American Medical Bio Care, Inc.

omnilight™ FPL

User's Manual

Physician Responsibility

United States federal law restricts prescription medical devices to sale by or on the order of a physician or properly licensed practitioner. AMBC makes no representation regarding state or local laws or regulations that might apply to the use and operation of any medical device. The Physician is responsible for contacting his or her local licensing agencies to determine any credentials required by law for clinical use and/or operation of the device.

Maintenance

The OmniLight FPL Pulsed Light System is a medical device that requires routine service as well as consumable parts. All service must be performed by either a AMBC technician or a technician trained by AMBC. Failure to obtain service and parts from Luxsano or its authorized distributors voids all warranties, express and/or implied.

Modification of the Device

Unauthorized modification of the hardware, software or any other specification of the OmniLight FPL Pulsed Light System voids all warranties express and/or implied. Luxsano accepts no responsibility for the use of a modified device.

Resale

The OmniLight FPL Pulsed Light System is a technically advanced medial device. If any device is resold by anyone other than an authorized sales representative, AMBC offers a resale inspection by a trained technician to ensure that the device is working according to specification and is properly calibrated. Use of a device that has been resold but not inspected is a misuse of the device and may result in injuries. All warranties, express and implied, will be void.

Copyright

Regulatory

The OmniLight FPL Pulsed Light System is designed to meet international safety and performance standards.

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Insert picture of ISO 9001/ISO13485 certification logo

Personnel operating this device 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. Read this manual prior to operation of the system.

The contents of this manual are not intended to replace physician or professional training in the clinical use of the OmniLight FPL Pulsed Light System.

Note: OmniLight is a trademark of Luxsano.

Introduction

The OmniLight FPL (Fluorescent Pulsed Light) system is the latest advancement in pulsed light technology. It can be used for multiple applications, including hair removal, treatment of pigmented lesions, and treatment of vascular lesions.

The intent of this manual is to provide the physician and technicians who operate the OmniLight FPL Pulsed Light System with information on the operating principles, controls, safety precautions, installation and maintenance of the system.

Section 1	Overview	Contains general information about the OmniLight FPL Pulsed Light System
Section 2	Safety Features	Contains explanation and direction concerning safety measures required for the OmniLight FPL Pulsed Light System
Section 3	System Description	Contains a complete description of the OmniLight FPL Pulsed Light System
Section 4	Installation	Explains requirements for the proper installation of the OmniLight FPL Pulsed Light System
Section 5	Operation	Explains how to safely operate the OmniLight FPL Pulsed Light System
Section 6	Maintenance and Troubleshooting	Provides a review of how to maintain the equipment, as well as a troubleshooting guide
Section 7	Accessories	Describes all available accessories and ordering information
Section 8	Treatment information	Provides details on the treatment process, as well as pre-treatment care, post treatment care, indication and contraindications

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Section 1

System Overview

Caution

This manual should be read thoroughly prior to Physician or other personnel operating or maintaining this equipment.

1.1 Use Principle

OmniLight® is the latest modality for aesthetic skin treatment and the operation principle is based on the **Selective and Extended theory of Photo Thermolysis**.

The principle of skin rejuvenation and hair removal is selective heating of the unwanted skin lesion to various temperatures depending on the type of the lesion – without any damage to the surrounding skin.

It operates through a creation of a directed incoherent light beam of spectrally balanced light. A sapphire crystal light guide is used to transport the resultant longer wavelength light to laser-dye impregnated polymer sheet, which emits the selected wavelength band. Incorporating all the benefits of both laser and Intense Pulse Light in a single system, OmniLight™ offers non-invasive, safe and effective method for skin rejuvenation

Selective Heating of Tissue by Photo-Absorption

The light emitted from the OmniLight® is composed of a lesion optimized broad band spectrum of colors. When the light hits an object, the target "*chromophores*" (e.g. melanin and hemoglobin) absorb specific wavelength bands, while the other structures in the object poorly absorb these wavelengths. The absorbed light energy is transformed into heat energy results in selective destructive heating of the target point.

Selective heating of melanin

Applying the same principle to the pigmented skin lesions and hair, the melanin pigment has a wide but wavelength dependant absorption spectrum. The light absorption in melanin is high at visible blue light (400-nm) but descends as wavelength increases further up to approximately 900 nm. Above this wavelength the melanin has insignificant absorption.

The optimal spectral range for treatment of unwanted hair and dark/thick pigmented lesions is 600-900 nm while the band 515-600 nm is more effective on shallow and light pigmented lesions. The spectral band 515-600 nm is not very useful in hair removal since the penetration depth is rather shallow due to strong competing hemoglobin absorption. As pointed out above the red and infrared portion of the spectrum is ideal in hair removal since this spectrum penetrates deep enough to heat the follicle by heat conduction from the selectively heated hair shaft. When the follicle's outer root sheath reaches 70ºC, the germinative cells denature, leading to permanent destruction of the complete hair follicle structure inhibiting hair re-growth.

1.2 Unique FPL features

The FPL provides superior clinical efficacy without compromising the safety aspects.

How is that possible?

The answer is the unique combination of user beneficial features built into the FPL device***:***

- ***Spectral power distribution control by utilization of patented fluorescent filter technology and lamp plasma current density control. The fluorescent filters also provide clear-cut blocking of harmful shorter wavelengths.***
- ***Advanced temporal pulse power forming of light energy for optimal heat control of the complete tissue target volume.***
- ***Skin contact cooling with the sapphire light guide. Sapphire temperature is accurately controlled by an external cooler. Cooling is confined exactly to the spot size providing consistent and repeatable clinical response.***
- ***High fluence***

1.3 System basics

The OmniLight™ Pulsed Light System is a computer-controlled system consisting of four major components: System console, power cube, treatment handpiece and an external cooler.

- The external cooler provides feed back temperature control of the sapphire waveguide range +5 to 25 C, accuracy +/-1.5 C. The user interface consists of an LED display having four push buttons to control input. In running mode the LED shows sapphire temperature.

- The user interface (Control Panel) consists of a flat-panel with three membrane switch push buttons and a LCD display located on the top of the system console. The panel displays the machine modes and parameters and is easily controlled with up and down arrows.

- The handpiece consists of an enclosed optical system which emits the pulse of light through a filter and into the sapphire waveguide. The handpiece is an ergonomic design which is easy to hold with only one hand and comfortable for the user.

1.4 Indications for Use

The OmniLight FPL Pulsed Light System can be used for:

- Hair removal for all skin types, including permanent hair reduction
- Treatment of vascular lesions
- Treatment of benign pigmented lesions
- Acne treatment (not FDA approved)
- Tattoo removal

Section 2

Safety

This chapter describes safety issues regarding the use of the OmniLight FPL Pulsed Light System, with emphasis on optical and electrical safety.

WARNING

Use or adjustment of controls or implementation of procedures other than those specified herein may result in hazardous radiation exposure.

Physicians and other personnel operating or maintaining the OmniLight FPL system should read this manual and become thoroughly familiar with all safety requirements and operating procedures before attempting to operate the system.

2.1 Introduction

The OmniLight FPL Pulsed Light System has been designed for safe and effective treatments. With proper use and maintenance, the system can be operated safely by trained, qualified physicians and licensed practitioners.

The primary considerations should be for the safety of the patient, the operator and other personnel.

When designing the OmniLight FPL Pulsed Light System, considerable effort was made to maximize safety for the patient and the operator. A self-test of the electrical circuits takes place after the machine is turned on. The test circuits continuously monitor the system operation during treatment.

- Light is only emitted through the front plane of the headpiece's sapphire lightguide.
- An interlock is placed in the handpiece interface that will not allow the system to function if the handpiece is attached improperly to the console.
- Interlocks are present also inside the console to prevent the equipment from functioning if any of the console panels are removed.

- Interlocks are present in the handpiece to prevent the system from functioning if the end caps are open.

WARNING

Pulsed light emitting devices can cause injury if used improperly. High voltage (10 kV) is generated inside the OmniLight FPL Pulsed Light System. Personnel who work with pulsed light systems should always be aware of the possible dangers and take the proper safeguards as described in this manual.

The Patient

Patient safety is assured by a well-trained staff and a well laid out treatment room. Patient education is important, including information about the treatment itself as well as the expected outcome of the treatment The patient shall wear the provided, protective eyewear during treatment.

Personnel Operating the OmniLight FPL

Exposure to fluorescent-pulsed light requires eye protection that lowers the intensity of the light. The operator and any other personnel present shall wear the provided, protective eyewear during treatment.

Treatment Room

The treatment room should be labeled with signs indicating that pulsed light is being used.

CAUTION

Fluorescent Pulsed Light device may present eye hazard
Use proper eye protection wear when in operation and/or in treatment.
Visible and near infrared light

2.2 Cautions and Warnings

CAUTIONS

- Technical service should only be performed by personnel authorized by Luxsano.
- The OmniLight FPL Pulsed Light System must be wired correctly for the wall voltage used in your country.
- Maintenance should only be performed when the unit is shut down and disconnected from power. Performing maintenance procedures with the system powered up may be hazardous.
- The lightguide must be kept clean at all times.
- Gel and any other liquids used near the system should not be allowed to seep inside the handpiece.
- If water is detected leaking from the handpiece, the power should not be turned on. If it is already on, it should be turned off immediately.

WARNINGS

- Pulsed light emission can present an eye hazard. Use the appropriate protective eyewear anytime the equipment is being operated.
- Using energy settings higher than those recommended during training, or previously established as safe, may cause thermal damage to the skin, including hypertrophy and/or atrophy and/or abnormal pigmentation.
- Always guard against accidental exposure to the pulsed light, including light that is emitted directly from the handpiece or indirectly from a reflecting or scattering surface.
- **Never look directly into the light beam or the distal end of the sapphire lightguide,** even if you believe the unit is non-operational.
- Never point the handpiece so that it discharges into free space.
- When not in use the handpiece should always be put back into the handpiece holder.

Labeling

Omnilight FPL
Model P/N:_____
S/N:_____

110 V 16 A 50/60Hz
220 V 8 A 50/60Hz

US PATENT:
#

DANGER
Fluorescent Pulsed Light
Use proper eye protection wear when operating and/or treating patients.
Never look directly into light the source.

Visible to near infrared light
500-1200 nm

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CAUTION
HIGH VOLTAGE/HIGH CAPACITANCE

Unit contains potentially LETHAL electrical charge
Before working on the unit:

- Switch off power supply
- Disconnect ALL cabling and or plugs
- Wear insulation gloves
- Short capacitors to ground

CAUTION
Federal (USA) law restricts this device to sale by or on order of a physician or any other practitioner licensed by the law of the state in which he practices to use or order the use of the device.

2.3 Operational Safety

The following guidelines should be followed to ensure good optical safety:

- Wear protective eyewear to guard against accidental exposure.
- Post a warning sign on the treatment room door.
- Do not allow access to the treatment room, except to essential personnel who are trained in the safety requirements.
- Never look directly at the pulsed light being emitted from the handpiece.
- Do not use the treatment head in any other way than that which is specified in this manual.
- Do not perform treatments in the presence of explosive anesthetics or other flammable materials.
- Only direct the light at the targeted treatment area.
- Never place reflective objects in the light path, including jewelry, watches, surgical instruments or mirrors.

2.4 Electrical and Mechanical Safety

- Keep the covers to the console in place at all times.
- Never leave the unit turned on while unattended.
- The OmniLight FPL Pulsed Light System weighs approximately 38 kg (84 pounds) and may cause injury if care is not taken when moving it.
- The unit is grounded through the conductor in the power cable. This grounding is essential to safe operation.

2.4 Fire Hazards

- The absorption of light raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials.
- Do not use a flammable substance such as alcohol or acetone in preparation of the skin for treatment. Only use soap and water.
- If alcohol is used to clean and disinfect the system, it must be allowed to dry completely before the system is used.

2.5 Safety Features

- Calibration Key Card (CalCard)
  In order to operate the system, the Calibration Key Card must be inserted into the slot located on the top of the unit. The calibration key card allows the system to start up in operational mode. This

prevents unauthorized use of the unit. *Note! Keep the CalCard in a safe place. Lost card will not be replaced free of charge.*

- On/ Off Switch
  An On/Off switch is located on the back of the unit at the top right hand corner.

- Console Interlocks
  If the console on the unit is opened, a series of interlocks shut down the power to the system to prevent accidental electrical shock.

- Handpiece Interlock
  When the handpiece is removed, an interlock shuts down the power to the system to prevent accidental electrical shock.

- Lamp Interlock
  If the end-caps on the handpiece have been removed to replace the flashlamp, an interlock shuts down the power to the system to prevent accidental electrical shock.

- Stand-By (Sleep) Mode
  If the unit has not been used for ten minutes, it will automatically go into a stand by mode, which will prevent accidental emission of energy and save power. Pressing the left of the three panel buttons will take user back to the main menu.

- Ready Indicator
  During use, a beep will sound each time the unit is ready to fire a pulse.

Section 3

System Description

3.1 System Components and Controls

The OmniLight FPL Pulsed Light System consists of four major components:

- System Console
- Power Cube Unit (transformer unit)
- Handpiece
- External Sapphire Cooler (required accessory)

System Console

The console contains the electrical components required for operation of the system.

Handpiece

The handpiece houses the mechanisms that generate the light pulse. It is connected by an umbilical cord containing the wiring and tubing that carries water to assist in cooling. A sapphire lightguide is mounted on the front side of the handpiece. The replaceable fluorescent filters are inserted between the sapphire lightguide and the body of the handpiece.

Pressing the trigger button on the handle activates the light pulse. The light passes through the fluorescent filter, and the spectrally corrected light passes through the sapphire lightguide and onto the treatment area.

3.2 Software

The software in the OmniLight FPL Pulsed Light System serves several purposes:

- It allows the user to select optimal treatment parameters for each patient
- It controls the machine operation and prevents the safety hazards

- It checks and ensures energy calibration
- It verifies that the correct handpiece is in place
- It serves two counting functions. One function counts the number pulses remaining on the filter and a second function counts the remaining number of pulses for the flash lamp.

3.3 Specification

Light Source: Fluorescent enhanced Xenon flash lamps

Spectral output: Laser dye-impregnated polymer filters cut on at 515, 535, 550, 580 and 615 nm. An internal water filter provides blocking of harmful IR radiation emitted above 1 000 nm.

Pulse Width: 2-500 ms, with standard or advanced pulse forming algorithms

Hair Removal (HR) Handpiece

Spot size: 20 x 10 mm

Fluence: up to 70 J/cm^2

Est. lamp life: 10 000 pulses

Fast hair Removal (HR^4) Handpiece (optional)

Spot size: 20 x 20 mm

Fluence: up to 35 J/cm^2

Est. lamp life: 10,000 pulses

Skin Rejuvenation (SR) Handpiece

Spot size: 20 x 10 mm

Fluence: up to 70 J/cm^2

Est. lamp life: 10 000 pulses

System console

Dimensions: 32 x 33 cm (footprint) x 135 cm high (12" x 12" x 52")

Weight: 38 kg (84 lbs)

Repetition Rate: Up to 1 pulse per second

Optical system: Sapphire lightguide

User interface: Monochrome LCD panel with push button control.

Power supply requirements: 100-120 VAC, 16 A, 50/ 60 Hz or 200-240 VAC 8A, 50/ 60 Hz

Environmental Conditions:

Operating temperature: 10^o C - 30^o C

Storage Temperatures: 0^o C - 55^o C

Operating Relative humidity:	Up to 80%
Storage Relative humidity	Up to 90%

Cooler System

Temperature range: + 5 to 25 °C, accuracy +/-1.5 °C

Cooling device: Cooling collar attached to the sapphire light guide

Dimensions: 15x25 (footprint) x 45cm height (6" x 10" x 18")

Weight: 10 kg (22 lbs)

Cooling media: Water/glycol solution

User interface: Monochrome LED panel with four push button control.

Power supply requirements: 90-240 VAC, <400 VA 50/60 Hz

Environmental Conditions:

Operating temperature:	10^{o} C - 30^{o} C
Storage Temperatures:	0^{o} C - 55^{o} C
Operating Relative humidity:	Up to 80%
Storage Relative humidity	Up to 90%

Section 4

Installation

The OmniLight FPL Pulsed Light System is designed for easy installation and requires minimal site preparation.

Installation is carried out by AMBC authorized personnel. Installation includes the following:

- Unpacking the OmniLight FPL and positioning it in the pre-selected location
- Verifying the integrity of the unit and its components
- Plugging the system into the designated electrical outlet
- Testing the system for proper calibration and function of all operations
- Coordinating the performance at an on-site inspection, if required
- Fill DI-water into the rear water reservoir (see section *"6.5 Filling and Changing the Coolant Water"*).

4.1 Omnilight Shipping Configuration

The OmniLight FPL Pulsed Light is multi purpose instrument that can be delivered to end user in configurations dependant on customers needs:

1. One OmniLight FPL Console assembly
2. One Power Cube set to customers defined operating voltage
3. One or more customer selected Handpiece/s, with lamp, filters and handpiece specific CalCard.
4. One spare Lamp replacement kit with each handpiece. (A kit contains one lamp, one CalCard, fluorescent filters, rubber finger tips and instructions.)
5. One Optical Power Meter
6. One OmniCool assembly with cooling liquid and manual. (The OmniCool is a required accessory and is not included in system price. The customer may have his own cooler that can be used instead if Omnicool if it is adapted to AMBC´s proprietary sapphire cooling collar.)
7. One system support kit contains:
   Power cords
   DI water fill-bottle/funnel
   Gel with spatula applicator
   Protective eye wear for patient
   Protective eye wear for operator

DI- water draining connector and hose
User's manual

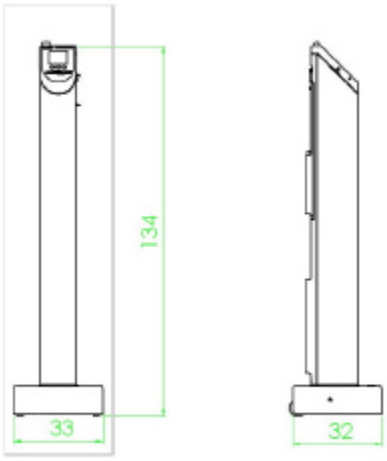
4.2 Facility Requirements

Prior to unpacking the OmniLight FPL Pulsed Light System, ensure that the site meets the following requirements:

Space

The physical dimensions of the system are: 33 x 32 x 135cm (1x 1 x 4.25 ft)

Place the system away from heating ducts and other outlets. Keep at least 60 cm (2 ft.) of free space around all sides of the system.



4.3 Electrical Requirements

The OmniLight FPL Pulsed Light System is pre-wired at the factory for the local line voltage specified by the customer at the time of order.

Accordingly, the unit will require a separate line supply of at least:

- Standard US 110 V AC ± 10%. 16A 50/60 Hz or
- Standard Japanese 100 V AC ± 10%. 16A 50/60 Hz or
- Single phase 230 V AC ± 10%. 8A 50/60 Hz or

The power supply line should not be shared with other heavy variable load equipment, such as elevator or air conditioners.

It is recommended that the system be connected to a separate power line with separate circuit breakers. AMBC cannot guarantee optimum performance unless the OmniLight FPL Pulsed Light System is connected to a dedicated circuit.

The 2 main fuses are located in the mains inlet receptacle on the power cube.

CAUTION

Before turning on your system the first time, verify that the OmniLight FPL Pulsed Light System is wired for the appropriate line voltage for your country by checking the label located on the Power cube that converts wall plug voltage to appropriate level for the Console unit.

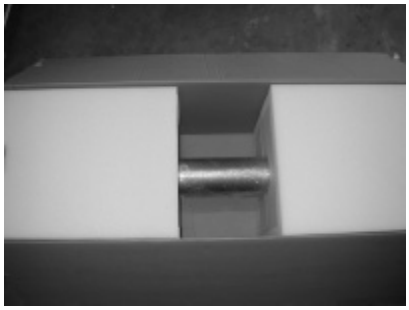
4.4 Environmental Conditions

The OmniLight FPL Pulsed Light System should operate in a non-corrosive atmosphere.

Airborne dust particles should be kept to a minimum.

To ensure that the OmniLight FPL Pulsed Light System operates optimally, it is recommended to maintain a room temperature between 20 °C and 25 °C, with relative humidity of less than 80%.

4.5 Installation



In order to ensure proper assembly and optimal working conditions, please follow these instructions for removal and basic set up:

- Lay down the transportation box on the floor.
- Open the box.
- Remove the two foam plastic holders from the console foot and top. This will release the console unit and three cases inside.
- Grabbing the bottom of the device and the rear of the tower near the base, gently lift the unit out of the case.
- The handpiece is packaged in the large case.
- Energy meter and lamp + filter and other accessories are packaged in the small two cases.
- Once you have checked to make sure the system is properly configured to your wall voltage (section 4.3), plug one end of the mains cable into the bottom of the device and the other into a wall jack.
- Before starting the device, check that sufficient coolant water is in the machine, **de-ionized de-mineralized water ONLY** (see section *"6.5 Filling and Changing the Coolant Water"*).

4.6 Moving the System

To move the system within the facility:

- Switch off power
- Disconnect the power cord to Power cube
- Disconnect the two cooling liquid connectors on the rear of the OmniCool
- Insure that the handpiece is secured in the hanger
- Grip the handle on the back and tilt the unit backwards (app. 20-30 deg)
- Slowly pull the unit.
- Never touch the screen panel

If the OmniLight FPL Pulsed Light System needs to be moved to another facility, it is highly recommended to use the original packaging.

Section 5

Operation

This section contains the operating instructions for the OmniLight FPL Pulsed Light System.

Information about the therapeutic application is provided in Appendix A.

WARNING

Dangerous voltages are present inside the unit. If the covers are removed, interlock switches will prevent the unit from being operated.

The handpiece should be placed in the holder during machine start up.

The OmniLight FPL emits pulsed light. Everyone present in the room must be wearing appropriate protective eyewear.

Never look directly into the lightguide, even when wearing protective eyewear.

Never direct the light pulse at anything other than the targeted area.

WARNING

Delivering excessive energy to the treatment site can result in thermal damage to the skin possibly resulting in hypertrophy, atrophy or abnormal pigmentation or the combination of all three.

5.1 Control Panel

The OmniLight FPL Pulsed Light system is operated by pressing the three keys pads located on the control panel. The key functionality is menu sensitive.

The Control Panel is used for selecting the:

- Pulse forming mode –"Standard Pulse Forming=**SPF**" or "Advanced Pulse Forming=**APF**"
- Fluence, displayed in Joules per centimeter squared (J/cm^2)
- The pulse width, displayed in milliseconds (ms)

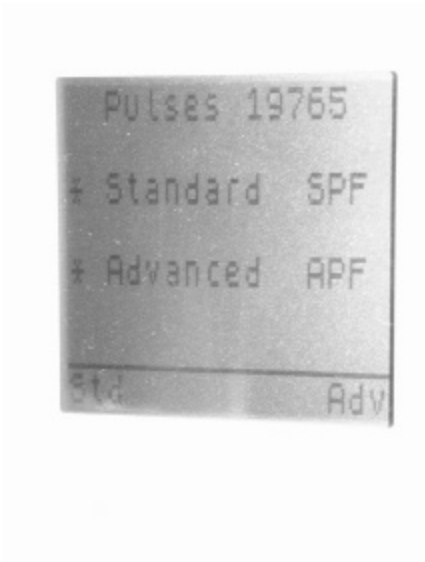
5.2 Start up

Start up the cooler 3-5 minutes before the treatment to reach operating temperature. Insert the Calibration Key Card. Switch on the OmniLight using the main power switch at the upper left corner on the back of the main body. You will hear a quiet hum as the water pump and cooling fans engage.

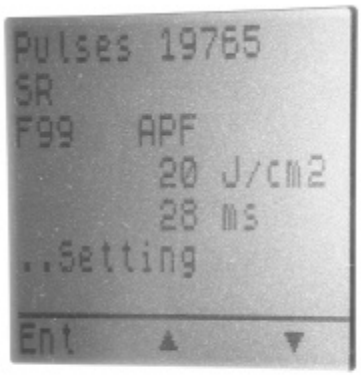
The Lamp and the Calibration Card are matched, thus insuring that the Output is standardized and optimal treatment results can be achieved. Each Lamp is serialized and the corresponding Calibration Card has the same serial number. Always make sure that the Lamp and Calibration Card are matched.

The LCD display will light up. The system will automatically go through a start-up routine. The display will show the basic product information, including the product name (OmniLight FPL), the application type (HR, SR, etc), and the software serial number versions. These items will display for 2 seconds.

The user will then be given a choice between "Standard"(SPF) or "Advanced"APF pulse forming mode. In each mode, both the Fluence (J/cm^2) and the pulse duration (ms) can be adjusted.



The display will also indicate if the correct handpiece (HR, SR, VL etc) is attached. If the incorrect handpiece is attached, a message "Wrong Handpiece" will be displayed on the LCD panel. If so, turn off the machine using the main power switch and install the correct combination of CalCard and handpiece. Then turn the machine back on. The up/down arrows on the front of the control panel are used to select between these options.



Once the desired settings have been selected, there will be a short delay while the capacitors in the system are charged up, and the flashlamp in the handpiece will be jump started with a high-voltage pulse. The sapphire lightguide on the handpiece will begin emitting a steady white light, indicating that the lamp is *simmering*. When the capacitors are fully charged, a beep will sound, indicating that the system is ready for use. After each pull of the trigger, the beep will indicate when the next output pulse can be emitted. There is a built-in function that controls the output timing of the flashlamp, which requires a minimum of two (2) seconds delay between pulses.

5.3 Treatment

Switch on the cooler unit. Set desired sapphire temperature (see OmniCool user's manual for instructions).

Start up Omnilight unit to simmer mode.

Select appropriate fluorescent filter and insert it into the filter holder.

Choose desired pulse forming mode. To be able to use the highest fluence range (>45 J/cm^2) the APF (Advanced Pulse Forming) mode is the *only* option. For lower range fluencies (<35 J/cm^2) the SPF (Standard Pulse Forming) mode is the recommended mode option.

Set the desired fluence and pulse width by pressing the up/down arrow keys. Check that the cooler has reached preset temperature range.
Prepare the skin area by smearing out a 1 mm thick gel layer.

When the desired parameters are selected, the treatment can begin.

During the actual treatment, it is highly recommended that you always wear dark green eye protection glasses. While the glasses offer some degree of light filtration, it can still be rather bright. Some users find that closing their eyes in synchronization with the pulses reduces this discomfort.

WARNING

The brightness of a flash may cause injury if the distance between the eye and the lightguide opening is less than 30 cm. Never look directly into the lightguide.

Likewise, the person being treated should always wear the non-transparent metal eye shields enclosed with the unit. Patient eye protection must be in place when the face is treated.

Although the handpiece is very light and ergonomic, it is recommended that you hang the umbilical cord over your shoulders to relieve any stress to your wrist, arm, shoulder or back.

Eye protection pieces for the user and patient.

To begin a new treatment, select parameter settings (filter type, fluence, pulse mode, pulse duration and sapphire temperature). For information on safe starting parameters, please see Appendix A. Larger areas to be treated should be broken up into quadrates approximately 6 x 6 cm (2 1/3" x 2 1/3"). Use a **orange/yellow** marker to draw the lines. Prepare one of these quadrates with a thin layer of gel about 0.5-1mm thick. The gel should be applied to only one area (6 x 6 cm or 2 1/3" x 2 1/3") at a time, and each area must be treated and the gel removed before gel is applied to the next quadrate.

Place the end of the lightguide in contact with the prepared skin. Once the handpiece is in position, carefully depress the trigger button on the handle.

Move the end of the lightguide to the next adjacent spot, ensuring that it lines up with the previously treated areas. Use the footprint of the lightguide in the gel to discern skin that has already been treated. While it is not dangerous to overlap, it is not recommended. This could cause an accumulation of pulse energy in the overlapped areas.

Apply a thin layer of contact gel to the next portion to be treated, and repeat the above procedures until the entire desired area has been treated.

Once the whole area has been treated, replace the handpiece in its holder. Clean the skin by sweeping off excessive gel with a spatula. If necessary, smear treated area with appropriate cream e.g. Aloe Vera lotion.

Record the treatment parameters in the patient's file.

It is recommended that the patient return several weeks after treatment for examination of the treated site and continuation of treatment, if necessary.

5.4 Turning off the system

Turn off the OmniLight FPL Pulsed Light system by using the main power switch. The shut-down process is immediate.
Remove CalCard and put in a safe place. Lost CalCard will not be replaced free of charge.

Turn off the complete system (including the cooler) at the end of each workday.

Section 6
Maintenance and Troubleshooting

This section describes routine maintenance procedures performed by the user: Cleaning the unit, cleaning the lightguide, replacing the filter and replacing the flashlamp.

The procedures listed in this section are the only maintenance activities you should perform. All other service procedures are to be performed only by the company's authorized service personnel.

WARNING

Maintenance by the user should be performed only when the unit is shut down and disconnected from power. Performing maintenance procedures with the system ON can be hazardous to you and/or cause damage to the system.

6.1 Cleaning the Unit

Clean the OmniLight FPL console at least once a week. Wipe surfaces with a soft, damp, non-abrasive cloth. Mild cleansing solution may be used. Be careful not to spill any liquids on the unit.

6.2 Cleaning the Sapphire Lightguide

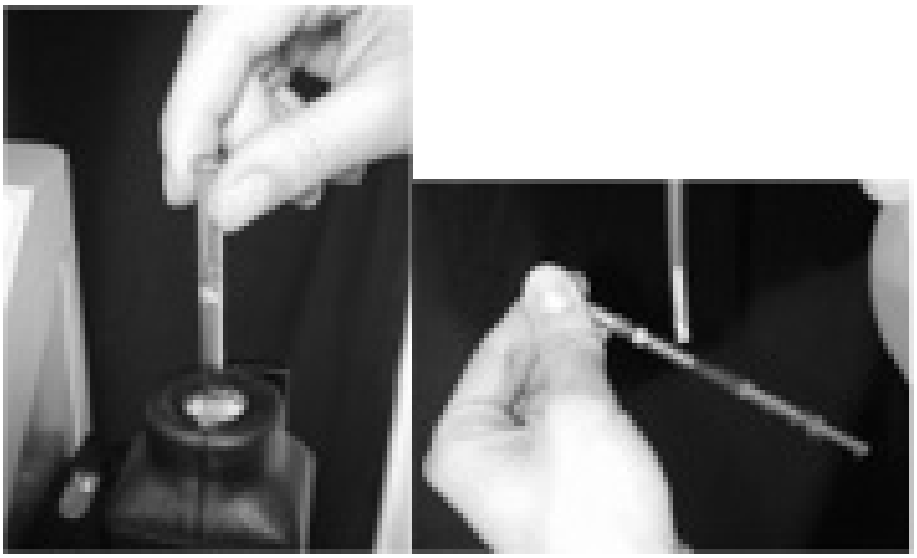
Before each application of the OmniLight FPL , the lightguide should be cleaned. First dry it with a lint-free cloth, and then with a cloth moistened with ethyl alcohol or isopropyl (70%) alcohol. Let the lightguide dry thoroughly before using. Do not use acetone or any product that could dissolve plastic.

6.3 Changing the Flashlamp

Turn the power switches OFF before beginning this process. Remove the end caps on the handpiece using a coin or the edge of the filter tool as a screwdriver. Place the small end of the filter tool into the bottom of the handpiece hanger. Slowly put the handpiece back in the hanger with the filter tool aligning against on the bottom of the flashlamp.

Push the flashlamp out of the handpiece slowly, and grab it with your fingers, and remove it completely. A small amount of water may come out, but this is normal. Remove the handpiece from the hanger.

Take a new flashlamp and put a small amount of de-ionized water on it. Insert the small end of the flashlamp into the top of the handpiece and push it slowly and carefully into place until firmly seated.



Using the filter tool put the caps back on the handpiece and ensures that each cap is rotated 90 degrees. Properly dispose of the old flashlamp.

CAUTION

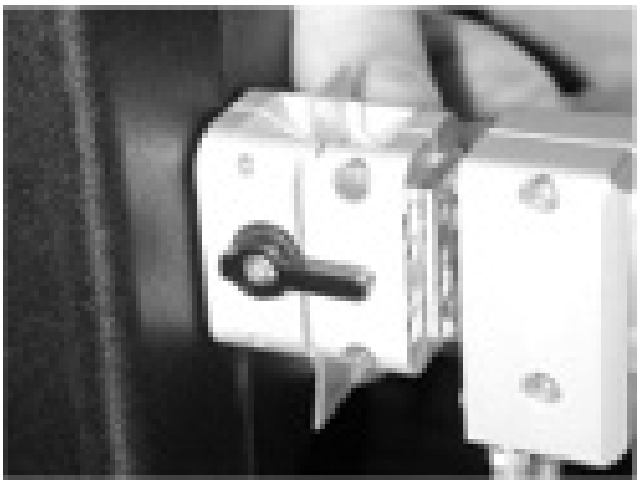
Do not touch the glass portion of the flashlamp at any time, as this may leave oil on the surface and cause flashlamp damage or alter the performance of the system.

6.4 Changing the Filter

The filter operates by transforming non-effective wavelengths into peaks that are beneficial during treatments. This "fluorescence" enhances the overall effect and. The control panel filter counter will indicate when filter has to be changed.

When the filters are received, they are in a packet of 50 filters. The filters have a small amount of optical lubricant on them. This should not be removed, and should be smeared on both sides of the filter. Open the lightguide by loosening the two small black levers. Place the filter *halfway* into the opening. Rotate the levers back to the lock position, and press the filter the rest of the way into the holder. **You should NEVER look directly into lightguide during this or any other procedure.** If an old filter is still in place, it will slide out the other side during insertion of the new one.

Tip: If a used filter is difficult to remove, fire 1-2 pulses immediately before replacement. The filter will loosen from the sapphire surfaces due to heat expansion in the polymer.



6.5 Filling and Changing the Cooling Water

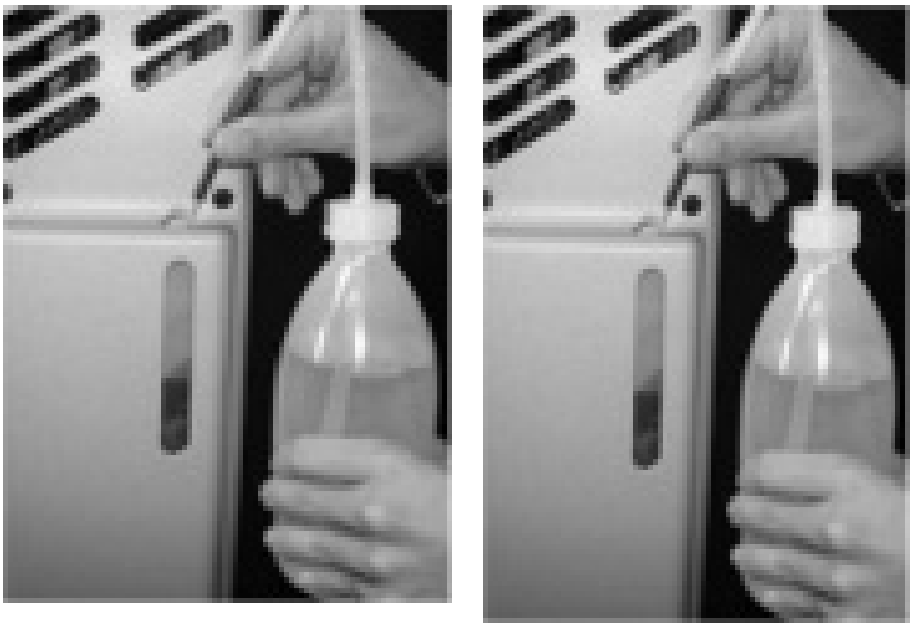
CAUTION

NEVER run the pump without water. Doing so will cause irreparable damage.

The water-filling tap is located on the back of the unit.

When filling:

- Remove the fill cap
- Use the water-filling bottle that came with the OmniLight FPL. Fill with the de-ionized water.
- **Fill with de-ionized water** up to the fill line in the slit window on the back.
- Start the OmniLight FPL and fill with more water, as the system replaces trapped air with water. Add water until it reaches the "fill" mark in rear window, indicating that the reservoir is full.
- Connect drain fitting and tubing to drain port at bottom rear of the unit with fill cap on the reservoir following, see picture below.



6.6 Replacing the Handpiece

! CAUTION

Do not drop the handpiece when removing it from the console. This could lead to damage to the handpiece and the sapphire lightguide.

- Turn off the main power switch (On/Off switch)
- Press in the three main latch buttons located on the handpiece where it connects to the console
- While pressing the three latch buttons, pull the handpiece hanger block slightly in a horizontal direction away from the console
- Press the two opposite water fitting latch buttons on the sides of the handpiece hanger with one hand and pull out the complete handpiece block from the main unit guidance pins.
- Align the guidance pins with the corresponding holes on the new handpiece and snap it into place.

1. Push and release the three latch buttons. Pull HP holder out a few millimeter.

2. Push and release the two opposite water fitting latches and.

3. Pull out the HP unit from the main console

4. Put back the HP by aligning the three guiding pins on the interface with corresponding holes on the hanger interface and push it firmly in place. Check that all three main latch knobs have snapped into to lock position.

Troubleshooting

If one of the following problems appears, follow the recommended action as listed below:

Problem	Possible cause	Action
No Display	Power disconnected	Check Power Cable Plug cable into wall socket Check fuses in the Power Cube
System does not start	Calibration Card not in stalled properly	Check Calibration Card Check fuses in the Power Cube
No response when pressing up/down arrow		Contact LUXSANO Service department

6.7 Error Messages

Code	Message	Action to be taken
17	Handpiece Open	Turn off the main power switch and reattach the handpiece
23	Calibration Key Card Removed	Properly insert the Calibration Key Card
19	Case Open	Insure that the console is closed properly. If this problem persists, contact the LUXSANO Service department
32	Lamp not simmering	Change lamp Contact the LUXSANO Service Department
20	Coolant Over temperature	Verify that the water reservoir is full. If problem persists, contact the LUXSANO Service Department
18	No Flow of water	Verify that the water reservoir is full. Contact the LUXSANO Service Department

21	Discharge board over temperature	Allow the cool down for 5 minutes. Contact the LUXSANO Service Department

Section 7
Accessories

The OmniLight FPL Pulsed Light System accessories are:

Protective Eyewear
Coupling Gel
Replacement kit of consumables (Lamp, filters and CalCard)
Two spare fuses

7.1 Protective Eyewear

Protective eyewear protects the eyes from the pulsed light emitted by the system. The eyewear must be worn by all those present during a treatment with the OmniLight FPL Pulsed Light System. The physician and other staff members should wear eyewear with optical density of 3 while the patients should wear the supplied metal eyewear cups.

1 pair of each type is supplied with the unit.

7.2 Coupling Gel

A clear, water-based ultrasound gel is used for optical coupling. The gel is available in 0.5 liter bottles.

7.3 Replacement Lamps and Filters

The consumable kit consists of 1 lamp, filters, and the CalCard.

7.4 Optional Treatment Handpieces

Optional handpieces are available. Call AMBC at 949-477-5795 for further information.

Section 8
PHYSICIAN INFORMATION

8.1 Training Requirements

The OmniLight FPL Pulsed Light system is designed to be operated only by properly trained personnel. This may include physician, nurses, technical staff or other professional staff members.

In-service training is provided by Luxsano or its distributors.

8.2 Indications and Contra-indications

The OmniLight FPL Pulsed light system is indicated for:

- Removal of unwanted hair in all skin types.
- Permanent hair reduction
- Skin rejuvenation;
    - Treatment of vascular lesions, such as telangiectasia, spider veins, spider nevi, port wine and rosacea and Achieving the desired result may take multiple treatments
    - Treatment of benign pigmented lesions.
    - Collagen stimulation (skin texture improvement)

Contraindications:

- Pregnancy
- History of keloidal scarring
- Diabetes
- Active localized or systemic infections
- Compromised immune system
- Coagulation disorders
- Photosensitivity or allergy

8.3 Pre treatment preparation

During the patient's first visit to the physician (or to an authorized staff member, if allowed by law)

- Take a detailed patient history, including previous treatment modalities, and determine the suitability for treatment

- Determine why the patient is seeking treatment and understand his/her expectations
- Discuss fluorescent pulsed light treatment with the patient
- Inform the patient of the following;
    - There may be some discomfort associated with the treatment
    - Transient erythema/edema may appear immediately following treatment
    - Achieving the desired result may take multiple treatments
    - There is a risk of adverse reaction, including change in texture and pigmentation of the skin.

8.4 Photography

It is recommended to take photographs before and after each session to document the progress of the treatment.

Because many patients often are unable to objectively assess the progress of the treatment, these photographs provide concrete evidence.

Standard conditions and similar speed, flash and focal length should be used to enable an objective comparison of photos taken at different times.

8.5 Side Effects of Treatment

The most common side effects are:

Discomfort	When a pulse is triggered, it may cause various degrees of discomfort. Some describe the sensations as stinging, while other liken it to a rubber band snap. A burning sensation may last for up to an hour after treatment. Most adults and older children are able to tolerate this discomfort, but some may require a topical anesthetic.
Damage to the skin texture	A crust or blister may form which may take from five to ten days to heal. As with any wound that results in a crust or blister, improper care could lead to long-term or permanent textural changes.
Change in pigmentation	There may be a change in pigmentation in the treated area. Most cases occur in people with darker skin, or when the treated area has been recently exposed to sunlight. In some people, hyper-pigmentation occurs despite protection from

	the sun. Such discoloration usually fades in three to six months, but in rare cases, the change of pigment may be permanent.
Scarring	There is a very small chance of scarring, such as enlarged hypertrophic scar or in very rare cases, abnormal, large raised keloid scars, mainly in people who have a pre-disposition to these conditions. To reduce the change of scarring, it is important to carefully follow all post-treatment instructions.
Excessive swelling	Immediately after treatment, especially of the nose and cheeks, the skin may swell temporarily. Swelling usually subsides quickly, but sometimes in three to seven days.
Fragile Skin	The skin at or near the treatment site may become fragile. If this happens, make up should be avoided and the area should not be rubbed, as it may tear the skin.

Appendix A
Treatment – Hair Removal

The OmniLight FPL Pulsed Light System uses fluorescent-pulsed light for hair removal. The OmniLight FPL eliminates hair, employing a method known as selective photothermolysis. This involves disabling hair regrowth mechanism by raising the temperature of the hair follicle high enough to irreversibly damage the follicle's germinative cells without damaging the epidermis and the surrounding tissue. The germinative do reside inside the follicle but is located to the outer follicles sheath. Therefore the complete follicle volume must be heated above 70 ^{o}C to accomplish permanent destruction of all stem cell.

Hair on different parts of the body is of different depths, for instance, upper lip or mustache hair follicles are 1 to 2.5 mm deep, while axillae or pubic hair follicles are 3.5 to 4.5mm deep. Hairs with deep/large follicles are normally more difficult to treat since the associated follicle volume is larger and requires higher total energy fluence to be heated up to coagulation temperature. A high fluency must always be delivered with pulse form/duration that prevents melanin destructive overheating of the hair shaft and matrix. If the melanin is overheated it will evaporate and lose it ability to absorb light. If this occurs during the pulse the follicle heating may not be completed properly. The effect would then be temporary, hair regrowth may occur up 6 months after treatment, reduction rather than permanent hair removal.

The OmniLight FPL only affects hair follicles that contain melanin rich hair shafts. The degree of effectiveness often depends on the fluence used during the treatment.

1.0 Preparation of the patient

The patient should be informed about the hair growth cycle, how the machine works, how much it costs per session, and how many sessions are expected. The client should also be aware of the restrictions and possible risks and side effects. Repeated sessions (3-6 treatments) at 2-3 month intervals are necessary to achieve complete or nearly complete removal of unwanted hair in most patients with ideal skin and hair color. Clinical studies have shown that most patients are satisfied after 3-7 treatments. Obstinate cases may require more than 8 treatments.

American Medical Bio Care, Inc. does not recommend treatment on children below the age of 16 years, because the hair follicles and endocrine system are not fully developed.

The number of treatments varies due to dissimilarity between people and hair follicles in different areas of the body, most likely because of the location and number of germinative cells that must be destroyed to achieve permanent hair reduction.

The level of pain perception varies between different people and various skin areas. The best means for pain control is keeping the sapphire at low temperature and in some cases extend the pre-cooling time (=sapphire in skin contact time before pulse) up to 1-2 seconds. The pain may also be reduced by applying a firm skin pressure with the sapphire to reduce the amount of blood in the treated area.

Blond, red, waxed or very thin hair is less likely to respond to the treatment than dark and thick hair, because there is less target to absorb the light energy and create the heat that destroys the germinative cells responsible for re-growth.

In cases of recently waxed hair, a minimum of 2 months should elapse before beginning treatment with the OmniLight FPL. This will provide enough time for every hair to redevelop and become a target.

2.0 Test Patch

It is recommended to spend the first visit with the patient imparting information and carrying out tests of 3-5 patches. These patches should be relatively close to each other. In Standard Pulse Forming mode, typically, one pulse with a selected duration (60 ms) and different fluency e.g. 25J/cm^2, 25 J/cm^2, 35 J/cm^2 is applied to each of the test patch areas. Always start with lower pulse durations and increase gradually. In the Advanced Pulse Forming, start with higher pulse duration (e.g. 80 ms) and higher fluencies such as 35 J/cm^2, 40 J/cm^2 etc. Gradually raise the fluence in approximately 5 J/cm^2 intervals until the ideal fluence is found.

For darker skin (skin type >III), start with a pulse duration of 120 ms or more.

Smear a small amount of contact gel onto the selected skin area. The gel acts as an optical and thermal coupler between the lightguide and the skin. Cool the bare lightguide (not the filter holder) with cold spray or ice water for 3-4 seconds, and hold the sapphire over the selected area. (The optional OmniCool™ Lightguide cooler may also be used.) Keep the sapphire in close contact with the skin, and depress the trigger. Apply one pulse to the selected patch and wait 15 minutes. If no significant redness, blisters, or burns occur, apply a slightly more powerful pulse to another patch area, and so on. If no reaction is detected after the second test patch, start the treatment. If a blister is formed after the weakest pulse test, stop treatment, and repeat the test patches with lower energy levels during another session (after 1-2 weeks).

Ideally, the patient should be asked to return after 3-5 days for evaluation and the first treatment. In those areas where the hair has fallen out, the energy used is sufficient. In some cases, you may need to test the results by pulling on the hair with a pair of tweezers. If the hair comes out with little or no resistance, then the energy used was sufficient. If not, it is advisable to increase the energy by increasing the fluence 3-5 J/cm^2 steps. If in doubt, use another trial area to test the higher energy.

3.0 Preparation of the treatment area

It is important to properly prepare the hair and skin in the region to be treated. Good preparation will enhance the treatment and ensure reliable results.

Before the treatment, remove excess hair from above the surface of the skin by shaving. One should leave a 1 mm stub to pull from with tweezers for testing the result. American Medical Bio Care, Inc. recommends a light shave using an electric beard trimmer.

It is always a good idea to clean the skin after shaving to remove any possible dirt, hair or make-up. Such specs, although small, can cause part of the light to be focused into a small area of skin, which may feel uncomfortable and/or cause damage.

When larger areas are to be treated, American Medical Bio Care, Inc. recommends that you mark the skin area in sectors of 6 × 6 cm (2 1/3" × 2 1/3") using a red marker pen. Note: it is enough to use dotted the lines.

Next, apply the coupling gel to one sector at a time and treat.

4.0 Pulse Width

Choosing the correct pulse is essential for a successful treatment. The time it takes for an object to cool is a function of that object's size. Cooling time is shorter for small objects and longer for large objects. The OmniLight FPL takes advantage of this thermal selectivity, i.e. longer cooling time of a relatively large hair follicle and shorter cooling time of the thinner epidermis. It does this by structuring each pulse as a series of small pulses with a delay, or off time in between.

Ideally, the delay should be long enough for the epidermis to cool down between the small pulses, by losing its heat to the cooler gel and the cooled light guide. But the delay should also be shorter than the cooling time of the follicle, so that the follicle retains much of its heat and its temperature increases with each pulse.

For most patients, a shorter pulse is suitable. Dark skin absorbs more light and heats to a higher temperature, thus, longer pulses are necessary.

5.0 Fluence

Fluence is a measure of the light energy delivered to the skin per unit area. Fluence is measured as Joules per centimeter squared (J/cm^2).

Fluorescent light created by the OmniLight FPL passes through the lightguide and the coupling gel onto the patient's skin. Contrary to many laser devices the fluence from the Omnilight FPL is constant over the treated spot due to the long wave guide in combination with a non-coherent light source. *The greater the fluence is, the higher the temperature of the target hair, the surrounding tissue and the epidermis.*

The pre-cooled sapphire kept in skin contact will efficiently remove excessive heat generated by light absorption in the epidermal melanin. By

doing so, the fluence can be raised safely when necessary with minimal or no adverse effects.

External cooling of the sapphire lightguide can be achieved by using (highly recommended) the optional external cooler attachment, the OmniCool™ system. If the external cooler is not used, the lightguide can be cooled by spraying it with cryogen-gas or by immersing the lightguide in iced water.

6.0 Recommended Parameters for Hair Removal:

Filter:	615 nm for dark/brown hair, skin type I - V
	580 nm for light/thin, skin type I-IV
Flashlamp:	20 mm
Power:	20 – 35 J/cm² standard pulse forming 40-80 ms
	30 - 65 J/cm² Advanced Pulse Forming 80 - 250 ms
External Chiller:	Set to the lowest setting (<+5 ^{o}C)

7.0 Treatment

- Select the desired pulse width and fluence.
- Place the protective eyewear on the patient and the user.
- Ensure that the lightguide is clean.
- Ensure that the desired filter is in place.
- Apply a thin (~1-mm) layer of coupling gel to the treatment site
- Place the lightguide perpendicular to the skin and apply firm pressure. The lightguide should be in contact with the skin. Excessive gel is pressed away from the contact area.
- Trigger a test pulse.
- Wipe off the gel and examine the treatment site. The smell of burn hair or a brownish color in the gel may be detected.
- If the skin shows no adverse effects from the test pulse, reapply gel to the treatment site and proceed with the treatment
- Try not to overlap treatment sites by more than 1 mm.

Note: American Medical Bio Care, Inc. recommends that the coupling gel only be applied to an area 6 x 6 cm. This will prevent the gel from drying during the treatment.

9.0 Post Treatment

After finishing the session, a cold towel or Aloe Vera gel is applied. The patient is informed to avoid using any soap during the same day of treatment, as well as direct, prolonged sun exposure for at least 2-4 weeks after treatment. Once the whole area has been treated, the handpiece must be replaced in its cradle, and the excess gel should be removed using a spatula or paper towels. Any remaining gel should be cleaned from the treated area. *Do not reuse gel*.

American Medical Bio Care, Inc. recommends the application of moisturizing lotion on the treated area twice a day for one week after each session.

8.0 Immediate Normal Response After Treatment:

- Medium to strong peri-follicular edema/erythema
- Appearance of mild erythema/edema over the treated area
- A brownish tint in the gel
- Skin tightening

9.0 Follow up

The patient should return several 2-3weeks after treatment for examination or at least report the outcome. The hair shall be lost in 7-12 days after the treatment. If not the treatment has not been effective and higher fluency has to be used in the next session.

If no additional treatment is necessary, the patient should return for an additional re-examination three to four weeks later.

If no change is noted, the Fluence for the next treatment should be increased at least 10-20 %.

Appendix B
Treatment – Skin Rejuvenation

The OmniLight FPL Pulsed Light System uses fluorescent pulsed light for skin rejuvenation. Skin rejuvenation can be defined as improvement in the appearance of skin by removing age spots (sun-induced freckles), benign brown pigmentation, and redness caused by flushing or broken capillaries.

The OmniLight FPL employs a method known as selective photothermolysis to selectively destroy targets in the skin, allowing the body to remove them naturally and replace them with fresher, healthy skin.

1.0 Preparation of the patient

The patient should be informed about how the machine works, how much it costs per session, and how many sessions are expected. The patient should also be aware of the restrictions and possible risks and side effects. Normally, patients will require usually 3-5 treatments at 3-week intervals. The number of treatments has been determined clinically as providing the maximum benefit while reducing side-effects and complications to near zero.

2.0 Test Patch

It is recommended to spend the first visit with the patient imparting information and carrying out tests of 3-5 patches. These patches should be relatively close to each other. In Standard Pulse Forming mode, typically, one pulse with a selected duration (50 ms) and different fluency e.g. 15J/cm^2, 20J/cm^2 25J/cm^2 is applied to each of the test patch areas. Always start with lower fluencies and increase gradually. In the Advanced Pulse Forming mode, start with fluences of typically 20 J/cm^2 and a pulse duration of 60 ms. Gradually raise the fluence in approximately 3-5 J/cm^2 intervals until the ideal fluence is found. For darker skin types (>III) start with a pulse duration of 80 ms or more. For conditions that are mainly

vascular, use filters with shorter wavelengths. For conditions that are mainly pigmentary, use filters with longer wavelengths.

Smear a small amount of gel onto the selected skin area. The gel acts as an optical and thermal coupler between the lightguide and the skin. Cool the bare lightguide (not the filter holder) with cold spray or ice water for 3-4 seconds, and hold the sapphire over the selected area. (The optional OmniCool™ Lightguide cooler will provide superior cooling.) Keep the sapphire in close contact with the skin, and depress the trigger. Apply one pulse to the selected patch and wait 15 minutes. If no significant redness, blisters, or burns occur, apply a slightly more powerful pulse to another patch area, and so on. If no reaction is detected after the second test patch, start the treatment. If a blister is formed after the weakest pulse test, stop treatment, and repeat the test patches with lower energy levels during another session (after 1-2 weeks).

Ideally, the patient should be asked to return after 5-7 days for evaluation and the first treatment.

3.0 Preparation of the treatment area

It is important to properly prepare the skin in the region to be treated. Good preparation will enhance the treatment and ensure reliable results.

It is always a good idea to clean the skin and remove any possible specs of dirt or make-up. Such specs, although small, can cause part of the light to be focused into a small area of skin, which may feel uncomfortable. It is also important to shave any hair in the area to be treated.

When larger areas are to be treated, American Medical Bio Care, Inc. recommends that you mark the skin area in sectors of 6 × 6 cm (2 1/3" × 2 1/3") using a red marker pen. Note: it is enough to use dotted lines.

Next, apply coupling gel to one sector at a time and begin treatment.

4.0 Pulse Width

Choosing the correct pulse is essential for a successful treatment. The total pulse burst duration should primarily be adapted to the typical thickness of the target. For example treatment of epidermal pigmentations and superficial vascular lesion will respond best to a pulse duration that is relatively short typically in the range 25-50 ms while pigmentations and vascular lesions that is "thicker or deeper" preferably is treated with longer pulse durations, typically in the range of 40-150 ms. The time it takes for an object to cool is a function of that object's size. Cooling time is shorter for small objects and longer for large objects. The OmniLight FPL takes advantage of this thermal selectivity, i.e. longer cooling time of a relatively large object (thickness or diameter) and shorter cooling time of the thinner epidermis. It does this by structuring each macro pulse as a series of micro pulses with a relatively short delay in between.

Ideally, excessive heat generated in the epidermis will be drained away by the by making contact with the cooled sapphire light guide.

5.0 Fluence

Fluence is a measure of the light energy delivered to the skin per unit area. Fluence is measured as Joules per centimeter squared (J/cm^2).

Fluorescent light created by the OmniLight FPL passes through the lightguide and the coupling gel onto the patient's skin. The greater the fluence is, the higher the temperature of the targets in the skin, the surrounding tissue and the epidermis.

The thin layer of gel acts as a thermal bridge between the skin surface and the externally cooled sapphire end face that effectively removes excessive heat from the epidermis. By doing so, the fluence can be raised safely when necessary with minimal or no adverse effects.

External cooling of the sapphire lightguide can be achieved by using the optional external cooler attachment, the OmniCool™ system. If the external cooler is not used, the lightguide can be cooled by spraying it with cryogen or by immersing the lightguide in iced water.

6.0 Recommended Parameters for Skin Rejuvenation

Filter: 480, 515, 535, 580 nm for skin type I – II
535, 550, 580 nm for skin type III-IV
580 nm for skin type V
Flashlamp: 20 mm nominal
Power settings: 15 J/cm^2 - 45 J/cm^2 (approx 20-80ms with SPF)
20 J/cm^2 - 70 J/cm^2 (approx 60-250 ms with APF)

7.0 Treatment

- Select the desired pulse width and fluence.
- Place the protective eyewear on the patient and the user.
- Ensure that the lightguide is clean.
- Ensure that the desired filter is in place.
- Apply a thin (~1-mm) layer of coupling gel to the treatment site.
- Place the lightguide perpendicular to the skin and apply gentle pressure. The lightguide should be in skin contact with very thin remaining gel layer.
- Trigger a test pulse.
- Wipe off the gel and examine the treatment site. The smell of burnt hair or a brownish color in the gel may be detected.
- If the skin shows no adverse effects from the test pulse, reapply gel to the treatment site and proceed with the treatment.
- Try not to overlap treatment sites by more than 1 mm.

Note: Luxsano recommends that the coupling gel only be applied to an area 6 x 6 mm. This will prevent the gel from becoming warm during the treatment.

9.0 Post Treatment

After finishing the session, a cold towel or Aloe Vera gel is applied. The patient should avoid using any soap during the same day of treatment, as well as prolonged, direct sun exposure for at least 2-4 weeks after treatment. Once the whole area has been treated, the handpiece must be replaced in its cradle, and the excess gel should be removed using a spatula or paper towels. Any remaining gel should be cleaned from the treated area. Never reuse gel.

Luxsano recommends the application of moisturizing lotion on the treated area twice a day for one week after each session.

10.0 Immediate Normal Response After Treatment:

- Appearance of erythema/edema
- Slight skin erythema, although not in the shape of the lightguide (2x1 cm^2)
- A brownish tint in the gel
- Skin tightening

11.0 Follow up

The patient should return several weeks after treatment for examination of the treatment site.

If no additional treatment is necessary, the patient should return for an additional re-examination three to four weeks later.

If no change is noted, the fluence for the next treatment should be increased.