PERFECTED™



USER
MANUAL



reveal™

Reveal Lasers Ltd

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VEGALUX™

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CHAPTER 1

System Overview

| Section | Title | Page |
|---------|----------------------------|------|
| 1.1 | Use of this Manual | 5 |
| 1.2 | Maintenance | 6 |
| 1.3 | Modification of the System | 6 |
| 1.4 | Abbreviations and Acronyms | 7 |

CHAPTER 1

System Overview

1.1 Use of this Manual

The VEGA LUX™ system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system. This manual has been prepared to aid medical and technical personnel to understand and operate the system.

Do not operate the system before reading this manual and gaining a clear understanding of system operation. If any part of this manual is not clear, please contact your representative for clarification.

The information provided in this manual is not intended to replace professional training on the clinical use of the system. Please contact your representative for current information on available training. For clinical information, refer to the clinical guides in this manual, which includes set up guidelines for each application. This manual should always accompany the system and all operating personnel must know its location.

 **Warning:**

Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure. Therefore, before attempting to use or operate the system, practitioners operating the system should read this manual and become thoroughly familiar with all its safety requirements and operating procedures.

For further information about REVEAL™v, visit the company website at: www.reveallasers.com

1.2 Maintenance

The VEGA LUX™ system is a precision, technical medical device that requires periodic routine maintenance service, which must be performed by REVEAL™ authorized technical personnel. Failure to obtain service voids all warranties expressed and implied. Please contact REVEAL™ personnel or your local representative for details.

1.3 Modification of the System

Unauthorized modification of the hardware, software or specifications of the VEGA LUX™ system voids all warranties, expressed and implied. REVEAL™ takes no responsibility for the use or operation of such a modified device.

⚠ Warning:

No modification of this equipment is allowed.



1.3 Abbreviations and Acronyms

| | | | |
|-------------------------|--|-------------|------------------------|
| " | Inches | LCD | Liquid Crystal Display |
| °C | Degree(s) Centigrade/Celsius | LED | Light-emitting Diode |
| °F | Degree(s) Fahrenheit | m | Meter(s) |
| A | Ampere(s) | mm | Millimeter(s) |
| AC | Alternating Current | msec | Millisecond |
| CFR | Code of Federal Regulations | NIR | Near Infrared |
| cm² | Centimeter(s) | nm | Nanometers |
| CW | Continuous Wave | OD | Optical Density |
| HR | Hair Removal | PWM | Pulse Width Modulation |
| Hz | Hertz | Sec | Second(s) |
| IEC | International Electro Technical Commission | SPF | Skin Protection Factor |
| J | Joule(s) | TEC | Thermoelectric Cooling |
| J/cm² | Joule(s) per square Centimeter | V | Volt(s) |
| Kg | Kilogram(s) | VAC | Volt(s) AC |
| Lbs | Pound(s) | W | Watt(s) |

CHAPTER 2

Safety

| Section | Title | Page |
|----------------|---|-------------|
| 2.1 | Introduction | 9 |
| 2.2 | System Safety Measures | 9 |
| 2.2.1 | Electrical Safety | 9 |
| 2.2.2 | Light and Laser Safety | 10 |
| 2.3 | General Precautions and Cautions | 11 |
| 2.3.1 | Precautions | 11 |
| 2.3.2 | Cautions | 11 |
| 2.4 | The Treatment Room | 12 |
| 2.5 | Warnings Related to Light/Laser Energy Emission | 12 |
| 2.5.1 | Burn Hazards | 12 |
| 2.5.2 | Direct and Reflected Eye Exposure Hazards | 12 |
| 2.5.3 | Safety Eyewear | 13 |
| 2.5.4 | Explosion and Fire Hazards | 13 |
| 2.5.5 | High Voltage Hazards | 13 |
| 2.5.6 | Grounding the System | 14 |
| 2.6 | System Safety Features | 14 |
| 2.6.1 | Emergency Shut-Off Knob | 14 |
| 2.6.2 | Main Circuit Breaker | 14 |
| 2.6.3 | Light/Laser Emission Indicators | 14 |
| 2.6.4 | Double-Tiered Security for Laser Emission | 15 |
| 2.6.5 | Foot-switch | 15 |
| 2.6.6 | Tissue Cooling System | 15 |
| 2.6.7 | Module Design | 15 |
| 2.6.8 | Compliance | 16 |

CHAPTER 2

Safety

2.1 Introduction

This chapter describes general safety issues regarding the use of the VEGA LUX™ system, with special emphasis on optical and electrical safety.

With proper operation and maintenance, trained and qualified medical practitioners can use the VEGA LUX™ system safely. The supervising physician and all other personnel operating or maintaining the VEGA LUX™ must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured with a well-trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

2.2 System Safety Measures

The VEGA LUX™ system is designed to maximize safety for both patient and personnel. The following are some of the preventive safety measures:

2.2.1 Electrical Safety

The following electrical safety features are incorporated in the VEGA LUX™ system.

1. A semi-automatic circuit breaker, located on the service panel, protects the system by tripping when power overload occurs. To resume normal operation, lift the circuit breaker handle and restart the system.
2. There are fuses in the machine to protect the system from any electrical spikes.
3. Software protection, includes:
 - The software checks all safety related hardware after the system is switched on.
 - A watchdog cycle continuously monitors operation of the system during treatment.
 - If an error occurs, the system displays a warning message to the operator and disables further operation. A self-test of the attached module is performed when the system is turned on. The test includes module identification.
 - A self-test of the electrical circuitry takes places after the system is turned on. The test circuits continuously monitor system operation during treatment.

2.2.2 Light and Laser Safety

The following Light & Laser safety features are incorporated in the VEGA LUX™ system.

1. Closed light-guide geometry is used to transmit Light/Laser energy to the treatment site. Light/ Laser energy is emitted only through the front plane of the light-guide.
2. An emergency shutoff knob expedites shutdown when necessary. When pressed, it immediately shuts down system operation.
3. The system can be turned on only when the key is inserted in the key-switch. When not in operation, the key should be removed to prevent unauthorized use of the system.
4. A password on the service screen prevents unauthorized changes to the system's basic operating parameters
5. The system features one emission indicators: a red emission indicator lamp located on the handpiece and a buzzer.
6. Light emission is enabled only when the operator switches to Ready mode and presses the footswitch (minimum risk).
7. Laser emission is enabled only if both the foot-switch and the module's trigger are pressed at the same time, reducing the risk of unintentional Light/Laser emission.
8. Water is circulated through the module as soon as the system is turned on in order to cool the light source.
9. The flow and temperature of the water are monitored in order to eliminate the risk of module overheating. Light/Laser emission is not permitted if the water flow stops or if the water temperature is equal to or higher than 40°C (104°F).
10. The system is equipped with an electric foot-switch for the ease of use.

Warning:

- Any Light/Laser emitting device can cause injury if used improperly. High voltages are present inside the VEGA LUX™ system. Personnel who work with lasers must always be aware of the possible dangers and must take the proper safeguards as described in this manual.
- Use carefully may cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the VEGA LUX™ system by children or incapacitated persons may be dangerous.

Caution:

Laser fume and/or plume may contain viable tissue particulates.

2.3 General Precautions and Cautions

The following precautions, cautions and warnings must be observed for the safe use of the VEGA LUX™ system.

2.3.1 Precautions

Observe the following precautions when using the VEGA LUX™ system.

1. Physicians and clinicians should read this manual thoroughly before attempting to operate the VEGA LUX™ system.
2. The module's light-guide must be kept clean at all times. Remember to clean the cooling gel from the light-guide after each patient.
3. The system weighs approximately 154 Lbs (70 Kg) and may cause injury if proper care is not used when moving it. The system is well balanced and is designed to be moved, but should always be moved carefully and slowly. Never pull the system by the module or its umbilical cable.

2.3.2 Cautions

Observe the following cautions when using the VEGA LUX™ system.

1. Only REVEAL™ authorized personnel may service the VEGA LUX™ system. This includes making internal adjustments to the power supply, cooling system, optics, modules, etc.
2. Verify that the VEGA LUX™ is wired for the appropriate electrical voltage of your country (230V AC).
3. Maintenance performed by the operator must only take place when the system is shut down and disconnected from the electrical power source. Performing maintenance procedures with the system powered-up can be hazardous to the operator and/or destructive to the system.
4. Always turn off the system when it is not in use.
5. Never leave the system in Ready mode unattended.
6. Never allow untrained personnel to operate the system.
7. Never press the module's trigger and/or foot-switch unless the module is safely oriented at a specific and intended target.
8. The module and tips must always be visually inspected before treating the patient. If any wear or damage is apparent, do not use the module or tip.
9. Never leave the system turned on, open or unattended during system maintenance.

2.4 The Treatment Room

The treatment room must be clearly labelled with a sign indicating that high intensity light/laser energy is in use. The treatment room sign that is supplied with the VEGA LUX™ system.

The treatment room should not include any light reflecting objects such as a mirror.

Access to the VEGA LUX™ treatment room should be allowed only to personnel essential to the procedure and who are well trained in the required safety procedures.

Assure that all of the treatment room personnel are familiar with the VEGA LUX™ controls and know how to shut down the system instantly.

2.5 Warnings Related to Light/Laser Energy Emission

2.5.1 Burn Hazards

The VEGA LUX™ emits high-intensity light/laser radiation which is invisible to the human eye and can cause third degree burns.

2.5.2 Direct and Reflected Eye Exposure Hazards

1. It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing REVEAL™ recommended protective eyewear.
2. It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eyeglasses.
3. If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.
4. If the treatment area is very close to the eyes (e.g. eyelids), protect the eyes with corneal shields.
5. The Ocular Hazard Distance (OHD) is 10 m.

2.5.3 Safety Eyewear

1. All personnel must use safety eyewear and must ascertain that the eyewear provides adequate protection: for the diode laser module OD> 7 at wavelength range of 750-820 nm.
2. The safety eyewear and opaque eye protectors supplied with the system offers adequate protection, and more can be ordered from your representative.

2.5.4 Explosion and Fire Hazards

1. The absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in and around the treatment area.
2. The system is not suitable for use in the presence of flammable mixtures with air or oxygen.
3. Do not operate in the presence of volatile solvents such as alcohol, gasoline or other solvents.
4. Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.
5. If alcohol is used to clean and disinfect any part of the VEGA LUX™ system, allow it to dry thoroughly before operating the system.
6. Flammable materials must be kept at a safe distance from the system.
7. During treatment also pay attention to the possible danger of ignition of endogenous gases.

2.5.5 High Voltage Hazards

The system utilizes 230V AC. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

The VEGA LUX™ system produces very high voltages in various components. Some components may retain a charge after the power supply has been turned off, so no part of the exterior housing should be removed, except REVEAL™ authorized personnel.

Whenever system maintenance is performed, never leave the VEGA LUX™ system turned on, open or unattended.

2.5.6 Grounding the System

The system is grounded through the grounding conductor in the power cable & internal grounding pin.

Warning:

To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

2.6 System Safety Features

The VEGA LUX™ system is equipped with a number of safety features. All treatment room personnel should be familiar with the location and operation of these safety features.

2.6.1 Emergency Shut-Off Knob

This red knob is used for emergency shutdown. When pressed, it immediately shuts off power to the entire system.

To release the emergency shut-off knob, turn it clockwise. Otherwise, the system will remain off.

Caution:

Use the emergency shut-off knob only in the event of an emergency.

2.6.2 Main Circuit Breaker

A semi-automatic circuit breaker, located on the rear panel, protects the system against excessive current consumption. The circuit breaker disconnects power to the system in case of an electrical overload. To resume system operation, lift the circuit breaker handle.

2.6.3 Light/ Laser Emission Indicators

The system features two emission indicators:

- A Red LED located on the handpiece and a buzzer.
- Continuous Blink - during light/ laser emission (module's trigger and/or foot-switch are pressed).

The buzzer beeps:

1. Once the light/ laser is Ready to emit.
2. Intermittently during light/ laser emission, at the same rate as the pulse repetition rate.

2.6.4 Double-Tiered Security for Laser Emission

Diode laser beam emission is enabled only when the operator presses both the foot-switch and module trigger; therefore, accidental lasing may only occur due to double error condition (minimum risk).

2.6.5 Foot-switch

The system is equipped with electric foot-switch for the ease of use.

2.6.6 Tissue Cooling System

The module light-guide is cooled by a thermoelectric cooling method to reduce patient discomfort during treatment and to reduce post-procedure side effects, such as local skin redness and swelling. The tissue is cooled through a metallic ring and a cold sapphire window. The light-guide's temperature is reduced to 4°C (39°F) during system operation.

2.6.7 Module Design

Several aspects of the module design contribute to the safety of the VEGA LUX™ system:

1. Since the Light/Laser energy is generated in the module itself and not in the console (as in conventional lasers), there is no need for an articulated arm or other beam delivery system with inherent beam quality and alignment concerns. Instead, the VEGA LUX™ modules incorporate a onepiece light mixer that combines the emission from thousands of emitters to produce a uniform square beam. Since light/laser emission is confined to the module, there is no hazardous optical radiation in the console or the umbilical cable.
2. The light-guide is placed against the patient's skin during the system use, reducing stray light/laser energy while increasing the therapeutic effect.

2.6.8 Compliance

In compliance with these standards, the system is equipped with:

| | |
|--|--|
| Light/Laser emission indicators | Key switch |
| Fluence Display | Emergency shut-off knob |
| Foot-switch connector | Trigger button (diode laser module) |
| Proper labeling | |

CHAPTER 3

Installation

| Section | Title | Page |
|----------------|--|-------------|
| 3.1 | Introduction | 17 |
| 3.2 | Equipment List | 17 |
| 3.3 | Facility Requirements | 18 |
| 3.3.1 | Space and Positioning | 18 |
| 3.3.2 | Electrical Requirements | 18 |
| 3.3.3 | Environmental Requirements | 19 |
| 3.4 | System Installation | 19 |
| 3.4.1 | Environmental Conditions during Storage and Transportation | 19 |
| 3.4.2 | Foot-switch Connection | 20 |
| 3.4.3 | Filling the Coolant Reservoir | 20 |
| 3.4.4 | Module Connection | 21 |
| 3.4.5 | Moving the System | 22 |

CHAPTER 3

Installation

3.1 Introduction

The VEGA LUX™ system is designed for installation in an office or a clinic and requires minimal site preparation. When the VEGA LUX™ system is purchased, complete on-site installation, including initial system testing and calibration, is included.

System transportation and installation is carried out by authorized technical personnel, who will do the following:

1. Unpack the system and position it in its pre-selected location.
2. Verify the integrity of the system and its components.
3. Connect system components (module, foot-switch).
4. Plug the system into a designated electrical outlet.
5. Fill the cooling system reservoir with de-ionized water.
6. Test the system for proper calibration and functional operation of all components and software.
7. Coordinate the performance of an on-site safety inspection, if required.

3.2 Equipment List

The VEGA LUX™ platform includes the following:

1. VEGA LUX™ system console
2. Selection of modules purchased with the platform
3. Module
4. Set of keys
5. Foot-switch
6. Safety eyewear
7. Opaque eye protectors
8. Operator's manual
9. Water filling kit for the cooling system
10. Light/Laser radiation danger sign



3.3 Facility requirements

Before unpacking the system, ensure that the site meets requirements described in the following sections:

3.3.1 Space and Positioning

Space should be allocated with adequate ventilation and free airflow. The working area for the system should be prepared according to the system dimensions presented. In order to guarantee proper ventilation, always keep the sides of the system at least 20" (0.5m) from the wall or from other obstructions to air flow. After positioning the system, lock the breaks on the front wheels by pressing the pedals on top of each wheel.

Caution:

In order to guarantee safe disconnection of the system in any hazardous situation, system shall be allocated in such a way that appliance coupler always accessible.

3.3.2 Electrical Requirements

The system is factory pre-wired for the local line voltage, as ordered by the customer. Accordingly, the system will require a separate line supply of: 220V AC single phase. Input power lines should be free of transients, voltage and current spikes, sags and surges. Consequently, the system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc. The system is grounded through the grounding conductor in the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation.

Caution:

The system should be connected to a separate power line with separate circuit breakers. REVEAL™ cannot guarantee adequate performance unless the system is connected to a dedicated circuit.

Caution:

In order to guarantee safe disconnection of the system in any hazardous situation, system shall be allocated in such a way that appliance coupler always accessible.

Caution:

The system should be connected to a separate power line with separate circuit breakers. REVEAL™ cannot guarantee adequate performance unless the system is connected to a dedicated circuit.

3.3.3 Environmental Requirements

Air Quality:

the system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components. Airborne dust particles should be kept to a minimum. Dust particles absorb light/laser energy and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Water Quality:

the system should be operated using de-ionized water only. Regular tap water contains sediments that may damage the cooling system.

Temperature:

to ensure that the system performs optimally, maintain room temperature between 17°C and 25°C (68°F - 77°F) and relative humidity of less than 80%.

Note: When the system is used intensively, it emits heat. Therefore, it is recommended to install air conditioning in the room in which the system will be used

3.4 System Installation

3.4.1 Environmental Conditions during Storage and Transportation

Transportation of the VEGA LUX™ system should be under normal environmental conditions within the following range:

1. Ambient temperature: 0°C to 50°C
2. Relative air humidity: 10% to 60%
3. Atmospheric pressure: 90 kPa to 110 kPa

Note: If the system is to be stored in a cold area where the temperature may fall below 0°C (32°F), the deionized water must be drained from the cooling system. Only authorized service personnel may perform this procedure.

3.4.2 Foot-switch Connection

The foot-switch supplied with the system is electrically operated. To connect the foot-switch, insert the foot-switch wire to the provided slot at the back of the machine & rotate the knob in the clockwise direction.

3.4.3 Filling the Coolant Reservoir

The cooling system's reservoir must be filled with de-ionized water. It is imperative that the level of the water in the reservoir be checked every three months and de-ionized water added if necessary.

The VEGA LUX™ cooling system's water reservoir must be filled (or refilled) with de-ionized water in the following instances:

1. Upon installation of a new system
2. Every six months
3. LCD screen shows an error message denoting low water level. Filling / Refilling the water reservoir is done with the water filling kit (Fig. 34) that is supplied with the VEGA LUX™ which includes:

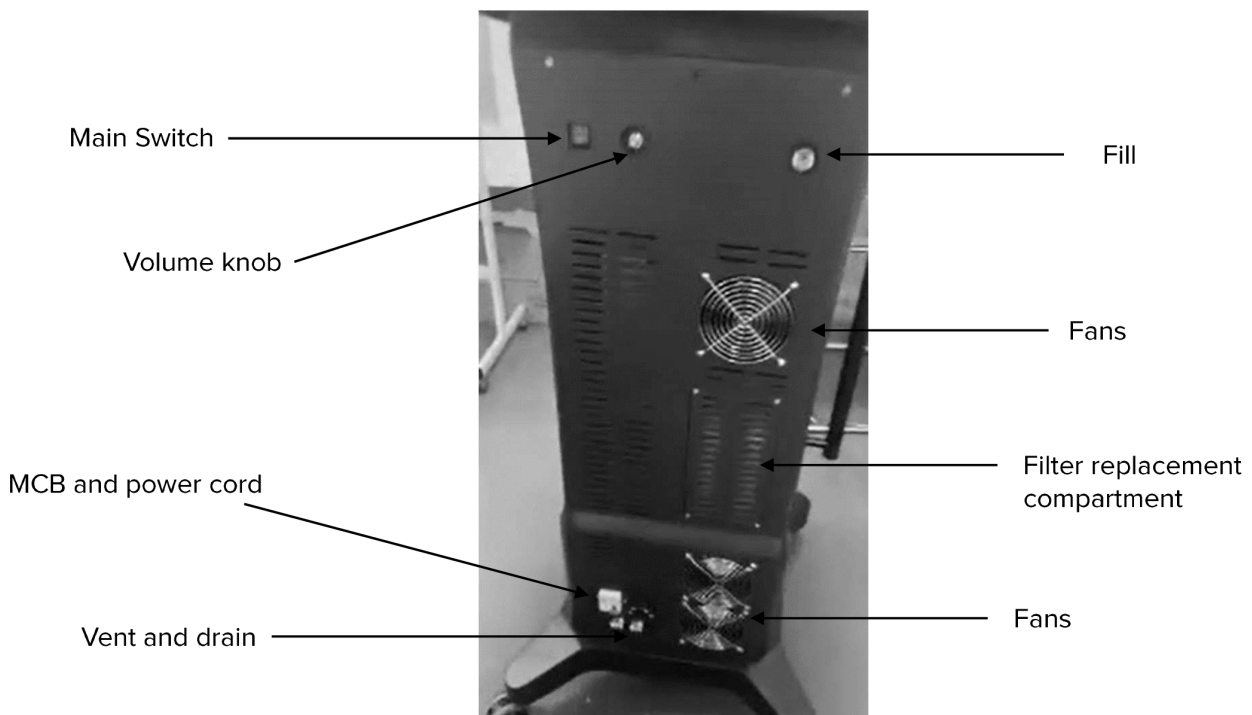


1. A water filling tube, with a funnel connected to one side and a quick-connector attached to the other side.
2. An elbowed white CPC connector.
3. A five liter (1.3 gallons) container of de-ionized water

Water Filling Procedure

1. Connect the small connector to the left port marked VENT on the lower right side of the service panel
2. Connect the clear tube with the funnel to the port marked FILL on the upper side of the service Panel
3. Use the supplied 5 liter (1.3 gal.) container of de-ionized water and pour it slowly into the funnel. Align the clear tubing with the service panel. Stop filling as soon as the water starts to spill from the VENT port.
4. Plug in the main power supply cable.

5. Disconnect the Fill/Drain Kit components.
6. Connect the desired module to the system.
7. Turn the system on and let it run for five minutes.
8. Turn the system on; it is ready for operation.



3.4.4 Module Connection

The Handpiece module is inside the box.

Connection of the module to the console is shown below. It is designed to enable easy replacement of the module when required. The module connection port is located on the middle of the front panel. Lift the cover in front of the machine for the access to connect and disconnect the handpiece.



For insertion & removal of the connector, proceed as follows:

1. Insert the module connector into the connection port (Fig. 22), as far as it will go in.
2. Turn the connector latch in a clockwise direction (Fig. 23).
3. After you turn the latch (Fig. 24), the connector will continue to go into the port until you can turn it no more - now the module is properly connected to the system.
4. To disconnect the module, reverse steps 1 through 3 above.



Caution:

Never use tools to tighten the module connector - finger-tight pressure is sufficient.

3.4.5 Moving the System

To move the system within the clinic, do the following:

1. Place the module in its box.
2. Disconnect the power cable.
3. Release the wheel breaks.
4. Slowly push or pull the system using the handle.

Caution:

- Never use the module or the umbilical cable to move the system.
- Do not use the module mast for moving or lifting the system.



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CHAPTER 4

System Description

| Section | Title | Page |
|----------------|---|-------------|
| 4.1 | Introduction | 25 |
| 4.2 | General System Description and Intended Use | 25 |
| 4.3 | System Components and Controls | 25 |
| 4.3.1 | Main Console | 26 |
| 4.3.2 | System Controls | 26 |
| 4.3.3 | System Controller | 26 |
| 4.3.4 | Cooling System | 27 |
| 4.3.5 | Isolation Transformer | 27 |
| 4.4 | revealVEGA™ Modules | 28 |
| 4.4.1 | Diode Laser Modules | 28 |
| 4.5 | System Specifications | 29 |

CHAPTER 4

System Description

4.1 Introduction

This chapter provides a detailed description of the VEGA LUX™ system. The description covers the system's main components, controls and functional sub-systems and system & module specifications.

4.2 General System Description and Intended Use

The VEGA LUX™ system is a multi-application, multi-technology platform that supports the following technology:

Diode laser technology: 2D (755 nm + 810 nm combined in 2 cm² spot size module) + Radiofrequency (2Mhz). The 2D+RF, 755nm, 810nm Diode Laser and Radiofrequency energy handpieces are intended for the removal of unwanted hair and to effect stable, long-term hair reduction. The complete system consists of its console, the various available modules and a footswitch. The module is pressed against the patient's skin and a light pulse is delivered when the module's trigger and the foot-switch are activated. The module's tip is cooled by the VEGA LUX™ cooling system. Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system's micro-controller through & LCD touch-screen

4.3 System Components and Controls

The VEGA LUX™ system consists of the following major components:

1. The main console unit that incorporates the control panel, power supply modules, cooling system, service panel and isolating transformer.
2. Modules (with umbilical cable and connector) that incorporates the optical head, tissue cooling system (the cold plate) and the trigger.
3. Foot-switch

4.3.1 Main Console

The console unit incorporates the following system components:

1. Control panel
2. Power supply modules
3. System controller
4. Cooling system
5. Isolation transformer

4.3.2 System Controls

The **VEGA LUX™** system controls offer the following features:

1. **Control Panel** - this touch-controlled screen provides information on the status and settings of the VEGA LUX™ system. The various screens of the display are described in detail
2. **Emergency Shut-off Knob** - this is a red, mushroom-like knob designed for emergency shutdown of the system.
3. **Key-switch** - turns on the system when activated.
4. **Light/ Indicator** - turns on when the system is activated.

4.3.3 System Controller

This board controls the operation of the sub-systems in real-time. It incorporates an advanced microprocessor, memory chip, and both digital and analog interfaces.

1. **System Software** - The VEGA LUX™ system incorporates embedded software. The software supports the graphic user interface, controls the system operating parameters and runs routine tests to ensure proper operation.
2. **Error Detection** - This VEGA LUX™ system is equipped with self-testing software that continuously monitors system operation, using the watchdog feature. The software continuously checks the hardware status, and if an error condition is detected:
 - An error message is displayed
 - The audible alarm signal is activated

4.3.4 Cooling System

The cooling system incorporates:

1. **Water-cooling system** - Water cooling is achieved in a closed-loop system operating with de-ionized water to ensure long life of the light/laser resonator. The cooling system comprises a heat exchanger, a water reservoir, a water pump, a particle filter and a deionizing filter. The system also includes a temperature sensor and flow & level switches to protect the system from a cooling system malfunction. As a safety feature, the light/laser energy emission is disabled when the water temperature reaches the high limit of 40°C (104°F).
2. **Integrated contact tissue cooling system** - The module light-guides are cooled by a thermoelectric cooling method to reduce patient discomfort during treatment & to reduce post-procedure side effects, such as local skin redness & swelling. The tissue is cooled through a metallic ring & a cold sapphire window. The light-guide's temperature is reduced to 4°C (39°F) during system operation. Thermistor monitors & keeps the temperature at this level to prevent overcooling of the treated area. The tissue cooling system is designed to cease operation in case of a pause in operation lasting for more than 5 minutes. This feature is included to prevent undesired condensation of water drops on the tip.
3. **Fans** - Five fans are located inside the system. Four fans cool the water system and the other fan cools the interior space of the console.

4.3.5 Isolation Transformer

The isolation transformer reduces the leakage current in the system to the ground for safety. It is designed as a medical grade unit.

4.4 VEGA LUX™ Modules

The following modules are available for use with the VEGA LUX™ system:

Diode Laser Modules: 2D (755 nm + 810 nm) combined in 2 cm² spot size module. The 2D, 755nm, 810nm Diode Laser Handpiece are intended for the removal of unwanted hair and to effect stable, long-term hair reduction.



4.4.1 Diode Laser Modules

The diode modules enable lasing Fluence up to 100 J/cm² at the module's laser aperture.

The laser energy is delivered in two modes:

1. **Stamping Mode**
2. **Smooth Mode™**

Laser energy is delivered through a 2cm² tip built into the module. The modules provide a preselected pulse duration as a function of the selected pulse type and fluence. The VEGA LUX™ diode laser modules are intended for hair removal and long-term hair reduction. It is indicated for use on all skin types (Fitzpatrick Skin Types I-VI).

The optical bench and the tissue cooling system are located inside the ergonomically designed module. The diode laser module is divided into 3 parts: an umbilical cable, a connector and the module itself. Power and control signals are exchanged with the console via the umbilical cable. The length of the cable is 170 cm (67"), which enables free access to any body part. The diode laser module is shown It incorporates the laser diode array with the light-guide, the protective sapphire window, the cold plate, and the module's trigger.

Caution:

- The module contains delicate optical components which may suffer severe damage if dropped. Except during treatment, the module should be always kept in its cradle.
- When moving the system, the module should be disconnected from the system and stored in its carrying case.

4.5 System Specifications

| | |
|--------------------|--|
| Laser Type | Double Wavelength Diode Laser |
| Laser Wavelength | 755+808nm |
| Display | 15.6 inches |
| Spot Size | 10*20mm |
| Handle Display | 2.4 inches |
| RF Power | 200W |
| UV Power | 5W |
| Pulse Width | 50ms-100ms |
| Energy Density | Stamping: Up to 60 Smooth Mode: Up to 20 |
| Frequency | Stamping: 0.5-3Hz Smooth Mode: 3, 5, 10Hz |
| Power of Handle | 1200W |
| Cooling | Water+ Air+ Semiconductor+ TEC |
| Temperature | -12 - 5°C |
| Language | English |
| Machine Dimensions | 58 x 64 x 159 cm |
| Packing Size | 85 x 78 x 178 cm |
| Net Weight | |
| Gross Weight | 158kg |
| Packaging | Aluminum alloy case, thick sponge cushion |
| Voltage | AC 220-230V / 50N60Hz |

CHAPTER 5

Controls and Indicators

| Section | Title | Page |
|----------------|---------------------------------|-------------|
| 5.1 | Introduction | 31 |
| 5.2 | Control Panel | 31 |
| 5.2.1 | LCD Touch-Screen Panel | 31 |
| 5.2.2 | Connected Module Indicator | 31 |
| 5.2.3 | Emergency Shut-off Knob | 31 |
| 5.2.4 | Light/Laser Emission Indicators | 31 |
| 5.2.5 | Key-switch | 32 |
| 5.3 | Service Panel | 32 |
| 5.3.1 | Main Circuit Breaker | 32 |
| 5.3.2 | Main Power Switch | 32 |
| 5.3.3 | Electrical Current Indicator | 32 |
| 5.3.4 | Diode Laser Module's Trigger | 33 |
| 5.3.5 | Foot-switch | 33 |

CHAPTER 5

Controls and Indicators

5.1 Introduction

This chapter details the controls, indicators and connection ports of the VEGA LUX™ system.

5.2 Control Panel

The control panel incorporates all the controls necessary to operate the VEGA LUX™ system, including a back-lit LCD graphic display with built-in touch-screen technology, key-switch, emergency shut-off knob and light/laser emission indicators (audio and visible).

5.2.1 LCD Touch-Screen Panel

5.2.2 Connected Module Indicator

The system automatically recognizes the connected module.

5.2.3 Emergency Shut-off Knob

In case of emergency the red shut-off knob should be pressed to switch off all electrical power supply to the system. To resume operation, release the knob (by a quarter of a turn clockwise).

5.2.4 Light/ Laser Emission Indicators

While Lasing a red LED starts blinking on the Handpiece, which indicates the Laser is being emitted. There is a buzzer in the machine which also indicates the Laser is firing.

5.2.5 Key-switch

The key-switch is located on the system's control panel. It is used to turn on the main operating menu after the system is activated. To switch the system into operational mode, the key-switch is turned a quarter of a turn, clockwise.

Warning:

To avoid misuse of the system, do not leave the key in the key-switch while the system is unattended.

5.3 Service Panel

The service panel is located on the system's back side. It incorporates all the required controls and connections for the system.

5.3.1 Main Circuit Breaker

A semi-automatic circuit breaker, located on the service panel, protects the system against power overload. When the circuit breakers handle is in the lower position, electrical power is not supplied to the system. To initiate system operation, lift the circuit breakers handle into the upper position

5.3.2 Main Power Switch

The main switch is located on the service panel. This is a green switch used to activate the LCD display. A correct operation sequence starts with switching on the main switch prior to turning on the key-switch.

5.3.3 Electrical Current Indicator

This green LED indicator illuminates when the power cable is connected to the wall outlet.

5.3.4 Diode Laser Module's Trigger

The module's trigger (Fig. 28) is the push-button located on the handle of the diode laser module. Diode laser energy emission is enabled only when both the diode laser module's trigger and the footswitch are activated.



⚠ Warning:

If the system is in Ready mode, laser beam emission occurs when the module trigger and the foot-switch are activated. This requirement for simultaneous activation of both triggers minimizes the risk of unintentional laser beam emission.

5.3.5 Foot-switch

The foot-switch is enabled only when the system is in Ready mode. Activation of the footswitch in Standby mode does not result in light/laser emission.

The foot-switch is an electric pedal that connects to the system through the foot-switch connection port on the service panel.

⚠ Warning:

If the system is in Ready mode, light/laser energy emission from the modules occurs when the footswitch or foot-switch and module's trigger are activated.

CHAPTER 6

Controls and Indicators

| Section | Title | Page |
|----------------|---------------------------------|-------------|
| 6.1 | Introduction | 35 |
| 6.2 | Control Panel | 35 |
| 6.3 | LCD Touch-Screen Panel | 36 |
| 6.3.1 | Connected Module Indicator | 36 |
| 6.3.2 | Emergency Shut-off Knob | 36 |
| 6.4 | Light/Laser Emission Indicators | 37 |
| 6.4.1 | Key-switch | 38 |
| 6.5 | Service Panel | 40 |
| 6.5.1 | Main Circuit Breaker | 41 |
| 6.5.2 | Main Power Switch | 41 |
| 6.6 | Electrical Current Indicator | 41 |

CHAPTER 6

Controls and Indicators

6.1 Introduction

This chapter describes in detail the operating instructions for the VEGA LUX™ system.

Caution:

- This system may only be operated by a licensed practitioner, according to the local laws in every country.
- A light/laser radiation danger sign, supplied with this system, should be placed at the entrance to the treatment room whenever the system is in use.
- Improper use or adjustment of this system may invalidate the VEGA LUX™ service warranty agreement. Please contact your authorized distributor before attempting to use the system in any manner other than those specified in this manual.

6.2 Error Detection

The VEGA LUX™ system is equipped with self-testing software that continuously monitors system operation by means of watchdog software & circuitry and by interrupts. The software continuously checks the hardware for any error condition:

1. The LCD displays an error message and disables further operation.
2. The audible indicator sounds an alarm signal which is longer than the normal light/ laser emission signals. In such a case you should shut the system down and restart it. If the problem persists, contact the engineer.

6.3 Preparing the System for Operation

1. Plug the system into the main power outlet.
2. Insert the key into the key-switch.
3. Connect the foot-switch to the service panel.
4. The patient and all personnel in the room should wear safety eyewear specific to the module being used
5. Lift up the circuit breaker on the rear panel to the upper position.

6.3.1 Module detection

The VEGA LUX™ system is equipped with sensors that automatically detect the module connected to the system. Based on the module connected, the system will enable the display of the available operation modes.

6.3.2 Starting the System

Mechanically turn on the system to begin working with the VEGA LUX™ system.

To start the VEGA LUX™ system:

1. Verify that the emergency shut-off knob is not engaged.
2. If it is, release it by turning clockwise until the
3. knob pops up. The emergency switch is situated
4. to the right side of the machine.

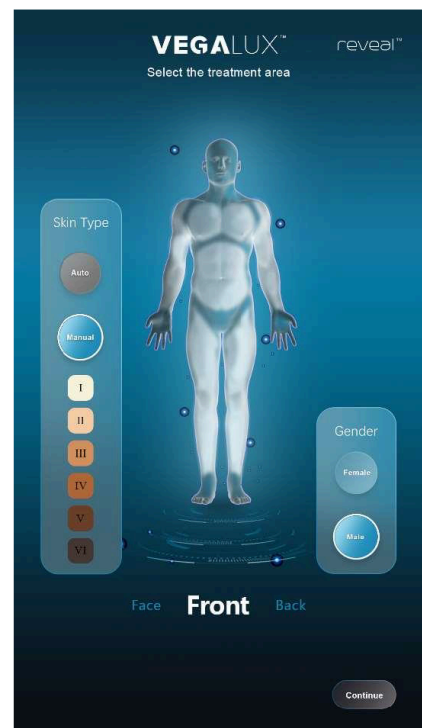
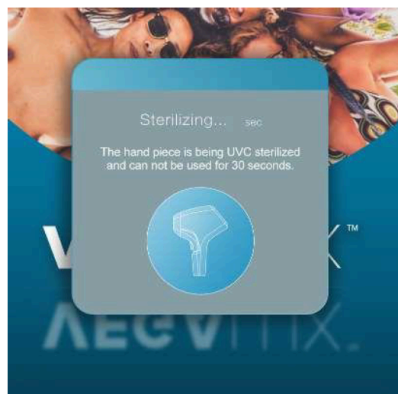


6.4 Operating the System

The system is operated by touching the soft keys on the touch-screen control panel to select and adjust treatment parameters. The control panel's various screens, their soft keys and informative tags & explanations to all tools & information tags on the screens are described in this chapter.

To start the VEGA LUX™ system:

1. Turn on the system. If you want to sterilize the Hand piece tip, click sterilize on the home screen. The UV light turns ON for 30 seconds and the tip gets sterilized
2. Rotate the key to start using the machine
3. The VEGA LUX, by default, will be switched to Smooth Mode.
4. Select the Gender "Male / Female" and the area to be treated. Toggle for the area to be treated in Front/Back/ Face. The selected area will be highlighted on the screen.
5. Select the Skin Type in the "Manual" segment between "I to VI". (Auto mode is disabled in this version) and click continue.



Warning:

- The VEGA LUX™ system emits intense light/laser pulses through the module. Make sure that all personnel are protected against accidental exposure to these pulses, either directly from the module or indirectly from a reflecting surface.
- To protect against eye damage and discomfort, make sure that everyone present in the room is wearing recommended protective eyewear.
- Never look directly at the pulse coming from the module, even when wearing appropriate protective eyewear.
- Never point the module so that it discharges into free space. Make sure that the module is pointed at the treatment site during actual treatment.
- The VEGA LUX™ system emits intense light/laser pulses through the module. Make sure that all personnel are protected against accidental exposure to these pulses, either directly from the module or indirectly from a reflecting surface.
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- Never point the module so that it discharges into free space. Make sure that the module is pointed at the treatment site during actual treatment.

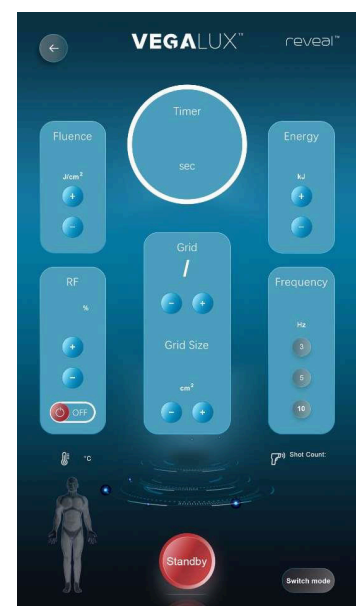
6.4.1 Diode Laser Modules

The VEGA LUX™ system is equipped with sensors that automatically detect the module connected to the system. Based on the module connected, the system will enable the display of the available operation modes.

Smooth Mode - Setting the operating parameters

Fluence: to set the Fluence parameter. To increase or decrease the parameter setting, use + or - arrow keys on the in the Fluence template. The maximum Fluence is 20J/cm

Energy: Set the total invested energy parameters, click on the energy window. To increase or decrease the parameter use + or - arrow keys on the right of the energy window. The exhibited value expresses the total energy applied per session counted in Kilo Joule(KJ)



Time duration: Counts the calculated duration of the pulses in seconds. The time is calculated on the basis of Fluence energy and frequency set.

Total Shots: The field counts the total number of laser pulses emitted by the Hand piece and it cannot be reset. The field will reset to zero only when a new Handpiece is connected.

Grids: To increase or decrease the no of grids use + or - arrow keys on the screen. The total number of grids depend upon the area to be treated.

For example, if you are treating lower hands and you select the 100cm² grid, there would be around 5 to 6 grids to be treated.

Grid Size: The Grid needs to be marked on the treatment area with the stencil. Select the Grid size 50 / 100 / 150 / 300 cm² on the screen with respect to the treatment area marked on the skin.

RF percentage: The percentage of RF Frequency can be adjusted from this setting, use the + or - arrow to adjust the Frequency from 0 to 100%. The RF can be disabled by clicking on the RED button and enabled by clicking the ON button.

Temperature: Displays the temperature of the machine.

Switch mode: Click on Switch mode at the bottom corner of the screen for the

Stamping Mode - Setting the operating parameters

The stamping mode can be accessed by clicking on switch mode in the parameter screen of Smooth mode. The System is operated by touching the soft keys on the touch screen control panels to select and adjust the treatment parameters.

Fluence: to set the Fluence parameter. To increase or decrease the parameter setting, use+ or - arrow keys arrow keys on the bottom of the Fluence window.

RF percentage: The percentage of RF Frequency can be adjusted from this setting, use the + or - arrow to adjust the Frequency from 0 to 100%. The RF can be disabled by clicking on the RED button and enabled by clicking the ON button.

Frequency: Frequency can be adjusted from 0.5 to 3 Hz, by clicking on + and -. Shot count: This field displays the total number of laser pulses emitted by the module and cannot be reset.

Pulse duration: The pulse duration is to be adjusted between short, Medium and Long.

Standby/Ready mode:

This soft key toggles the VEGA Lux between standby and ready modes. Press the Ready button when you are ready to start the treatment. Once the treatment is done toggle the machine back to standby mode.

Temperature: Displays the temperature of the machine.



6.5 Initiating Light/Laser Emission

1. Position the module's light-guide on the area to be treated.
2. Diode laser energy emission is enabled only when both the foot-switch and the module's trigger are activated together.

Note: If the foot-switch and/or the module's trigger are inadvertently activated while the system is not in Ready mode, light/laser emission will not occur and an audible alarm signal will sound

3. The light-guide should always be in contact with the treated area during treatment. An audio signal sounds with each emitted pulse.
4. The pulse counter is updated with each pulse.
5. To stop light/ laser emission, release the foot-switch or the foot-switch and the module's trigger.

6.5.1 Pause in Operation

As a standard safety measure whenever light/laser emission is not immediately required, the system should be set to Standby mode. Before leaving the room, the operator should turn the system off as described.

6.5.2 Changing Parameters during Operation

The body area, Fluence, invested energy and stamping rate can be changed during system operation. To change the operating parameters, perform the following:

1. Release the trigger and foot-switch.
2. Transition the system to Standby mode.
3. Change the parameters as required.
4. Return to Ready mode.

6.6 Turning the System Off

To turn off the system:

1. Set the system to Standby mode.
2. Turn the key-switch counter-clockwise a quarter of a turn.
3. Toggle the main power switch to the Off position.
4. Move the circuit breaker's handle to the lower position.
5. Disconnect the power cable from the mains outlet.
6. Clean the module and other accessories
7. Set the module in its cradle.

Warning:

To prevent unauthorized use of the system, do not leave the key in the key-switch unattended.

CHAPTER 7

Treatment Guidelines

| Section | Title | Page |
|----------------|---|-------------|
| 7.1 | Safety Checks | 43 |
| 7.2 | Purpose of Test Patch | 43 |
| 7.3 | Preparation of Skin Before Treatment | 44 |
| 7.4 | Why Treatments May Cause Negative Reactions | 45 |
| 7.5 | Managing Patient Discomfort | 46 |
| 7.6 | Post-Treatment Care - Advice Sheet | 46 |
| 7.7 | Other Treatments and LHR | 48 |
| 7.8 | Consultation Discussions | 48 |
| 7.9 | What to Expect During and After Treatment | 49 |
| 7.10 | Possible Side Effects | 50 |
| 7.11 | Clinical Photography | 50 |
| 7.12 | Consent Forms and Treatment Records | 50 |

Treatment Guidelines

7.1 Safety checks

1. Check All Equipment and Laser.
2. Check cooling devices.
3. Treatments should be 90 degrees to tissue (hand piece angle to skin)
4. Tips of distant gauge (if available) should be touching skin.
5. Try stamping or gliding techniques.
6. Go at a speed you are comfortable with.
7. Make yourself comfortable with hand piece.

7.2 Purpose of Test Patch

1. Performing a Test Patch is obligatory for Medical and Legal reasons.
2. Allows you to check the patient's skin response.
3. Gives the patient an opportunity to see how laser will feel
4. Perform only after signed consent.
5. Test patch on area to be treated but the least conspicuous area.
6. A test patch should be performed on each of the areas the patient is interested in.
7. The patient should come with some hair for test patch, so the hair can be assessed for color and thickness
8. The area to be treated should be cleansed with a non-alcohol non-lanolin skin cleanser & marked.
9. Establish skin type and hair.
10. Use three different fluence levels starting with the lowest.
11. Choose the highest fluence that gives the best efficacy with no adverse side effects.
12. Record reactions

7.3 Preparation of Skin before treatment

1. Remove all makeup, deodorant, and other barriers. (jewelry, clothing etc.)
2. Use baby wipes or a mild non alcohol cleanser.
3. Trim or shave the hair if necessary.
4. Mark out area with white pencil.

Treating Sensitive Areas

1. Upper Lip/ Nose

Ask the patient to hide lips/ protect vermilion border. You can use a wooden spatula to block off each nostril as you work close to it. If using Air cooler to cool skin lower the level and supplement with ice packs. You can ask the patient to hold the nose or take deep breaths after each shot.

2. Ears

Place dry cotton wool down ear canal. Place hand piece so that the light fires away from the ear canal.

| CLINICAL ENDPOINTS | COMMENTS |
|------------------------|--|
| Erythema (pinkness) | Redness on the area treated is a good clinical endpoint |
| Peri-follicular oedema | <ul style="list-style-type: none">• Looks like goose pimples around the follicle.• This is the best indicator that the correct fluence has been used. |
| Hair Vaporization | <ul style="list-style-type: none">• Frazzled hair, or can smell burnt hair.• Hairs popping out the follicle are a very good indicator that the treatment is working. |
| Comfortable treatment | <ul style="list-style-type: none">• The patient will feel uncomfortable and feel slight pain.• Clients should never be treated on a greater than level 5 of a pain scale of 0-10, where 10 is the maximum pain. |

| NEGATIVE REACTION | COMMENTS |
|---|--|
| Excessive Pain | <ul style="list-style-type: none"> • If the patient experiences excessive pain, stop treatment, cool the skin and moisturize with Aloe Vera gel. • Review and then if all is OK restart treatment. |
| Excessive Persistent Erythema | <ul style="list-style-type: none"> • Normally resolves within 24 hours however, in rare cases it can last up to 72 hours. • Advise the client to apply Aloe Vera or hydrocortisone cream. |
| Blistering/Crusting/Scabbing | <ul style="list-style-type: none"> • This is rare. Cover with antibacterial ointment. • Should be left to heal naturally, scabs should not be picked. |
| Burn | <ul style="list-style-type: none"> • Stop the process. • Cool the burn with cold compresses or covered ice packs. • Take over the counter pain reliever. • Do not retreat till completely healed. |
| Pigmentation Changes/ Hyper or Hypo pigmentation | <ul style="list-style-type: none"> • Discontinue treatment until normal pigmentation returns, • Moisturize the area and protect from the sun. • Hypo pigmentation can heal, although in some cases it can be permanent. |

7.4 *Why treatments may cause negative reactions*

1. Deciding wrong Fitzpatrick Skin Type
2. Treating patients with tan, sun exposure or fake tan.
3. Distant gauge/handpiece not 90 degrees to the skin surface
4. Forgetting to switch on chilled air cooling, or not using enough cooling
5. Not lowering the fluence on target rich area. (melanin)
6. Not test patching pre-treatment
7. Too heavy an overlap
8. Failure to monitor patient comfort
9. Not recording parameters correctly
10. Not cleaning laser consumables, glass pieces, distant gauges, inserts etc.

7.5 Managing Patient Discomfort

1. For those with chilled air cooling only, consider applying a thin layer of ultrasound gel in the area of discomfort.
2. Turn down the fluence (energy)
3. Turn up the cooling and or apply cold packs
4. Distract patient - engage in conversation
5. Topical Anesthetic creams (EMLA)6. Paracetamol (taken before treatment)
6. Reduce/increase Repetition rate
7. Massage areas during / after treatment. This can really help with pain on areas such as upper lip.

7.6 Post-Treatment Care - Advice Sheet

1. Immediately after treatment, there will be erythema (redness) & oedema (swelling) of the follicles which may last up to 2 hours or longer.
2. A topical soothing skin care product such as Aloe Vera gel may be applied following treatment. If the area still feels hot you can apply a cold flannel or cool pack at home.
3. If your skin is particularly sensitive & prone to histamine reactions, you may take an antihistamine medication.
4. Makeup can be used after the treatment if the skin is not irritated.
5. Avoid picking or scratching the treated area.
6. **DO NOT** depilate between laser treatments with waxing, plucking, threading or creams that will disturb the hair follicle. Shaving is the preferred method.
7. Anytime from 10-21 days after the treatment, shedding of the treated hair may occur & this appears as new hair growth.
8. This is **NOT** new hair growth. You can clean & remove the hair by washing or wiping the area with a wet cloth or loofah sponge.

9. After an axillae (underarms) treatment, you may wish to use a powder instead of a deodorant for 24 hours after the treatment to reduce skin irritation.
10. There are no restrictions on bathing except to treat the skin gently, as if you had sunburn, for the first 24 hours.
11. Avoid very hot bath or shower.
12. It is extremely important to avoid sun exposure before, during and after treatment.
13. After Laser your skin is more sensitive, and you are more likely to burn and therefore get hyper pigmentation or hypo pigmentation issues.
14. Laser treatment increases light sensitivity; all the areas treated by a laser must be covered with plenty of sunscreen because the skin is sensitive to darkening.
15. Recently tanned skin cannot be treated with a laser because it increases the risk of developing hypo pigmentation.
16. We recommend using sunscreen protection of at least SPF 30 all day
17. Irritated skin may be more susceptible to injury. Recently tanned skin cannot be treated as you may develop hypo- pigmentation (loss of skin color).
18. You may be asked to stop any topical medications 1-2 weeks before treatment.
19. You MUST avoid waxing, threading, plucking, epilating or bleaching the hair 4 weeks prior to treatment.
20. The melanin containing hair must be present in the follicle as it is the 'target' for the laser light.
21. You will need to prepare the area to be treated in advance of treatment.
22. The area will need to be shaved & kept clean & free from any cosmetic products on the day of the treatment.
23. Failure to prepare the area may result in unproductive session.
24. A medical history is taken at the consultation, but we rely on you to inform us of any changes to this.
25. We need to know of any medication you are taking including those bought from a chemist or herbalist/homeopath (inter sessions as well).

7.7 *Other treatments and LHR*

1. Hydroquinone: Should be stopped a week before Laser Hair Removal, it is a chemical bleach.
2. Beauty products containing Glycolic Acid, Benzoyl Peroxide, Bleach, Salicylic Acid & bleach: These need to be stopped before treatment, they contain strong chemical & make the skin more sensitive.
3. Glycolic Acid Peel: Wait 1-2 weeks before Laser hair removal. If 70 % wait longer.
4. Moderate Peel: Wait 1 month before Laser hair removal.
5. Deep Peel: Wait 3-6 months before Laser Hair Removal.
6. Botox/Injectables: Allow 10-14 days after treatment
7. Moles/Birthmarks/Tattoos/Permanent Makeup: It is not recommended to treat over any moles, birthmarks, Tattoos or permanent make-up; as any pigmented areas will absorb the light and is likely to burn & blister & permanent make up is likely to turn black.
8. Cut, broken, irritated or infected skin: The appointment will need to be rescheduled as you cannot treat over these areas.

7.8 *What MUST be discussed at the Consultation*

1. **Client concerns and & Expectations from treatment**

Communicate with the client and gain an understanding of what they want from the treatment.

Good questions to ask would be: What is it that concerns you most? How do you remove hair at present? How often do you need to? How quickly does your hair grow back?

2. **Confirm Client's Medical history.**

Go through any underlying medical conditions

Ask if the client is taking / applying any medications.

3. Assessment of Hair & Skin Type

The hair needs to be dark and there needs to be enough contrast between hair and skin color for the Laser to work.

You need to ensure you have the correct equipment to treat the patient's skin type.

4. Type of technology & How Hair Removal works

Explain to the client in simple words how the laser works - e.g. -the light from laser heats the hair follicle and destroys it completely.

This should include an explanation of the hair growth cycle.

Inform them which technology you are going to use.

7.9 What to expect during & after treatment

1. Treatment sensation: this can be described as a rubber band being snapped against the skin.

The treatment can be uncomfortable and should be described as such to the client. Client may feel mildly uncomfortable to extremely uncomfortable depending on their pain threshold, the thickness of the hair and the area being treated. Cooling before and after can reduce the pain.

2. Results are not immediately visible. After laser treatment some hair will be vaporized immediately, and some will take 3-7 days to shed.
3. Multiple treatments will be required. Go through treatment intervals. Maintenance sessions may be required, particularly if there is a known hormonal imbalance such as PCOS.
4. Results to expect: Differs for different hair and skin types and body areas being treated. 100% clearance cannot be guaranteed.

7.10 Possible Side Effects of treatment

1. Temporary Hyper pigmentation (darkening of the skin)
2. Temporary Hypo pigmentation (lightening of the skin)
3. Temporary erythema (Redness) settles within hours
4. Temporary peri-follicular oedema
5. Temporary blistering and scabbing

All of these conditions are temporary however in some cases they can be permanent.

7.11 Importance of Photograph

1. Gain client's permission to take photographs of the area before treatment.
2. It is a good idea to take picture of the area before session to catalogue the progress
3. As treatments progress clients may forget how bad the problem was.

7.12 Consent Forms & Record Sheet

1. The patient must fill out a consent form.
2. Patient consent form must be signed prior to the treatment, and every session if any changes to body parts or extending areas.
3. Which explains any possible side effects, and confirmation that the patient has been given an explanation of the procedure and expected outcome.

A consent form is necessary for Insurance /Legal and Medical purposes



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