

Palomar MediLux™ Pulsed Light System

Operator's Manual



Caution: In the United States, federal law restricts this device to sale by or on the order of a physician or any practitioner licensed by state law to use or order the use of this device.

Prior to use: Warning: do not use this product without reading and understanding the complete instructions enclosed.

This is the English version operator manual. Additional versions are available upon request in German, Spanish, Italian, French, Greek, Finnish and Swedish text.

Document Number:

1100-0001 Rev B

Manufactured by: Palomar Medical Products, Inc.



82 Cambridge St.
Burlington, MA 01803 USA

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Warranty Information

Limited Warranty and Claims

Palomar Medical Technologies, Inc. ("Palomar") warrants that reasonable care has been used in the design and manufacture of this instrument. Palomar warrants to the original purchaser of this equipment (excluding consumables) that it will be free from defects in material and workmanship under normal use and service for the period of one year from the original date of installation.

Consumables and/or disposable products are warranted to have shipped from Palomar in functional condition, but no additional warranty period shall apply.

Palomar's obligation under this warranty is limited, in its exclusive option, to repair or replacement of parts and materials which prove defective. **Palomar shall not be liable for any incidental, special or consequential loss, damage, or expense due to any cause whatsoever, including causes related directly or indirectly to the use of this instrument. In no case shall the damages exceed the replacement value of the equipment.**

The happening of one or more of the following events will serve to void the warranty:

1. Failures resulting from negligence, alteration, modification, abuse or misuse of the equipment by the purchaser or operation of the equipment inconsistent with Palomar's published operating instructions.
2. Attempted or actual dismantling, disassembling, service or repair of equipment not expressly authorized by Palomar.

All merchandise should be inspected for obvious damage upon arrival. If merchandise has been damaged in transit, the Palomar Service Department must be notified within 72 hours.

Furthermore, the purchaser agrees to indemnify Palomar against all claims where the equipment was abused or misused by the operator. No suit or action shall be brought against Palomar more than one year after the cause of action has accrued.

THE FOREGOING CONSTITUTES PALOMAR'S SOLE LIABILITY AND THE PURCHASER'S SOLE REMEDY WITH RESPECT TO PRODUCTS SOLD BY PALOMAR MEDICAL TECHNOLOGIES, INC. EXCEPT AS THUS PROVIDED, WE DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Limited Warranty and Claims (cont.)

Palomar neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Handling, storage and cleaning of this instrument as well as factors relating to the consumer, diagnosis, treatment and other matters beyond Palomar's control directly affect the instrument and the results obtained from its use.

If service is required, this product is to be returned to Palomar or authorized service center for repair. For warranty repair Palomar or authorized distributor will pay for the shipping charges. For systems returned for repair not covered by warranty the customer shall pay for all shipping charges.

All returns must be accompanied by a Return Authorization Number (RMA) contact Palomar by phone at 888-543-6700 or 781-993-2315, fax 781-993-2340 or email service@palmed.com to obtain the RMA number.

Revision History:

Revision	Date	ECO#	Explanation of Changes
X1	04/18/03	N/A	Draft
A	10/28/03	3239	Release
B	03/16/04	3387	corrected fluence settings in Lux G chapter; updated information to be consistent with new flip chart information; changed paragraph for Lux Rs description

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General Description

The Palomar MediLux™ System is designed to deliver light pulses (10-100 ms) of broadband incoherent light to a predetermined target site. Output wavelengths range from 400nm to 1400nm. The Palomar MediLux System is specially developed for hair removal, pigmented and vascular lesion treatment and other cosmetic applications. Melanin, hemoglobin and other chromophores primarily absorb the light output.

The Palomar MediLux System is user friendly, allowing the treatment provider to select output fluence (J/cm^2) and pulse width (ms). This enables the user to safely perform treatments on skin types I –VI as indicated. (review Chapter 6 Clinical Application).

The system is housed in a protective cabinet. Delivery of the energy to the treatment site is through a handpiece that has a sapphire window for direct light delivery to the treatment site.

Light delivery activation is through a footswitch and trigger button on the handpiece. Light is administered to the treatment area by placing the handpiece window in contact with the skin, and depressing the footswitch and trigger button.

About The Manual

The Palomar MediLux System Operator's Manual provides information about the system and the handpieces:

- Safety
- System Description
- Installation
- Operation
- Clinical Applications
- Maintenance and Troubleshooting
- Customer Support

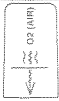
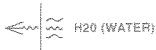
Although the operator's manual provides necessary information for the safe use of the Palomar MediLux System, it is meant to supplement, not replace, a formal training program in the use of this device. It is not meant to replace good judgment, clinical experience, or common sense when treating consumers.

SYMBOLS USED**Danger**

Indicates an imminent situation in which the possibility of exposure to electrical shock or a fire hazard could result in serious injury to the operator, consumer, or staff.

**Caution**

Indicates a potentially hazardous situation that, if not avoided, could result in damage to the equipment and serious injury to the operator, consumer, or staff.

Symbol	Description
	Air Filter location and direction. Located at the rear of the system, inside the Filter Cover. There are two locations.
	Fluid Filter location and direction. Located at the rear of the system, inside the Filter Cover. There is one location.
	IEC 417, No. 5032. Alternating Current this symbol is placed next to the input voltage ratings.
	IEC 417, No. 5019. Protective Earth (ground) this symbol is used internally within the system.
	IEC 417, No. 5017. Earth (ground) this symbol is used internally within the system.
	IEC 417, No. 5007. On (power) this symbol is for the power switch located on the rear of the system
	IEC 417, No. 5008. Off (power) this symbol is for the power switch located on the rear of the system
	IEC 417, No. 5264. On for part of the equipment. This symbol is for the keyswitch position.
	IEC 417, No. 5265. Off for part of the equipment. This symbol is used for the keyswitch position.
	IEC 417, No. 5235. Low Water Level. Located at the rear of the system. This symbol is next to the Reservoir Light. When the light is lit, the reservoir is full.
	IEC 417, No. 5382. Injection syringe. This symbol indicates the port where the fill syringe is connected to the Fluid Reservoir.
	IEC 417, No. 5114. Foot Switch. This symbol indicates the port where the foot switch is connected.
	IEC 417, No. 5570. Unlocking. Remote Interlock. This symbol is next to the connector where the Remote Interlock connector must be connected.
	IEC 417, No. 5333. Type BF equipment.
	IEC 417, No. 5036. Dangerous voltage.
	ISO 3864 No. B 3.6 Caution refer to accompanying documents
	IEC 417 No. 5016 Fuse location
T5AL250V	5Amp fuse 5amp fuse, 250VAC used in 110VAC systems
T2.5AL250V	2.5 Amp fuse 2.5amp fuse, 250VAC used in 220VAC systems

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Safety Overview

The Palomar MediLux™ is an electro-optical device intended for safe and reliable hair, pigmented and vascular lesion removal. Personnel operating and maintaining the MediLux should be familiar with the safety information provided in this section.

Palomar Medical assumes no liability whatsoever for any damage or injury as a result of an application of a product which is not in strict accordance with the instructions provided with the product. Palomar Medical also assumes no liability for any damage or injury arising as a result of user error or mistake, including but not limited to damage from injury arising from user's lack of qualification to evaluate the treatment administered in the actual individual circumstances, or as a result of errors or mistakes committed by such user who would otherwise be considered as having the necessary professional skills to apply such treatment.

Read the operating instructions thoroughly before connecting the unit to the main power connection and prior to use. The unit must be set, regulated and used in accordance with the instructions for use. Failure to observe usual safety precautions may present a risk of hazardous exposure to light radiation.

All persons operating the Palomar MediLux System and all that are in the vicinity of the system must be aware of the potential hazards of the Palomar MediLux System output. Be certain all personnel carefully review the safety precautions pertaining to the Palomar MediLux System. Only authorized individuals with appropriate safety training and knowledge should operate, assist in the operation of, or provide maintenance to the system. Only the operator should be responsible for system controls during the procedure.

Any pulsed light emitting device can cause injury if used improperly. High voltages are present inside the MediLux Pulsed light System.

Personnel who work with pulsed light sources should always be aware of the possible dangers and should take the proper safeguards as described in this operator manual.



The Palomar MediLux System is an eye-safe device when operated properly, however as with any pulsed light device never look directly at the light output. During treatments, all persons must wear protective eyewear to protect against possible eye damage.



No one other than Palomar Medical authorized personnel may service inside the protective covers of the MediLux System. Dangerous voltages are present inside the system. Maintenance should be performed by the operator 30 minutes after the system is shut down and disconnected from power. Performing maintenance procedures with the system while it is powered up or before 30 minutes from disconnecting the system may be hazardous to the operator and destructive to the system.

Staff and Consumer Safety

- Delivering energy to the treatment site may cause thermal damage to the skin, resulting in superficial damage to the skin, crusting, skin redness, hypopigmentation or hyperpigmentation.



- Consumer safety is assured by a well-trained staff.
- Consumer education is also important and information about the nature and expectations of the treatment should be provided.
- Never look directly at the light coming from the distal end of the handpiece as this may cause eye injury.
- Never direct the pulsed light at anything other than the targeted area.
- Never point the handpiece so that it discharges into free space. Make sure it is pointed at, and in full contact with, the treatment site during treatment or when performing test spots.

Handpiece and CoolRoller™ Applicator Disinfection

- The sapphire lens on the handpiece requires disinfection before, and after treatments.
- The CoolRoller applicator requires disinfection before and after use.

The sapphire handpiece and the CoolRoller applicator are non-critical products per the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) Guidelines. Non-critical is defined as an item that comes in contact with intact skin, but not with mucous membranes. Therefore, cleaning with ethyl or isopropyl alcohol (70% to 90%) between consumers is all that is required by the APIC.

Warning

Do not submerge the handpieces in any solution. Submersing the handpieces may cause a hazardous condition for the user and possibly the consumer. Submersing may also cause the system to malfunction. Apply disinfecting or cleaning solution to wipes or gauze pads to be used on the handpieces.

Handpiece Cleaning

- Clean a handpiece window during treatments using a cloth moistened in a mixture of 70% alcohol and 30% water. It is recommended to use Palomar Laser Wipes™ lens cloths.
Note: Pure undiluted alcohol or detergents should not be used.
- During cleaning of the handpiece between clients the MediLux system should be in the standby mode.
- Clean the handpiece before, during and after use on each consumer using Palomar LuxWipes lens cloths.

Room Safety

- Identify the treatment room clearly.
- Restrict entry to the treatment room when the system is in use. Allow access to the treatment room only to those personnel both well trained and essential to the procedure.
- When the system is not in use, ensure that it is rendered inaccessible to unauthorized personnel. Remove the key to disable the unit.
- Make sure that all personnel are familiar with the system controls and know how to shut down the system instantly.
- Block all appropriate windows, etc. to prevent light from escaping the treatment room.

ELECTRICAL SAFETY

The electrical safety hazard of any pulsed light system cannot be ignored or taken lightly. Although the Palomar MediLux™ System has many safety features in its design, certain precautions must be observed.



It is possible for the high voltage components to retain a charge even after the system has been turned off. Therefore, no part of the exterior housing of the main system or handpiece should be removed except by trained and authorized technicians.



This may expose personnel to dangerous high voltages and potentially dangerous light radiation. A qualified Palomar Service Representative must perform any service requiring access to the interior of the instrument only. To contact a Service Representative, dial toll free (800) PALOMAR or I-781-993-2315

FIRE SAFETY

The potential for fire hazard exists because of the nature of light treatment. The absorption of emitted energy no matter how brief may raise the temperature of any material. This phenomenon is the basis of many useful medical and surgical applications. It is also the reason that these applications often require precautions against the risk of igniting combustible materials in and around the treatment area. When the Palomar MediLux System is used, the following precautions should be taken:

- Anesthetics administered must be approved as non-flammable.
- Ensure that the system and ancillary equipment are working properly before beginning a procedure.
- Never direct the light output at anything other than the intended treatment site, especially at reflective objects such as metal surgical instruments.
- Be certain the footswitch is clean and working properly. Place the footswitch where it will not be mistaken for another piece of equipment.

Room Safety cont:

- Exercise particular care in the use of oxygen. The presence of oxygen can accelerate the combustion of any flammable material.
- Avoid using combustible materials, such as gauze and drapes, in the treatment area. When they are required, these materials may be made fire-retardant by keeping them moist with water or saline. Clothing should be kept well away from the area of treatment.
- Know the location and operation of the nearest fire extinguisher.
- Always turn off the system and remove the key whenever possible. This will prevent accidental light emissions.

MediLux Safety Features

The Palomar MediLux™ System offers safety features to prevent the misuse or unintentional activation of the system. All personnel who operate the system or assist in the operation of the system should be knowledgeable of safety features.

KEY SWITCH

The key switch activates the system.

- The start key should be kept in a secure location to prevent the unauthorized use of the system
- The key must never be left in the system.
- Only those personnel authorized to operate the system should have access to the key.

EMERGENCY STOP

The Emergency Stop button is a large red button that immediately disables the system. This button should be depressed only in the event of an emergency. The Palomar MediLux System can be reset after an "Emergency Stop" by rotating the Emergency Stop button in the direction of the arrows, allowing the button to be reset.

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Palomar MediLux™ System Specifications

<i>Item</i>	<i>Description</i>
System Type	Pulsed Light Class IIb Medical Device
Wavelength	400nm - 1400nm
Spot Size	Handpiece specific (see chapter 6)
Pulsewidth	10ms, 20ms, 40ms, 60ms, 100ms (user selectable)
Fluence	Handpiece Specific (see Chapter 6)
Light Delivery	Flashlamp within handpiece, 1.5m umbilical
Repetition Rate	0.5Hz to 1 Hz, single shot
Actuator	Footswitch and Handpiece trigger
Voltage Max Power Input	100 - 120 / 220 - 240VAC, 50 or 60Hz <600VA
Operating Environment	Temperature: 15-27° C (60-80° F) Humidity: 0 - 40%
Transport/Storage Environment	Temperature: 0-50° C (32-124° F) Humidity: Below 80% Air Pressure: >0.7atm
System Cooling	Cooling system for flashlamp Cooling system for sapphire
Dimensions	19" (48 cm) L x 11" (29 cm) H x 14" (36 cm) D
Weight	48 lbs. (22kg)
Classification	Class I equipment Type BF applied part

System Components, Controls and Indicators

The Palomar MediLux™ System delivers light energy from the handpiece. The design for the Palomar MediLux System incorporates a number of features that provide high reliability, versatility, safety, performance and portability. The system is designed to ensure maximum safety, flexibility in function, and ease of operation.

The Palomar MediLux System consists of three separate components

- The Palomar MediLux Console
- The Handpiece
- Starter Kit

The Palomar MediLux System is equipped with features designed specifically to provide safe operation for users. All personnel should become familiar with the location and operation of the safety features discussed. (Safety Chapter 2)

The Palomar MediLux™ System

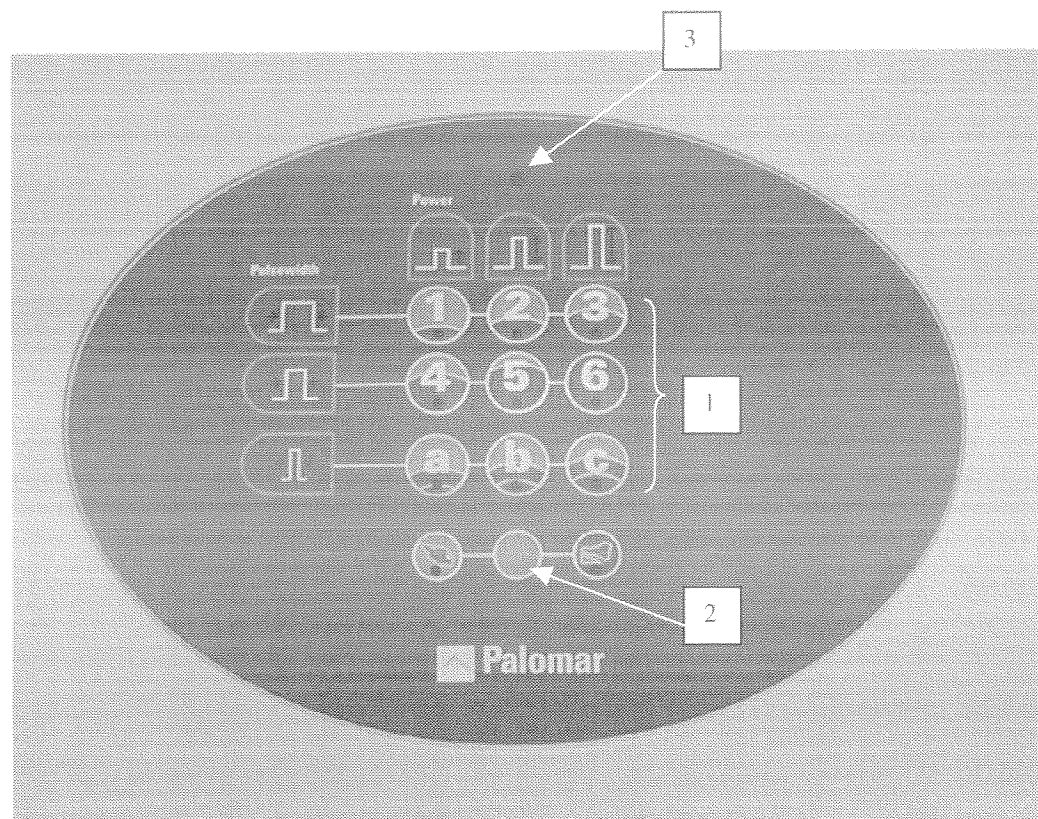


Figure 3-1. Control Panel

Front Panel

1. There are nine buttons on the Front Control Panel (refer to Figure 3-1). Each button is set to deliver a specific fluence and pulse-width. (see Chapter 5: Setting Parameters and Chapter 6 for the handpiece selected.)
2. Foot pedal mode select switch: presses selected handpiece or foot pedal activation.
3. The Emission Indicator is illuminated when the handpiece is removed from the holster. And the system is ready to emit light (see Chapter 5: Setting Parameters)



Figure 3 – 2. MediLux Front View

- 4 Handpiece connection port. All Palomar MediLux handpieces will connect in this location.
- 5 Handpiece dock port. The handpiece must be in the dock when the system is turned on.
- 6 Key switch and Emergency stop button are located on the left side of the console.

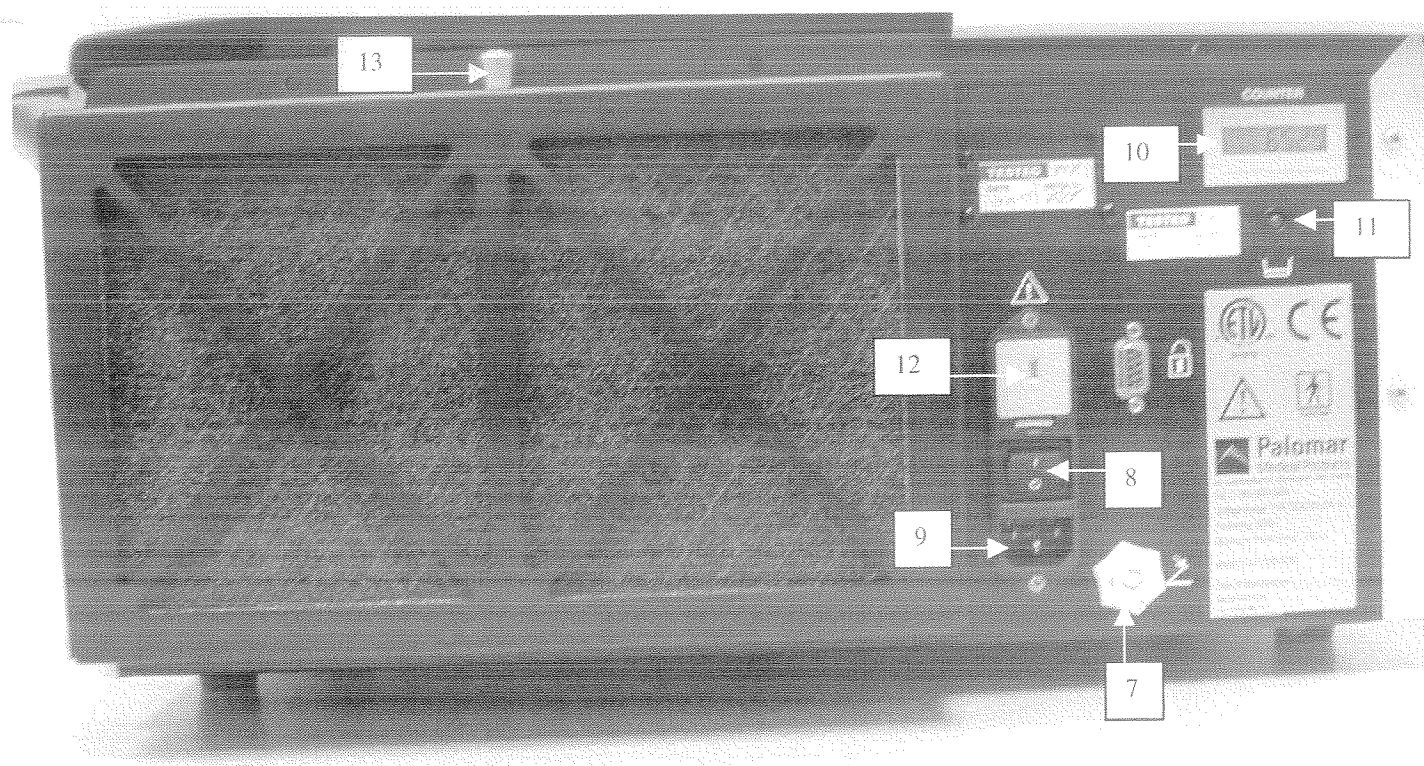


Figure 3-3 MediLux back panel

7. Connection for footswitch.

8. Power switch. Located on the rear panel, disconnects the system from the power source when placed in the down, or OFF (○) position.

9. Power Cord connection.

10 Shot Counter The shot counter keeps track of the total number of shots on the MediLux system. The shot counter can only be reset at the factory.

11. Fluid Reservoir Indicator. The fluid indicator will light if there is sufficient amount of fluid in the MediLux system.

12. Fuse holder and Voltage indicator Push up on the tab to remove the fuse holder and fuse

13. Rear Cover Release. Pull up to lower the cover when fluid needs to be added or filters changed.

MediLux Handpiece

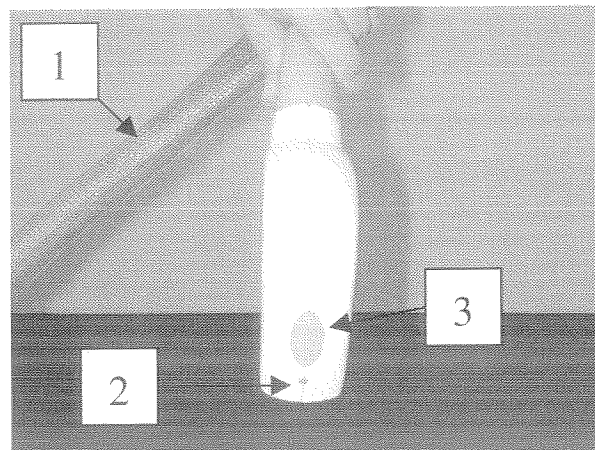


Figure 3-4 Sample MediLux Handpiece top view.

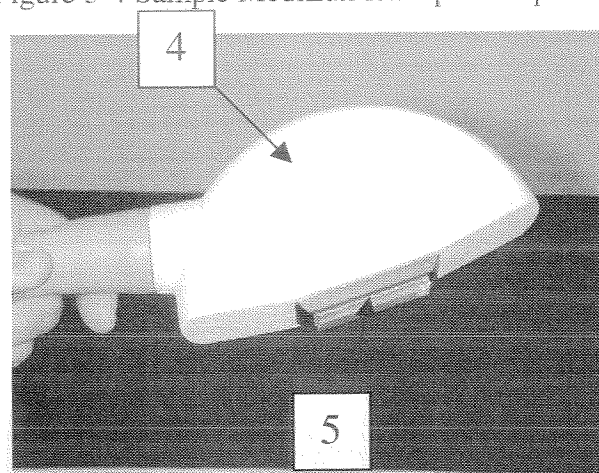


Figure 3-5 Sample MediLux Handpiece side view.

1. **Umbilical.** The umbilical contains fluid lines that provide cooling to the flashlamp, air hose for sapphire and skin cooling, electrical wires supplying power to the flashlamp, electrical wires for safety sensors and trigger/indicator button.
2. **Ready Indicator.** The Ready Indicator will illuminate when the system is ready to administer treatment.
3. **Trigger Button.** When the Ready Indicator is lit, pressing the Trigger Button will activate the flashlamp.
4. **Handpiece Body.** The user holds the handpiece by the Handpiece Body during treatment.
5. **Treatment Window.** It must be in direct, firm, full contact with the treatment area and provides compression of the treatment area in order to maximize the light delivery. The window is a sapphire requiring cleaning/disinfection (See Chapter 2).

CoolRoller™ Applicator

Cooling reduces patient discomfort. Efficient skin cooling is best obtained by using the CoolRoller. Cool skin before and after each treatment. Palomar has developed the CoolRoller effectively cool the skin before and after each treatment.

See chapter 6 for handpiece specific CoolRoller requirements. Ice or an ice pack/gel pack may be used if CoolRoller is not available.

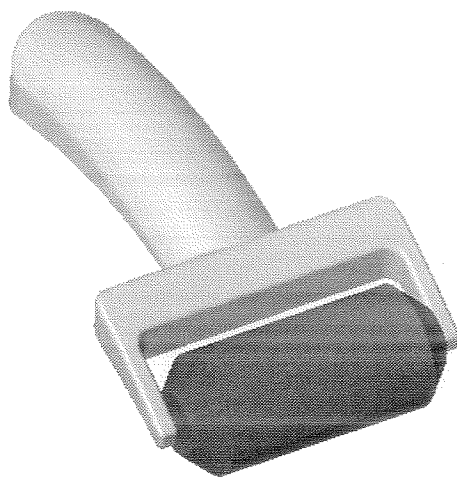


Figure 3-6 CoolRoller Applicator

Peripheral Devices

Peripheral devices contained with the Palomar MediLux™ System:

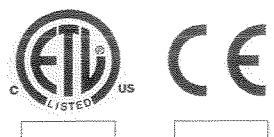
- Footswitch
- Keys on Ring
- Fill kit
- Operator's Manual
- Gel Ice Packs
- Cool Roller
- User Safety Glasses
- Patient Safety EyeShields

Required Labels

Government regulations require that certain labels appear on the Palomar MediLux™ System and be reproduced in this manual.

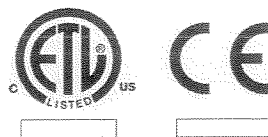
NOTE: DO NOT REMOVE ANY LABELS

Chassis Labels



82 Cambridge St., Burlington, MA 01803
Tel: 1-781-993-2300
Voltage Range: 100-120 / 220-240 V~
Frequency: 60Hz
Maximum Power Input: 600 VA
Model: Palomar EsteLux
Date of Manufacture:
Serial Number:
1311-0006 REV A

60 Hz Label on rear of system



82 Cambridge St., Burlington, MA 01803
Tel: 1-781-993-2300
Voltage Range: 100-120 / 220-240 V~
Frequency: 50Hz
Maximum Power Input: 600 VA
Model: Palomar EsteLux
Date of Manufacture:
Serial Number:
1311-0008 REV A

50 Hz Label on rear of system

Chapter 4: Installation

Installation & Set-Up

Palomar Medilux™ System

Verify Operation

4-2

Installation & Set-Up

Palomar Medilux™ System

The Medilux™ System is designed to operate within temperate temperature and humidity conditions. (59 - 81°F 15-27°C and less than 40% humidity). The unit must be allowed to acclimatize before use following exposure to extreme temperature or humidity. Do not install the unit close to radiators or other sources of heat.

No attempt should be made by unauthorized persons to open the unit. Failure to observe this caution may present a serious safety hazard and will void the warranty. There are no user serviceable parts inside the system.

Palomar cannot be held liable for events resulting from negligence, abuse or incorrect operation of the unit. Please acquaint yourself thoroughly with the instructions for use, and in the event of doubt contact Palomar.

The system is shipped with the coolant reservoir full. If the system requires filling please refer to Chapter 7.

System Installation and Set Up

- Remove the system and accessories from the packing material.
- Place the system on a cart or other support structure.

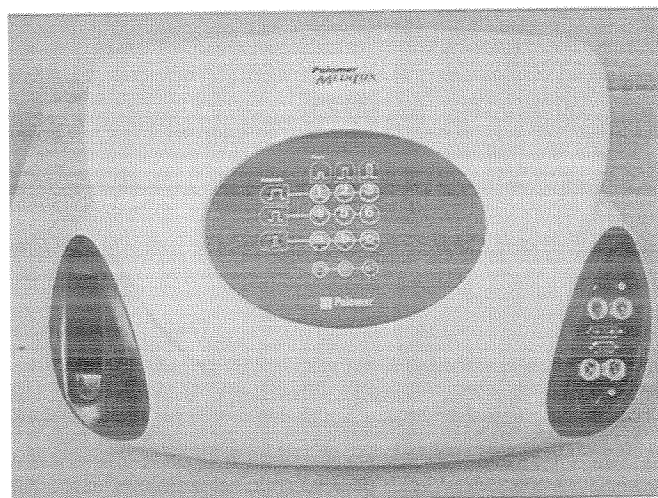


Figure 4-1 Medilux system

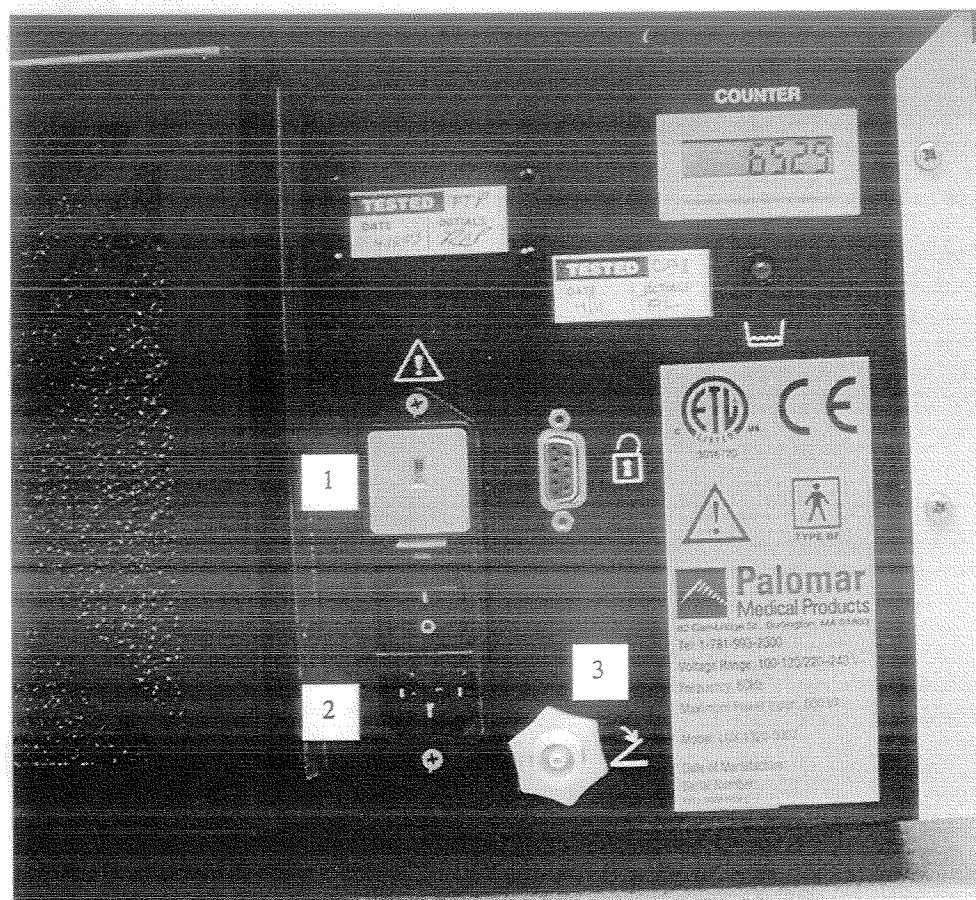


Figure 4-2 Medilux back connections

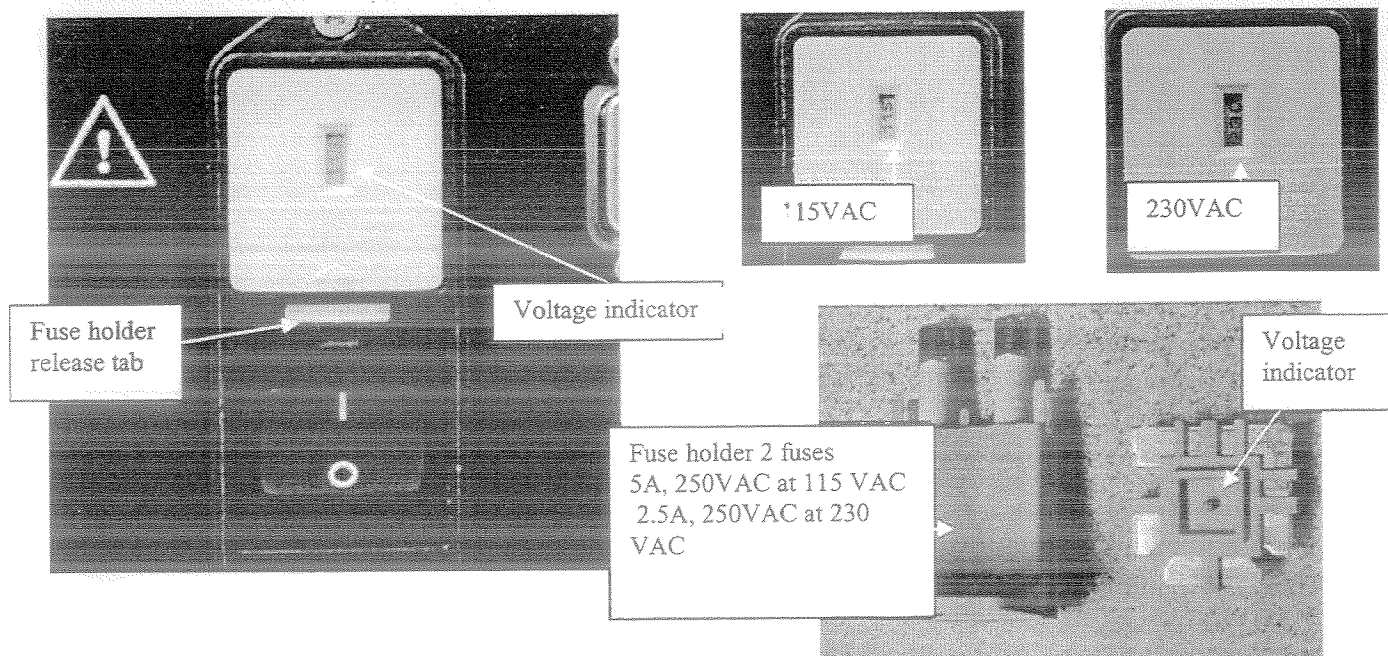


Figure 4-3 Fuse holder and voltage indicator



- (1) Verify voltage tab on the fuse holder is the same as the supply voltage (100-120VAC or 220- 240VAC), to adjust remove the fuse holder assembly and internal tap assembly, rotate the assembly so the input voltage is visible in the window. Figure 4-4 (see also Chapter 7)
- Caution: the input voltage range is selectable, the input frequency is not. The system is labeled for 50Hz or 60Hz. Operating the system at frequencies other than labeled may cause damage to the system.
- (2) Attach the power cord. Figure 4-3 Note: International customers must supply the power cord separately. An approved cord and plug set shall be used appropriate for the country of use. An IEC 60320-1 Style Appliance Coupler, Inlet: C13, shall be used.
- (3) Attach the footswitch connector to the receptacle at the back of the system.

Chapter 5: System Operation

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Preparing for Use

Those who use the system should be properly trained and authorized by the practitioner or institution.



- All connections to the system and handpiece should be made and checked before powering the system for use (See Chapter 4 Installation).
- Attach the footswitch connector to the receptacle at the back of the system.
- Connect the system to the power source from the main power connection.



- Do not use the handpiece if it has been dropped, is damaged, or has been submerged in fluid. Call Palomar Medical. (see chapter 8 Customer Service)

Palomar MediLux Operation

System Start-up

- Once all the connections are in place, and the handpiece is docked, the system is ready to be turned on.
- Turn on the power switch at the main power connector on the rear of the system.
- To turn on the system, turn the key clockwise.
- The system will power up, and perform a self test.
- The default setting is button #1.
- All persons in the room should wear protective eyewear.

Palomar recommends performing test spots of the area to be treated to determine appropriate treatment parameters (See Chapter 6 Clinical Application for the handpiece selected).

- The system is ready to emit light when the handpiece is removed from the dock holster. The Ready Indicator is illuminated.
- Inspect the handpiece for damage and cleanliness; it should feel cool to the touch.
- Press the treatment window of the handpiece **firmly** onto the target treatment site per Chapter 6.
- Select either footswitch and trigger button or footswitch only. Step on the footswitch. Press the trigger button. The system emit a pulse of light if the trigger button and footswitch remain depressed based on the set parameters. When the system is emitting light, an audible tone will signal with every pulse. The Ready Indicator will illuminate only when the footswitch is pressed and the system is ready to pulse. If the footswitch and/or trigger button are continuously depressed, in between pulses, the Ready Indicator will dim until the system is ready for the next pulse.
- Lifting the foot off the footswitch or lifting the finger off the trigger button will prevent the system from emitting light.

System Shut Down

- When treatment is complete, turning the key to the off position shuts down the system.
- Turn off the main power switch.

Note: Emergency button and key switch will immediately interrupt light radiation.

Emergency Stop

Press the emergency stop button of the Palomar MediLux during an **EMERGENCY**. This stops light emissions. The emergency stop must be rotated to restart the system.

Cleaning the console



Clean the console using a cloth moistened in a mixture of 30% alcohol and 70% water. Palomar Wipes™ lens cloths are recommended.

NOTE: Pure undiluted alcohol or detergents should not be used.

Disinfecting the console

It is recommended to disinfect the console with a cloth moistened with ethyl or isopropyl alcohol (70% to 90%) between consumers.

Warning:



Do not spray cleaning fluid or any water onto the console or the handpiece. Fluid inside the console may cause a hazardous condition for the operator, consumer, and presents a fire hazard.

- During cleaning the unit must be switched off and disconnected from the main power supply
- Do not submerge the handpiece in any fluid.
- Clean the handpiece before, during, and after use on a patient using Palomar Wipes lens cloths. (See Chapter 2 for handpiece cleaning).

Chapter 6: Clinical Application

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Operator Training

Practitioners handling light-based devices should complete a training program. A Palomar representative will provide a basic training in the operation of the Palomar MediLux™ System.

Practitioners may consider the following additional training avenues:

1. An accredited training course within the practitioner's specialty,
2. "Hands-on" training under the preceptorship of a qualified user.

Indications For Use

The Palomar MediLux System indications for use are based upon the selective absorption of the emitted light by natural chromophores, including melanin & hemoglobin. The MediLux System is designed to effectively remove hair, benign pigmented lesions, e.g., solar lentigines (also known as age or liver spots) and actinic bronzing, and vascular lesions, e.g., telangiectasia, rosacea, spider veins, port-wine stain, flushing, etc. For hair removal and treatment of pigmented lesions the melanin in hair follicles and in hyperpigmented basal layer cells is targeted by selecting the desired fluence with pre-set pulse width. Hemoglobin in the abnormal vasculature is the primary target in treatment of vascular lesions.



Effectiveness of the MediLux System for applications other than hair removal and treatment of benign pigmented lesions and vascular malformations has not been established at this time.

Operator Guidelines

All use of the equipment is based on the practitioner's knowledge and experience. The practitioner is responsible for correct diagnosis and treatment results.

Consumers must be informed of possible side effects and given an Informed Consent Form to read and sign. See Sample 6.1. Realistic expectations of long-term hair reduction, and clearance of benign pigmented lesions and vascular lesions should be discussed. Furthermore, consumers should be well instructed about pre- and post-treatment care. The MediLux system is designed to address multiple cosmetic and dermatological conditions, such as:

- removal of unwanted hair
- clearance of benign pigmented lesions
- clearance of vascular lesions.

The multi-tasking is achieved through the use of specialized detachable hand-pieces: LuxY, LuxR, LuxG, LuxRs, LuxB and LuxV. Specifications and suggested indications for use for these handpieces are summarized in the table below:

Table 6.1.1 MediLux HandPieces

Chapter Section	Hand-piece	Spot Size	Spectral Range	Fluence Range* (J/cm ²)	Application
6.2	LuxY	16 x 46-mm	525-1200-nm	6-14	Hair removal & pigmented lesions (skin type I-IV)
6.3	LuxR	16 x 46-mm	650-1200-nm	4-12	Hair removal (all skin types)
6.4	LuxG	12 x 12-mm	500-670 & 870-1400-nm	10-30	Pigmented & facial vascular lesions (skin type I-IV)
6.5	LuxRs	12 x 28-mm	650-1200-nm	9-27	Hair removal (all skin types) Permanent Hair Reduction (skin type I-IV)
6.6	LuxB	12 x 12-mm	470-1400nm	14-40	Pigmented and vascular lesions (skin type I-III)
6.7	LuxV	16 x 46-mm	400-700 & 870-1200nm	6-16	Pigmented lesions, Hair removal (skin type I-III)

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size.

General Recommendations:

The practitioner should carefully screen all potential candidates for treatment.

- Any cosmetic or dermatological skin condition must be correctly diagnosed by a physician and recommended for treatment prior to the initiation of treatment with the MediLux.
- The light is absorbed in hemoglobin, melanin and other chromophores. Therefore it is important to assess the content of the melanin in the epidermis determine the consumer's skin type to insure proper treatment setting selections and to avoid unnecessary damage of the epidermis
- Verify the consumer has had no unprotected sun exposure in the areas to be treated. This means the consumer wore protective clothing or used a SPF-30 or greater sunscreen for the past 4 weeks on the areas to be treated. See appropriate sections of Chapter 6 for Test Spot Recommendations with different handpieces.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the appropriate handpiece and energy setting is safe for use in all skin types. The Skin type worksheet on page 6.1-9 of Chapter 6 should be used to assist in skin type determination.

Table 6.1.2. Fitzpatrick Scale

<i>Skin Type</i>	<i>Working Classification</i>	<i>Color</i>	<i>Tentative grouping based on ethnicity & skin complexion*</i>
I	Always burn easily; never tans; <i>extremely</i> sensitive to sun	White	Primarily red headed individuals and blonds with light complexion.
II	Always burns easily; tans minimally, <i>very</i> sensitive to the sun	White	The largest percentage of Caucasian individuals fall into these categories
III	Sometimes burns; tans gradually to light brown, sun sensitive skin	White/Asian	
IV	Burns minimally; always tans to moderate brown; <i>minimally</i> sun sensitive	Moderate brown	Individuals of oriental, American Indian, Mediterranean and Latin American descent.
V	Very rarely burns; tans well; sun <i>insensitive</i> skin	Dark brown	Light complexion African-American individuals, and those of Indian descent.
VI	Never burns; deep pigmented; sun <i>insensitive</i> skin	Black	Dark-skinned individuals

* From Naylor, M.F. & Farmer K.C. Guidelines for Minimizing UV Exposure. In: The Electronic Textbook of Dermatology. Drugge, R. and Dunn, HA. (eds) The Internet Dermatology Society, 2000

Warning



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection for yourself and the consumer, during treatments.
- Should bleeding occur at any time during treatment discontinue use immediately and clean/disinfect the hand-piece, per manual Chapter 2.
- If handpiece is replaced tests spots should be performed on every consumer prior to treatment regardless of results from prior handpiece.

Medical History



After a consumer has met necessary criteria for treatment, a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure** -or use of tanning beds or creams in the areas to be treated in the last 4 weeks. Protected sun exposure means the wearing of protective clothing or the daily use of a SPF # 30 or greater sunscreen.
- **Pregnancy**- there is no evidence at this time of fetal harm from a light-based system, but the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** – less than 6 weeks prior to treatment for consumers seeking hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring.
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights may trigger a seizure.
- **Medications**- both prescription and non-prescription. Be sure to include herbal and natural remedies as some of those may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment
- **History of keloid & hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars.
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared.
- **Open lesions** - treatment should only be done on intact, healthy skin
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®)**: although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin for the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It might also increase skin sensitivity to light.

Advise the consumer to:

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course and 4-6 weeks after treatment. This will reduce the chance of skin color changes and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day. Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 6 weeks prior to treatment and for the duration of treatments. It is best to shave or trim excess hair during the course of treatment.

Operator considerations:

- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

SKIN TYPE WORKSHEET

CONSUMER NAME:		DATE:				
SCORE		0	1	2	3	4
	WHAT IS THE COLOR OF YOUR EYES?	LIGHT BLUE, GRAY OR GREEN	BLUE, GRAY OR GREEN	BLUE	DARK BROWN	BROWNISH BLACK
	WHAT IS THE NATURAL COLOR OF YOUR HAIR?	SANDY RED	BLOND	BROWN, CHESTNUT, DARK BLOND	DARK BROWN	BLACK
	WHAT IS THE COLOR OF YOUR SKIN (UNEXPOSED AREAS)	REDDISH	VERY PALE	PALE WITH BEIGE TINT	LIGHT BROWN	DARK BROWN
	DO YOU HAVE FRECKLES ON SUN EXPOSED AREAS?	MANY	SEVERAL	FEW	INCIDENTAL	NONE
	WHAT HAPPENS WHEN YOU STAY IN THE SUN TOO LONG?	PAINFUL REDNESS, BLISTERING, PEELING	BLISTERING FOLLOWED BY PEELING	BURNS SOMETIMES FOLLOWED BY PEELING	RARELY BURNS	NEVER HAD BURNS
	TO WHAT DEGREE DO YOU TURN BROWN?	HARDLY OR NOT AT ALL	LIGHT COLOR TAN	REASONABLE TAN	TAN VERY EASILY	TURN DARK BROWN QUICKLY
	DO YOU TURN BROWN SEVERAL HOURS AFTER SUN EXPOSURE?	NEVER	SELDOM	SOMETIMES	OFTEN	ALWAYS
	HOW DOES YOUR FACE RESPOND TO THE SUN?	VERY SENSITIVE	SENSITIVE	NORMAL	VERY RESISTANT	NEVER HAD A PROBLEM
	WHEN DID YOU LAST EXPOSE YOURSELF TO THE SUN, TANNING BED, OR SELF-TANNING CREAMS?	MORE THAN 3 MONTHS AGO	2-3 MONTHS AGO	1-2 MONTHS AGO	LESS THAN 1 MONTH AGO	LESS THAN 2 WEEKS AGO
	DO YOU EXPOSE THE AREA TO BE TREATED TO THE SUN?	NEVER	HARDLY EVER	SOMETIMES	OFTEN	ALWAYS
TOTAL SCORE :	SCORE	FITZPATRICK SKIN TYPE				
	0-7	I				
	8-16	II				
	17-25	III				
SKIN TYPE:	26-30	IV				
	OVER 30	V - VI				

Instructions for Use of Palomar cryogen CoolSpray™ with CSD™ Diffuser



CAUTION!! Use only *Palomar CoolSpray with CSD Diffuser* 10oz can (Fig. 6.1-1)

CAUTION!! Do not spray directly onto skin or into eyes. Intended for use only on the Palomar hand-piece treatment window.

See CoolSpray label for health and safety data

The crystal of the handpiece serves to extract excess heat from the epidermis and to protect it from overheating. Hence the lower the temperature of the handpiece crystal in relation to the epidermis the better it protects the skin.



Fig. 6.1-1. Palomar cryogen CoolSpray with CSD™ Diffuser

Step 1 – Insert red tube into nozzle (Fig. 6.1-2)

Step 2 – Remove tamper-proof seal from a can (Fig. 6.1-3)

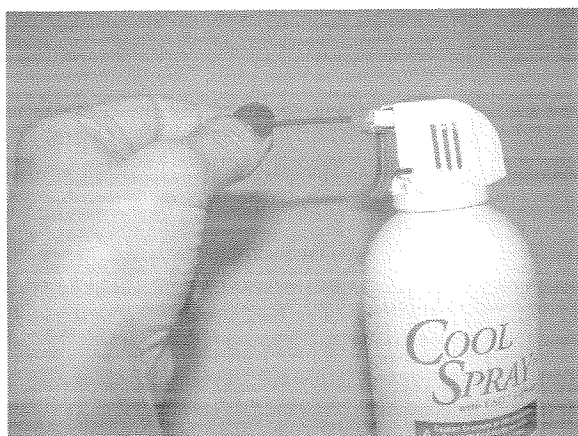


Fig. 6.1-2. Insertion of red tube into diffuser

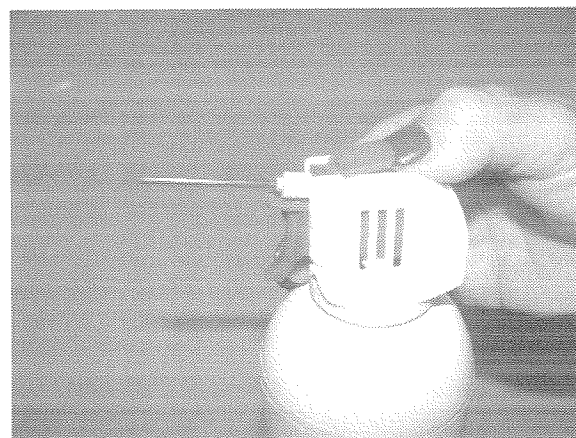


Fig. 6.1-3. Removal of tamper-proof seal

Step 3 – Spray the lens (treatment window) (Fig. 6.1-4 & 6.1-5)



Fig. 6.1-4. Pre-cooling of the LuxG

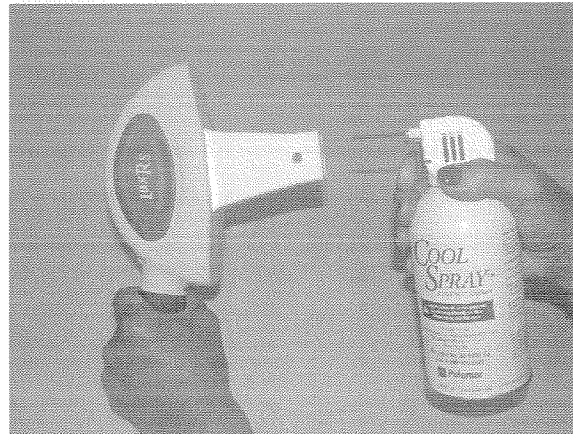


Fig.6.1-5. Pre-cooling of the LuxRs

The hand-piece is equipped with a temperature sensor that is located on each side of the distal end near the treatment window. At room temperature the sensor displays as a GREEN dot with a GREEN concentric ring (Fig. 6.1-6). When temperature of the crystal in the hand-piece drops below 5° C (LuxG) or 20° C (LuxRs) the sensor turns SOLID GREEN (Fig. 6.1-7).

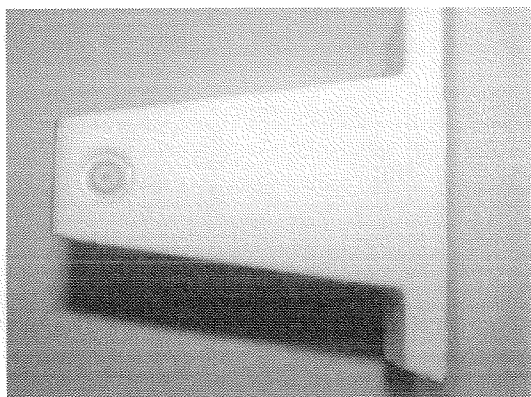


Fig. 6.1-6. Temperature sensor not cold

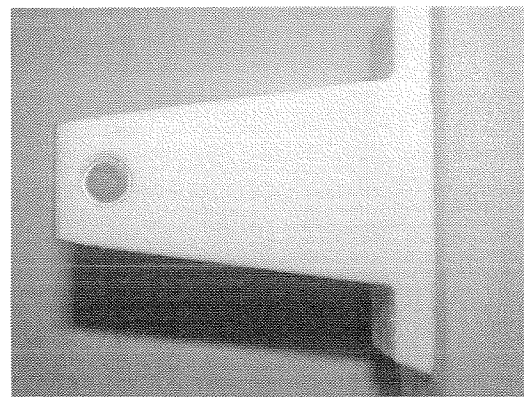


Fig. 6.1-7. Temperature sensor cold

LuxG. It takes about 10 of 1-sec sprays of cryogen to lower the LuxG treatment window 5° C. It lasts for 5-7 consecutive shots before the hand-piece needs re-cooling.

LuxRs: It takes about 20 of 1-sec sprays of cryogen to lower the LuxRs treatment window to 20° C. It lasts for 20-30 consecutive shots before the hand-piece needs re-cooling.

If there is a significant delay between shots (2-3 min) check color of the sensor and, if necessary, re-cool before resuming treatment. The margin of safety is significantly reduced when treating with a handpiece that is at room temperature.

EsteLux Informed Consent

I authorize _____ to perform laser/pulsed light hair removal, pigmented lesion, or vascular removal treatment on me. I understand that the procedure is purely elective.

I understand that: Serious complications are rare, but possible. Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (lightening or darkening of spots on the skin) lasting 1-3 months or longer may occur. In addition, freckles may temporarily or permanently disappear in treated areas. Other potential risks include crusting, itching, pain, bruising, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. In some individuals, there is a remote chance of more hair regrowth occurring but successive treatments are intended to address this situation. Lasers and/or intense light can cause eye injury and protective eyewear must be worn during treatment.

I understand that I must be completely honest in divulging my exposure, whether direct or indirect, to sun or tanning lamp because I understand that sun or tanning lamp exposure may increase my chance of complications. I also understand that not adhering to the post-care instructions provided to me may increase my chance of complications.

To determine skin type, check one of the following:

TYPE	SKIN COLOR	REACTION TO FIRST SUN EXPOSURE YEARLY
_____ I	white	always burn/never tans
_____ II	white	usually burns/tans with difficulty
_____ III	white/asian	sometimes mild burn/average tan
_____ IV	moderate brown	rarely burns/tans with ease
_____ V	dark brown	very rarely burns/tans very easily
_____ VI	black	never burns

I consent to photographs to be taken to evaluate treatment effectiveness, for medical education, training, professional publications or sales purposes. No photographs revealing my identity will be used without my written consent. If my identity is not revealed, these photographs may be used and displayed publicly without my permission.

Before and after treatment instructions have been discussed with me. The procedure as well as potential benefits and risks have been explained to my satisfaction. I have had all my questions answered and freely consent to the proposed treatment.

Patient's Signature: _____ Date: _____

Print Name: _____

Witness Signature: _____ Date: _____

Print Name: _____

MEDILUX Treatment Record

Patient Name: _____	Date: _____
---------------------	-------------

- ☐ Informed consent
- ☐ Protective eyewear
- ☐ Safety precautions explained to patient

Physician: _____

Laser Tech: _____

Other: _____

MEDILUX IPL Parameters					
Diagnosis	Energy Density J/cm ²	Hand-piece	Number of Pulses	Area Treated	Notes

Comments: _____

Signature: _____

EsteLux / MediLux Informed Consent

I authorize _____ to perform laser/pulsed light hair removal, pigmented lesion, vascular or tattoo removal treatment on me. I understand that the procedure is purely elective.

I understand that: Serious complications are rare, but possible. Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (lightening or darkening of spots on the skin) lasting 1-3 months or longer may occur. In addition, freckles may temporarily or permanently disappear in treated areas. Other potential risks include crusting, itching, pain, bruising, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. In some individuals, there is a remote chance of more hair regrowth occurring but successive treatments are intended to address this situation. Lasers and/or intense light can cause eye injury and protective eyewear must be worn during treatment.

I understand that I must be completely honest in divulging my exposure, whether direct or indirect, to sun or tanning lamp because I understand that sun or tanning lamp exposure may increase my chance of complications. I also understand that not adhering to the post-care instructions provided to me may increase my chance of complications.

I consent to photographs to be taken to evaluate treatment effectiveness, for medical education, training, professional publications or sales purposes. No photographs revealing my identity will be used without my written consent. If my identity is not revealed, these photographs may be used and displayed publicly without my permission.

Before and after treatment instructions have been discussed with me. The procedure as well as potential benefits and risks have been explained to my satisfaction. I have had all my questions answered and freely consent to the proposed treatment.

Patient's Signature: _____ Date: _____

Print Name: _____

Witness Signature: _____ Date: _____

Print Name: _____

MEDICAL HISTORY

Last Name: _____ First Name: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone #: home: () _____ D.O.B _____ Sex: _____

work: () _____ Family Doctor: _____

PLEASE ANSWER ALL OF THE FOLLOWING QUESTIONS

	YES	NO
1. Do you have ANY current or chronic medical illness we should know about? Please List: _____ _____	☐	☐
2. Do you take ANY medications on a regular or daily basis? Please List: _____ _____	☐	☐
3. Do you have ANY allergies to medicine or skin sensitivities? Please List: _____ _____	☐	☐
4. (For women) are you pregnant?	☐	☐
5. (For women) are menstrual periods regular?	☐	☐
6. Do you have a history of herpes simplex in the area to be treated?	☐	☐
7. Do you have a history of keloid scarring?	☐	☐
8. Have you taken Accutane or anticoagulants in the last 6 months?	☐	☐

9. To determine skin type, check one of the following:

TYPE	COLOR	REACTION TO FIRST SUN EXPOSURE YEARLY
_____ I	white	always burn/never tans
_____ II	white	usually burns/tans with difficulty
_____ III	white/asian	sometimes mild burn/average tan
_____ IV	moderate brown	rarely burns/tans with ease
_____ V	dark brown	very rarely burns/tans very easily
_____ VI	black	never burns

Signature: _____ Date: _____

Hair Removal Pricing
ALL HAIR COLORS & ALL SKIN TYPES

<u>Area</u>	<u>Single Treatment</u>	<u>Package of 3</u>	<u>2nd</u>	<u>3rd</u>
Upper Lip	\$100	\$225	\$75	\$50
Chin	\$100	\$225	\$75	\$50
Sideburns	\$100	\$225	\$75	\$50
Eyebrows	\$100	\$225	\$75	\$50
Ears	\$100	\$225	\$75	\$50
Toes, Fingers	\$100	\$225	\$75	\$50
Full Face	\$250	\$675	\$225	\$200
Neck	\$250	\$675	\$225	\$200
Under Arms	\$250	\$675	\$225	\$200
Bikini	\$250	\$675	\$225	\$200
Neck	\$250	\$675	\$225	\$200
Upper Back	\$275	\$750	\$250	\$225
Full Back	\$450	\$1225	\$400	\$375
Forearms	\$275	\$750	\$250	\$225
Full Arms	\$325	\$850	\$275	\$250
Lower Legs	\$325	\$850	\$275	\$250
Upper Legs	\$375	\$1000	\$325	\$300
Full Legs	\$450	\$1225	\$400	\$375

<u>Sun Spots</u>			
<u>Area</u>	<u>Single Treatment</u>	<u>Package of 2</u>	<u>3rd (rarely needed)</u>
Hands	\$250	\$450	\$200
Forearms	\$300	\$550	\$250
Arms	\$350	\$650	\$300
Chest	\$400	\$750	\$350
Upper Back	\$350	\$650	\$300
Partial Face	\$275	\$500	\$225
Full Face	\$500	\$950	\$450

<u>Vessels</u>			
<u>Area</u>	<u>Single Treatment</u>	<u>Package of 2</u>	<u>3rd (rarely needed)</u>
Few Vessels	\$175	\$300	\$125
Partial Face	\$275	\$500	\$225
Full Face	\$500	\$950	\$450
Neck	\$275	\$500	\$225
Chest	\$400	\$750	\$350
Legs	\$275	\$500	\$225

<u>ACNE</u>		
<u>Area</u>	<u>Single Treatment</u>	<u>Package of 4</u>
Face	\$150	\$400

Consumer Exclusion Criteria:

- **Unprotected sun exposure or use of tanning beds or creams.** If you have had unprotected sun exposure in the areas to be treated in the last 4 weeks you must notify your treatment provider. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy**-If you are pregnant you should not have any treatments with light based devices. Although there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – If you have menstrual dysfunction or are known to have elevated androgen levels you should see an endocrinologist for evaluation and possible medical treatment. You may tend to have excess hairiness due to your disease, which may respond to medical treatment.
- **Use of mechanical epilation** –Notify your treatment provider if you are seeking hair removal and have used a mechanical epilation method less than 6 weeks prior to treatment. This includes plucking, waxing, tweezing, electrolysis or sugaring.
- **Allergies** – Inform your treatment provider of any allergies to medications, latex, foods or other substances.
- **History of seizures** –If you have a history of seizures or are taking a anti-seizure medication you should not have treatments with a light based device. Flashing lights may trigger a seizure.
- **Medications**-Inform your treatment provider of both prescription and non-prescription medications you are taking. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumers should not be taking Accutane, anti-coagulants or St. John's wort.
- **History of keloid & hypertrophic scar formation** - Although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude you from the treatment if you have a known tendency to form keloid or hypertrophic scars.
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. If you currently have an active infection your treatment will be postponed until the infection is cleared.
- **Open lesions** - Treatment should only be done on intact, healthy skin
- **Herpes I or II** - within the treatment area. If you have a history of herpes outbreaks in the area of treatment you should consult your Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A[®], Renova[®])**: Although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. You are advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** – You will be excluded from treatments with the light based device if you have taken Accutane within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Sample

CONSENT TO PULSED LIGHT-BASED TREATMENT

I authorize _____ to perform pulsed light hair removal or pigmented lesion or vascular lesion treatment on me. I understand that the procedure is purely elective.

I understand that: Serious complications are rare, but possible. Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. I understand that treatment of benign pigmented lesions and vascular lesions cannot be accomplished without producing some epidermal damage and that this may take 2-4 weeks to resolve.

Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. There is the likelihood of coincidental hair removal when treating pigmented/vascular lesions in hair bearing areas.

Other potential risks include blistering, crusting, itching, pain, bruising, skin whitening, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment.

I understand that sun exposure or use of tanning lamps or self tanning creams and not adhering to the post-care instructions provided to me may increase my chance of complications.

I understand the importance of having an accurate diagnosis by a physician of brown spots prior to treatment, as treatment of an undiagnosed skin cancer may delay proper medical care.

I understand that since hair follicles generally grow at angles within the skin it is possible to affect follicles that are not directly in the beams apparent path at the skin surface, and for that reason it is not advisable to shape or sculpt precise hair bearing areas such as eyebrows etc.

I consent to photographs being taken to evaluate treatment effectiveness, for medical education, training, professional publications or sales purposes. No photographs revealing my identity will be used without my written consent. If my identity is not revealed, these photographs may be used and displayed publicly without my permission

Before and after treatment instructions have been discussed with me. I have read and understand the attached exclusionary criteria. The procedure as well as potential benefits and risks have been explained to my satisfaction. I have had all my questions answered. I freely consent to the proposed treatment.

Patient's Signature: _____

Date: _____

Print Name: _____

Witness Signature: _____

Date: _____

Print Name: _____

CONSENT TO PULSED LIGHT-BASED TREATMENT

I authorize _____ to perform pulsed light hair removal or pigmented lesion or vascular lesion treatment on me. I understand that the procedure is purely elective.

I understand that: Serious complications are rare, but possible. Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. I understand that treatment of benign pigmented lesions and vascular lesions cannot be accomplished without producing some epidermal damage and that this may take 2-4 weeks to resolve.

Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. There is the likelihood of coincidental hair removal when treating pigmented/vascular lesions in hair bearing areas.

Other potential risks include blistering, crusting, itching, pain, bruising, skin whitening, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment.

I understand that sun exposure or use of tanning lamps or self tanning creams and not adhering to the post-care instructions provided to me may increase my chance of complications.

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I understand that since hair follicles generally grow at angles within the skin it is possible to affect follicles that are not directly in the beams apparent path at the skin surface, and for that reason it is not advisable to shape or sculpt precise hair bearing areas such as eyebrows etc.

I consent to photographs being taken to evaluate treatment effectiveness, for medical education, training, professional publications or sales purposes. No photographs revealing my identity will be used without my written consent. If my identity is not revealed these photographs may be used and displayed publicly without my permission.

Before and after treatment instructions have been discussed with me. I have read and understand the attached exclusionary criteria. The procedure as well as potential benefits and risks have been explained to my satisfaction. I have had all my questions answered. I freely consent to the proposed treatment.

Patient's Signature: _____

Date: _____

Print Name: _____

Witness Signature: _____

Date: _____

Print Name: _____

Sample Consumer Exclusion Criteria: Sample

- **Unprotected sun exposure or use of tanning beds or creams.** If you have had unprotected sun exposure in the areas to be treated in the last 4 weeks you must notify your treatment provider. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy**-If you are pregnant you should not have any treatments with light based devices. Although there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – If you have menstrual dysfunction or are known to have elevated androgen levels you should see an endocrinologist for evaluation and possible medical treatment. You may tend to have excess hairiness due to your disease, which may respond to medical treatment
- **Use of mechanical epilation** –Notify your treatment provider if you are seeking hair removal and have used a mechanical epilation method less than 6 weeks prior to treatment. This includes plucking, waxing, tweezing, electrolysis or sugaring.
- **Allergies** – Inform your treatment provider of any allergies to medications, latex, foods or other substances.
- **History of seizures** –If you have a history of seizures or are taking a anti-seizure medication you should not have treatments with a light based device. Flashing lights may trigger a seizure.
- **Medications**-Inform your treatment provider of both prescription and non-prescription medications you are taking. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumers should not be taking Accutane, anti-coagulants or St. John's wort.
- **History of keloid & hypertrophic scar formation** - Although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude you from the treatment if you have a known tendency to form keloid or hypertrophic scars.
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. If you currently have an active infection your treatment will be postponed until the infection is cleared.
- **Open lesions** - Treatment should only be done on intact healthy skin
- **Herpes I or II** - within the treatment area If you have a history of herpes outbreaks in the area of treatment you should consult your Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®)**: Although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. You are advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** – You will be excluded from treatments with the light based device if you have taken Accutane within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Sample

LuxY, LuxR, LuxRs, LuxV Hair Removal Pre Treatment Instructions

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course. This will reduce the chance of skin color changes, and development of new lesions. Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day. Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- It is best to shave or trim excess hair during the course of treatment
- If you have a history of herpes outbreaks in the area of treatment you should consult your Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.

Sample

LuxY, Lux G, LuxV, Lux B Pigmented and Vascular Lesion Pre Treatment Instructions

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course. This will reduce the chance of skin color changes, and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day. Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- If you have a history of herpes outbreaks in the area of treatment you should consult your Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- An accurate diagnosis by a physician of brown spots prior to treatment is necessary before treatment of lesions.
- Be aware there is the possibility of coincidental hair loss when treating pigmented lesions in hair bearing areas
- Topical anesthetics are not recommended for treatment of vascular lesions because of potential vasoconstriction that renders treatment less effective.

Sample

LuxY, LuxR, LuxRs, LuxV Hair Removal Post Treatment Instructions:

- Mild sunburn-like sensation is expected. This usually lasts 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to the treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing, use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas, as well as the use of sun tanning beds and self-tanning creams.
- Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease the likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed within 1-2 weeks of new hair growth.
- Avoid, swimming, hot tubs/Jacuzzis, and excessive exercise for 7 days after treatment or until redness resolves.
- If blisters occur, apply antibiotic ointment to the areas 2 times a day until healed.
- Do not pick or remove scabs or crusting; this will help decrease the chance of infection and scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Sample

LuxY, Lux G, LuxV, Lux B Benign Pigmented Lesion Post Treatment

Instructions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed, to reduce discomfort and heat sensation.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 2-3 days.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- The lesion is usually healed in 7-30 days. It will continue to fade over the next 2-4 weeks.
- Be aware of the likelihood of coincidental hair removal when treating pigmented lesions in hair bearing areas
- Direct sunlight to the treated area should be avoided.
- Daily application of a # 30 SPF is recommended to prevent development of new lesions.

Sample

LuxG, LuxB Post-Treatment Vascular Lesion Instructions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed, to reduce discomfort and heat sensation.
- The treated area can be gently cleansed and topical bactericidal ointment can be applied if needed.
- The vessels undergo immediate graying or blanching. In some cases, only a slight purplish change is noted. Vessels either fully or partially resolve in about 10-14 days, areas of diffuse flushing gradually fade leaving skin with normal appearance.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
 - Avoid sun exposure to treated areas.
 - Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin.

Chapter 6.2 - LuxY HandPiece

LuxY handpiece is recommended for treatment of benign pigmented lesions and hair removal in consumers with skin type I-IV.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples in chapter 6.1)

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes, but is not limited to:

Physical assessment to establish hair color and skin type:

- The light is absorbed in hemoglobin, melanin and other normal chromophores. Therefore it is important to assess the content of the melanin in normal epidermis determine the consumer's skin type and hair before *any* treatment to ensure proper treatment setting selections and to avoid potential thermal damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that the consumer wore protective clothing or used a SPF-30 or higher sunscreen in the areas to be treated for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment. See page 6.2-5 for Test Spot Recommendations.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxY handpiece is safe for use in skin types I-IV. The Skin type worksheet page 6.1-9 Chapter 6 should be used to assist in skin type determination.



Prior to initiation of treatment all pigmented lesions must be correctly identified by a physician to be benign and be recommended for laser or lamp-based device treatment.

It is very important to have an accurate diagnosis of the brown spots considered for treatment prior to actual treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the consumer receiving proper medical care.

- The mechanism of pigmented lesion removal by the MediLux System is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which resolves within a one-to-two-week period.

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method using the test spot tables and wait 24 hours before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** -less than 6 weeks prior to treatment for hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort.
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared
- **Open lesions** - treatment should only be done on intact healthy skin
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the handpiece, per manual Chapter 2.

Warning:

During hair removal procedure avoid treating over darkly pigmented lesions and tattoos to avoid skin damage and color change.



Every consumer must have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area. Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

- Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects.
- Treatment parameters should be based on test spots appropriate to both the treatment site and skin type of the consumer to be treated.
- Parameters of treatment should be determined by a trained operator based on the results of the test spots.
- **PhotoEpilation:** A fast and comfortable hair removal treatment method. This treatment method will provide long term to permanent reduction of hair.
- **PhotoWaxing:** A high speed and virtually pain free alternative to waxing. This method of treatment will temporarily delay new hair growth from one to three months

Pre-Treatment Instructions

Hair Removal and Benign Pigmented Lesions

Warning:



- Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Inform the consumer to:

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course. This will reduce the chance of skin color changes, and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- Shave or trim excess hair during the course of treatment.

Operator considerations:

- The area should be cleansed thoroughly before test spot administration and treatment
- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

LuxY handpiece Fluence chart

Button Label	Fluence*(J/cm ²)	Pulse width (ms)
Photo Epilation™ Settings		
1	13	100
2	14	60
3	15	40
4	17	20
5	18	20
6	20	20
Photowaxing™ Settings		
a	8	10
b	9	10
c	10	10

Table 6.2-2 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size.

Performing Test Spots:

- The treatment area should be shaved or closely clipped prior to administering test spots.
- Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots
- The area should be cleansed thoroughly before test spot administration and treatment.
- Apply Palomar Lotion to treatment area using gauze.
- To perform test spots, place a provided pre-punched paper mask on the sapphire lens (treatment window). The use of a mask limits exposing a large area for testing. Be certain that the hole in the mask is where you intend to place the test spot on the skin.
- Start test spots with the lowest setting listed in the table 6.2.1 (A&B) corresponding to the consumers skin type and increase slowly after checking for skin side effects. If there is evidence of darkening, blistering, deep reddening of the skin, or strong pain lower the setting, and re-test.
- Treatment (with the mask removed) may be performed at settings *below* the threshold for adverse skin reactions as determine by test spots.

Table 6.2.1 A. UN-TANNED Skin Spot Test Recommendations: LuxY

Skin Type	Starting settings for test spots In the following order	Maximum setting for test spots	Evaluate Test Spot
I, II, III	c, 1, 2, 3	6	30 min
IV	a, b, c, 1, 2, 3	4	24 to 48 hours
V	Treatment not recommended	Not applicable	
VI	Treatment not recommended	Not applicable	

Table 6.2.1 B. TANNED Skin Spot Test Recommendations: LuxY

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spots	Evaluate Test Spot
I, II, III	a, b, c, 1	b, 2	24 to 48 hours
IV	a	1	24 to 48 hours*
V	Treatment not recommended	Not applicable	
VI	Treatment not recommended	Not applicable	

Note:

The recommended maximum setting for treatment of any tanned consumer is 2.

*In rare instances darkening of skin can be delayed up to 72 hours after test spots are administered.

Treatment Instructions

Hair Removal:

- Check documentation of test spot treatment parameters.
- Check for recent sun or tanning exposure, and re-administer test spots, if necessary.
- Trim the area to be treated with a hair clipper, if necessary.
- If topical anesthetic is used apply after the hair is clipped, it should be washed off prior to treatment.
- Apply Palomar Lotion to treatment area. Use gauze or the CoolRoller to spread the lotion over the treatment site immediately prior to administering treatment.
- Apply CoolRoller over 2 x 8 inches, 4 x 4 inches or smaller area for 5-10 seconds or use the ice/gel pack for 2-3 min.
- Handpiece can also be cooled with the CoolSpray (see "Instructions for Cooling Handpiece" page 6.1-9).

NOTE: Prolonged application of CoolRoller or cold packs may provide greater comfort but could reduce treatment efficacy due to overcooling. If consumer experiences discomfort, re-apply CoolRoller.

- Regularly clean the lens surface of the handpiece (every 20-30 pulses) using Palomar wipes or other soft moist cloth.
- Follow Chapter 5 for system operation.

NOTE: The system settings depend on skin type, hair color and test spot skin response. It is recommended that the pulses be overlapped (25-30%) to ensure that effective energy is delivered to the treatment site. The risk of injury to the skin from overlapping pulses is minimal. Use the imprint of the treatment window on the skin as a guide in lining up subsequent pulses.

- To assure delivery of the light energy to the proper depth apply light pressure to compress the skin and to force the blood out of the skin during treatment. This improves light transmission and enhances delivery of light to the hair follicles.

NOTE: Skin cooling is necessary to lower the temperature in the epidermis and provide partial anesthesia. For this reason it is imperative that the CoolRoller or ice pack is applied over the treatment site immediately prior to the MediLux treatment.

- Maintenance of firm, constant pressure of the handpiece against the skin is essential to minimizing adverse effects.

Caution: If treatment window becomes warm and causes consumer discomfort, use CoolSpray directly on the window (see instructions) or hold treatment lens against ice or ice pack for 30-60 seconds. When treating dark or tanned skin you may need to cool the treatment window every 5 - 10 shots (See page 6.2-4 for Test Spot Recommendations).

- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. **For this reason, it is not advisable to use the Palomar MediLux™ System for shaping or sculpting precise hair-bearing areas such as the eyebrows, etc.**
- To help better visualize the treatment site and quickly look for areas that may have been missed during treatment, a direct light illumination is helpful.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that Palomar MediLux users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue.

Clinical Endpoints

There are no ideal clinical end points in hair removal with the MediLux System because pre- and post-cooling of skin significantly reduces perifollicular edema and erythema.



Although the likelihood of tissue damage is low, observe for epidermal damage, such as blistering or whitening of the skin. If the fluence is too high or improper technique is used the skin may look wrinkled or whitish/gray in color as if it were touched to a hot surface, similar to what you would see from a curling iron. If this occurs decrease preset power setting fluence and insure firm constant pressure of the handpiece against the skin. If blistering is encountered, the fluence should be decreased until this reaction is no longer present. If blistering occurs at even the lowest pulse width and fluence, that person should be excluded from treatment.

Benign Pigmented Lesions

- Benign pigmented lesions vary in size from a few millimeters to more than 1 cm across.
- The area should be cleansed thoroughly before test spot administration and treatment
- Decide on the treatment approach:
 - *Treat the entire area of skin containing lesions* (**Caution:** Suntan or solar bronzing will be affected by the treatment and may result in lighter patches of skin in the shape of the treatment window), or
 - *Treat the lesions only*
- If the entire area of the skin containing lesions is to be treated be sure the selected fluence does not exceed the recommendations for test spots on page 6.2-4 for surrounding non-pigmented skin
- If the lesions are to be treated individually use the pre punched paper test spot mask provided by Palomar. Moisten gauze with Palomar Lotion and apply to the area, align the opening in the mask with the lesion and bring the treatment window in firm contact with the skin.
- Do not cool the skin during pigmented lesion treatment. If treatment lense becomes warm during extended use, cooling the skin may become necessary.
- For best results button #5 is recommended for dark brown/black lentigines and button #6 for all others.
- Immediately after treatment the lesions may turn darker in color. The area surrounding the lesion may turn red. The lesion may elevate and appear swollen. These are all expected outcomes and resolve in 7-10 days.

Post-Treatment Instructions

Hair Removal:

- Using ice, CoolRoller, cold packs and/or a steroid cream immediately after treatment has been found to minimize erythema and edema, and to provide comfort to the consumer.
- Provide the consumer with both verbal and written instructions including, but not limited to:
- Mild sunburn-like sensation is expected. This usually lasts 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to the treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing and use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas, as well as the use of sun tanning beds and self-tanning creams. Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed within 1-2 weeks of new hair growth.
- Avoid, swimming, hot tubs/Jacuzzis, and excessive exercise do not apply any cosmetics to treated area for 7 days after treatment or until redness resolves.
- If blisters occur, apply antibiotic ointment to the areas 2 times a day until healed.
- Do not pick or remove scabs or crusting; this will help decrease the chance of infection and scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Benign Pigmented Lesions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed.
- The treated area can be gently cleansed and topical bactericidal ointment may be applied if needed.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 7-14 days.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.

- The lesion is usually healed in 21-30 days. It will continue to fade over the next 6-8 weeks.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
- Avoid sun exposure to treated areas. Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin between treatments and 4-6 weeks after treatment.

Side Effects /Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and **reduce the risk of complications and unwanted side effects.**

Possible side effects or complications that may arise from use of the Palomar MediLux™ System include, but are not limited to:



- **Blisters** may sometimes occur. If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced. Be sure to maintain firm contact with the skin's surface before pulsing the MediLux.
- **Pigmentary changes** such as lightening or darkening of the skin may occur. In some consumers it may not be visible for 2 – 4 days after treatment. Most skin color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment, this usually resolves in <72 hours
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. The blisters are intra-epidermal in nature and usually heal without scarring.

NOTE: These side effects/complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment. These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques.

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin)

lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. During treatment of pigmented lesions in hair bearing areas, there is a likelihood of hair removal in those areas treated. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.2 - LuxY HandPiece

LuxY handpiece is recommended for treatment of benign pigmented lesions and hair removal in consumers with skin type I-IV.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples in chapter 6.1)

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes, but is not limited to:

Physical assessment to establish hair color and skin type:

- The light is absorbed in hemoglobin, melanin and other normal chromophores. Therefore it is important to assess the content of the melanin in normal epidermis determine the consumer's skin type and hair before *any* treatment to ensure proper treatment setting selections and to avoid potential thermal damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that the consumer wore protective clothing or used a SPF-30 or higher sunscreen in the areas to be treated for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment. See page 6.2-5 for Test Spot Recommendations.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxY handpiece is safe for use in skin types I-IV. The Skin type worksheet page 6.1-9 Chapter 6 should be used to assist in skin type determination.



Prior to initiation of treatment all pigmented lesions must be correctly identified by a physician to be benign and be recommended for laser or lamp-based device treatment.

It is very important to have an accurate diagnosis of the brown spots considered for treatment prior to actual treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the consumer receiving proper medical care.

- The mechanism of pigmented lesion removal by the MediLux System is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which resolves within a one-to-two-week period.

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method using the test spot tables and wait 24 hours before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** -less than 6 weeks prior to treatment for hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort.
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body Reschedule the consumer when infection is cleared
- **Open lesions** - treatment should only be done on intact healthy skin
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the handpiece, per manual Chapter 2.

Warning:

During hair removal procedure avoid treating over darkly pigmented lesions and tattoos to avoid skin damage and color change.



Every consumer must have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area. Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

- Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects.
- Treatment parameters should be based on test spots appropriate to both the treatment site and skin type of the consumer to be treated.
- Parameters of treatment should be determined by a trained operator based on the results of the test spots.
- **PhotoEpilation:** A fast and comfortable hair removal treatment method. This treatment method will provide long term to permanent reduction of hair.
- **PhotoWaxing:** A high speed and virtually pain free alternative to waxing. This method of treatment will temporarily delay new hair growth from one to three months

Pre-Treatment Instructions

Hair Removal and Benign Pigmented Lesions

Warning:



- Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Inform the consumer to:

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course. This will reduce the chance of skin color changes, and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- Shave or trim excess hair during the course of treatment.

Operator considerations:

- The area should be cleansed thoroughly before test spot administration and treatment
- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

LuxY handpiece Fluence chart

Button Label	Fluence*(J/cm ²)	Pulse width (ms)
Photo Epilation™ Settings		
1	3	100
2	14	60
3	15	40
4	17	20
5	18	20
6	20	20
Photowaxing™ Settings		
a	8	10
b	9	10
c	10	10

Table 6.2-2 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size.

Performing Test Spots:

- The treatment area should be shaved or closely clipped prior to administering test spots.
- Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots
- The area should be cleansed thoroughly before test spot administration and treatment.
- Apply Palomar Lotion to treatment area using gauze.
- To perform test spots, place a provided pre-punched paper mask on the sapphire lens (treatment window). The use of a mask limits exposing a large area for testing. Be certain that the hole in the mask is where you intend to place the test spot on the skin.
- Start test spots with the lowest setting listed in the table 6.2.1 (A&B) corresponding to the consumers skin type and increase slowly after checking for skin side effects. If there is evidence of darkening, blistering, deep reddening of the skin, or strong pain lower the setting, and re-test.
- Treatment (with the mask removed) may be performed at settings *below* the threshold for adverse skin reactions as determine by test spots.

Table 6.2.1 A. UN-TANNED Skin Spot Test Recommendations: LuxY

Skin Type	Starting settings for test spots In the following order	Maximum setting for test spots	Evaluate Test Spot
I, II, III	c, 1, 2, 3	6	30 min
IV	a, b, c, 1, 2, 3	4	24 to 48 hours
V	Treatment not recommended	Not applicable	
VI	Treatment not recommended	Not applicable	

Table 6.2.1 B. TANNED Skin Spot Test Recommendations: LuxY

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spots	Evaluate Test Spot
I, II, III	a, b, c, 1	b, 2	24 to 48 hours
IV	a	1	24 to 48 hours*
V	Treatment not recommended	Not applicable	
VI	Treatment not recommended	Not applicable	

Note:

The recommended maximum setting for treatment of any tanned consumer is 2.
 *In rare instances darkening of skin can be delayed up to 72 hours after test spots are administered.

Treatment Instructions

Hair Removal:

- Check documentation of test spot treatment parameters.
- Check for recent sun or tanning exposure, and re-administer test spots, if necessary.
- Trim the area to be treated with a hair clipper, if necessary.
- If topical anesthetic is used apply after the hair is clipped, it should be washed off prior to treatment.
- Apply Palomar Lotion to treatment area. Use gauze or the CoolRoller to spread the lotion over the treatment site immediately prior to administering treatment.
- Apply CoolRoller over 2 x 8 inches, 4 x 4 inches or smaller area for 5-10 seconds or use the ice/gel pack for 2-3 min.
- Handpiece can also be cooled with the CoolSpray (see "Instructions for Cooling Handpiece" page 6.1-9).

NOTE: Prolonged application of CoolRoller or cold packs may provide greater comfort but could reduce treatment efficacy due to overcooling. If consumer experiences discomfort, re-apply CoolRoller.

- Regularly clean the lens surface of the handpiece (every 20-30 pulses) using Palomar wipes or other soft moist cloth.
- Follow Chapter 5 for system operation.

NOTE: The system settings depend on skin type, hair color and test spot skin response. It is recommended that the pulses be overlapped (25-30%) to ensure that effective energy is delivered to the treatment site. The risk of injury to the skin from overlapping pulses is minimal. Use the imprint of the treatment window on the skin as a guide in lining up subsequent pulses.

- To assure delivery of the light energy to the proper depth apply light pressure to compress the skin and to force the blood out of the skin during treatment. This improves light transmission and enhances delivery of light to the hair follicles.

NOTE: Skin cooling is necessary to lower the temperature in the epidermis and provide partial anesthesia. For this reason it is imperative that the CoolRoller or ice pack is applied over the treatment site immediately prior to the MediLux treatment.

- Maintenance of firm, constant pressure of the handpiece against the skin is essential to minimizing adverse effects.

Caution: If treatment window becomes warm and causes consumer discomfort, use CoolSpray directly on the window (see instructions) or hold treatment lens against ice or ice pack for 30-60 seconds. When treating dark or tanned skin you may need to cool the treatment window every 5 - 10 shots (See page 6.2-4 for Test Spot Recommendations).

- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. **For this reason, it is not advisable to use the Palomar MediLux™ System for shaping or sculpting precise hair-bearing areas such as the eyebrows, etc.**
- To help better visualize the treatment site and quickly look for areas that may have been missed during treatment, a direct light illumination is helpful.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that Palomar MediLux users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue.

Clinical Endpoints

There are no ideal clinical end points in hair removal with the MediLux System because pre- and post-cooling of skin significantly reduces perifollicular edema and erythema.



Although the likelihood of tissue damage is low, observe for epidermal damage, such as blistering or whitening of the skin. If the fluence is too high or improper technique is used the skin may look wrinkled or whitish/gray in color as if it were touched to a hot surface, similar to what you would see from a curling iron. If this occurs decrease preset power setting fluence and insure firm constant pressure of the handpiece against the skin. If blistering is encountered, the fluence should be decreased until this reaction is no longer present. If blistering occurs at even the lowest pulse width and fluence, that person should be excluded from treatment.

Benign Pigmented Lesions

- Benign pigmented lesions vary in size from a few millimeters to more than 1 cm across.
- The area should be cleansed thoroughly before test spot administration and treatment
- Decide on the treatment approach:
 - *Treat the entire area of skin containing lesions* (**Caution:** Suntan or solar bronzing will be affected by the treatment and may result in lighter patches of skin in the shape of the treatment window), or
 - *Treat the lesions only*
- If the entire area of the skin containing lesions is to be treated be sure the selected fluence does not exceed the recommendations for test spots on page 6.2-4 for surrounding non-pigmented skin
- If the lesions are to be treated individually use the pre punched paper test spot mask provided by Palomar. Moisten gauze with Palomar Lotion and apply to the area, align the opening in the mask with the lesion and bring the treatment window in firm contact with the skin.
- Do not cool the skin during pigmented lesion treatment. If treatment lense becomes warm during extended use, cooling the skin may become necessary.
- For best results button #5 is recommended for dark brown/black lentigines and button #6 for all others.
- Immediately after treatment the lesions may turn darker in color. The area surrounding the lesion may turn red. The lesion may elevate and appear swollen. These are all expected outcomes and resolve in 7-10 days.

Post-Treatment Instructions

Hair Removal:

- Using ice, CoolRoller, cold packs and/or a steroid cream immediately after treatment has been found to minimize erythema and edema, and to provide comfort to the consumer.
- Provide the consumer with both verbal and written instructions including, but not limited to:
- Mild sunburn-like sensation is expected. This usually lasts 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to the treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing and use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas, as well as the use of sun tanning beds and self-tanning creams. Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed within 1-2 weeks of new hair growth.
- Avoid, swimming, hot tubs/Jacuzzis, and excessive exercise do not apply any cosmetics to treated area for 7 days after treatment or until redness resolves.
- If blisters occur, apply antibiotic ointment to the areas 2 times a day until healed.
- Do not pick or remove scabs or crusting; this will help decrease the chance of infection and scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Benign Pigmented Lesions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild sweating and/or redness may accompany this which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed.
- The treated area can be gently cleansed and topical bactericidal ointment may be applied if needed.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 7-14 days.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.

- The lesion is usually healed in 21-30 days. It will continue to fade over the next 6-8 weeks.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
- Avoid sun exposure to treated areas. Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin between treatments and 4-6 weeks after treatment.

Side Effects /Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and **reduce the risk of complications and unwanted side effects.**

Possible side effects or complications that may arise from use of the Palomar MediLux™ System include, but are not limited to:

- 
- **Blisters** may sometimes occur. If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced. Be sure to maintain firm contact with the skin's surface before pulsing the MediLux.
 - **Pigmentary changes** such as lightening or darkening of the skin may occur. In some consumers it may not be visible for 2 – 4 days after treatment. Most skin color changes will resolve within 3-12 months.
 - **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
 - **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment, this usually resolves in 2-72 hours.
 - **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. The blisters are intra-epidermal in nature and usually heal without scarring.

NOTE: These side effects/complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment. These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques.

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin)

lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. During treatment of pigmented lesions in hair bearing areas, there is a likelihood of hair removal in those areas treated. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.3 *LuxR HandPiece*

LuxR handpiece is recommended for hair removal in consumers with skin type I-VI.

Prior to treatment have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples in chapter 6.1)

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes, but is not limited to:

Physical assessment to establish hair color and skin type:

- The light is absorbed in hemoglobin, melanin and other normal chromophores. Therefore it is important to assess the content of the melanin in the normal epidermis determine the consumer's skin type and hair before *any* treatment to insure proper treatment setting selections and to avoid potential thermal damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure in the areas to be treated, this means the consumer wore protective clothing or used a SPF#30 or higher sunscreen for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment. See Chapter 6.3-5 for Test Spot Recommendations.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxR handpiece is safe for use in skin types I-VI. The Skin type worksheet on page 6.1-9 should be used to assist in skin type determination.

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If the consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method using the test spot tables and wait 24 hours before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** -less than 6 weeks prior to treatment for hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring.
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment..
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared.
- **Open lesions** - treatment should only be done on intact, healthy skin.
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It might also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use inside the bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the handpiece, per manual Chapter 2.



Warning:

During hair removal procedure avoid treating over darkly pigmented lesions and tattoos to avoid skin damage and color change.

Every consumer must have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area.

Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

- Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects.
- Treatment parameters for hair removal should be based on **test** spots appropriate to both the treatment site and skin type of the consumer to be treated
- Parameters of treatment should be determined by a trained operator based on the results of the test spots.
- **PhotoEpilation:** A fast and comfortable hair removal treatment method. This treatment method will provide long term to permanent reduction of hair.
- **PhotoWaxing:** A high speed and virtually pain free alternative to waxing. This treatment method will delay new hair growth from one to three months.

Pre-Treatment Instructions

Warning:



- Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Advise the consumer to:

- Discontinue use of sun-tanning bed and self-tanning cream 4 weeks before and throughout the treatment course is recommended. This will reduce the chance of skin color changes.
- Always use a SPF#30 or greater sunscreen on all exposed treatment areas, reapply every 2 hours throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other exfoliating products 2 weeks prior to and for the entire treatment course. Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- Shave or trim excess hair during the course of treatment.

Operator considerations:

- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

LuxR Handpiece Fluence Chart

Button Label	Fluence* (J/cm ²)	Pulse width (ms)
Photo Epilation™ Settings		
1	10	100
2	10	60
3	10	40
4	11	20
5	13	20
6	15	20
Photowaxing™ Settings		
a	7	10
b	8	10
c	9	10

Table 6.3-2 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size.

Performing Test Spots:

- The treatment area should be shaved or closely clipped prior to administering test spots.
- Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots
- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to treatment area using gauze.
- To perform test spots, place a provided pre-punched paper mask on the sapphire lens (treatment window). The use of a mask limits exposing a large area for testing. Be certain that the hole in the mask is where you intend to place the test spot on the skin.
- Start spot tests with the lowest setting listed in the Table 6.3.1 (A & B) corresponding with the consumers skin type and increase slowly after checking for skin side effects. If there is evidence of darkening, blistering, deep reddening of the skin, or strong pain lower the setting, and re-test.
- Treatment (with mask removed) may be performed at settings below the threshold for adverse skin reactions as determine by test spots.

Table 6.3.1 A.

UN-TANNED Skin Test Spot Recommendations for LuxR:

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spot	Evaluate Test Spot
I, II, III	c, 4, 5	6	30 min
IV	c, 1, 2, 3	6	24-48 hrs
V	b, 3, 4	c, 5	24-48 hrs
VI	a, b, 3	c, 4	24-48 hrs*

Table 6.3.1 B.

TANNED (Sun-exposed) Skin Test Spot Recommendations for LuxR:

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spot	Evaluate Test Spot
I, II, III	c, 4, 5	6	24-48 hrs
IV	c,1,2,3	6	24-48 hrs*
V	b, 3, 4	c, 5	24-48 hrs
VI	3, a, b, c	4	24-48 hrs*

Note:

The recommended maximum setting for treatment of any tanned consumer is 6.
 *In rare instances darkening of skin can be delayed up to 72 hours after test spots are administered.

Treatment Instructions Hair Removal:

- Check documentation of test spot treatment parameters.
- Check for recent sun or tanning exposure, re-administer test spots if necessary.
- Trim the area to be treated with a hair clipper, if necessary.
- If topical anesthetic is used apply after the hair is clipped, it should be washed off prior to treatment.
- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to treatment area. Use the CoolRoller or gauzes to spread the lotion over the treatment site.
- Apply CoolRoller over 2 x 8 inches, 4 x 4 inches or smaller area for 5-10 seconds or use the ice/gel pack for 2-3 min.
- Handpiece can also be cooled with the Palomar CoolSpray™ (see "Instructions for Cooling Handpiece" page 6.1-9).

NOTE: Prolonged application of CoolRoller or cold packs may provide greater comfort but could reduce treatment efficacy due to overcooling. If consumer experiences discomfort, re-apply CoolRoller and re-cool the handpiece.

- Regularly clean the lens surface of the handpiece (every 20-30 pulses) using Palomar wipes or other soft moist cloth.
- Follow Chapter 5 for system operation.

NOTE: The system settings depend on skin type, hair color and test spot skin response. It is recommended that the pulses be overlapped (25-30%) to ensure that effective energy is delivered to the treatment site. The risk of injury to the skin from overlapping pulses is minimal. Use the imprint of the treatment window on the skin as a guide in lining up subsequent pulses.

- To assure delivery of the light energy to the proper depth apply light pressure to compress skin and to force the blood out of the skin during treatment. This improves light transmission and enhances delivery of light to the hair follicles.

NOTE: Skin cooling is necessary to lower the temperature in the epidermis and provide partial anesthesia. For this reason, it is imperative that the ice, CoolRoller or ice pack is applied over the treatment site immediately prior to the MediLux treatment.

- Maintenance of firm, constant pressure of the handpiece against the skin is essential to minimizing adverse effects.

Caution: If treatment window becomes warm and causes consumer discomfort, use Palomar CoolSpray™ cryogen spray directly on the window (see instructions) or hold it against ice or ice pack for 30 - 60 seconds.. When treating dark or tanned skin you may need to cool the treatment window every 5 - 10 shots.

- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. **For this reason, it is not advisable to use the Palomar MediLux™ System for shaping or sculpting precise hair-bearing areas such as the eyebrows, etc.**
- To help better visualize the treatment site and quickly look for areas that may have been missed during treatment, a direct light illumination is helpful.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that Palomar MediLux users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue.

Clinical Endpoints

There are no ideal clinical end point in hair removal with the MediLux System because pre- and post-cooling of skin significantly reduces perifollicular edema and erythema.



Although the likelihood of tissue damage is low, observe for epidermal damage, such as blistering or whitening of the skin. If the fluence is too high or improper technique is used the skin may look wrinkled or gray in color as if it were touched to a hot surface, similar to what you would see from a curling iron. If this occurs decrease preset power setting fluence and insure firm, constant pressure of the handpiece against the skin. If blistering is encountered, the fluence should be decreased until this reaction is no longer present. If blistering occurs at even the lowest pulse width and fluence, that person should be excluded from treatment.

Post-Treatment Instructions Hair Removal

- Using ice, CoolRoller, cold packs and/or a steroid cream immediately after treatment has been found to minimize erythema and edema, and to provide comfort to the consumer.
- Provide the consumer with both verbal and written instructions including, but not limited to:
- Mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing and use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas, as well as the use of sun tanning beds and self-tanning creams. Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed 1-2 weeks of new hair growth.
- Avoid shaving, waxing, swimming, hot tub/jacuzzi, and excessive exercise do not apply any cosmetics to treated are for 7 days after treatment or until redness resolves.
- If blisters occur, apply antibiotic ointment to the area 2 times a day until healed.
- Do not pick or remove scabs or crusting, this will help decrease the chance of infection or scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Side Effects /Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and **reduce the risk of complications and unwanted side effects.**

Possible side effects or complications that may arise from use of the Palomar MediLux™ System may include, but are not limited to:



Blisters may sometimes occur. If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced. Be sure to maintain firm contact with the skin's surface before pulsing the MediLux.

- **Pigmentary changes**, such as lightening or darkening of the skin , may occur. In some consumers it may not be visible for 2 – 4 days after treatment. Most color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatmentthis usually resolves in few hours or a couple of days.
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. They are intra-epidermal in nature and usually heal without scarring.

NOTE: These side effects/complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment. These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas.

Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.4 LuxG Hand-Piece

LuxG hand-piece is recommended for treatment of benign pigmented lesions and vascular lesions (e.g., telangiectasia, rosacea, port-wine stain, hemangioma, etc.) in consumers with skin type I-IV only.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions (See samples in chapter 6.1).



It is required to use Palomar Spray™ when treating with the LuxG hand-piece.

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment.

Physical assessment to establish skin type and nature of pigmented lesion:

- The light is absorbed in hemoglobin, melanin and other chromophores. Therefore it is important to assess the content of the melanin in the normal epidermis determine the consumer's skin type and in the benign pigmented lesion to insure proper treatment setting selections and to avoid unnecessary damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that is the consumer wore protective clothing or used a SPF-30 or greater sunscreen in the areas to be treated for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxG hand-piece is safe for use in skin types I-IV. The Skin type worksheet on page 6.1-9 should be used to assist in skin type determination.



Prior to initiation of any treatment, the pigmented lesions in question should be correctly identified by a physician to be benign and be recommended for laser or lamp-based device treatment.

It is very important to have an accurate diagnosis of the brown spots considered for treatment prior to actual treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to the delay in the consumer receiving proper medical care.

- **The mechanism of removal of benign pigmented lesions by the MediLux System is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which usually resolves within a 2 to 4 week period.**
- The mechanism of removal of facial vascular lesions by the MediLux System is based on selective coagulation of abnormal vessels. Use of any topical anesthetic cream is not recommended for treatment of vascular lesions because it may cause vasoconstriction (blanching of blood vessels) and minimize effectiveness of treatment.

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If the consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method by performing test spots before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared.
- **Open lesions** - treatment should only be done on intact, healthy skin.
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only.
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the hand-piece, per manual Chapter 2.

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or tanning delay follow-up treatment for a few weeks.

During treatments the LuxG handpiece will likely remove hair. Consumers should be cautioned of the possibility of coincidental hair loss when treating pigmented or vascular lesions in hair bearing areas.

Pre-Treatment Instructions

Warning:



Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Inform the consumer to:

- Discontinue sun tanning, use of sun-tanning beds and self-tanning cream 4 weeks before and throughout the treatment course is recommended. This will reduce the chance of skin color changes and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas, liberally re-apply throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to treatment.

Operator considerations:

- The area should be cleansed thoroughly before test spot administration and treatment
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Topical anesthetics are not recommended for treatment of vascular lesions because of potential vasoconstriction that renders treatment less effective.
- Test spots should be performed immediately prior to treatment.

LuxG Handpiece Fluence Chart

Button Label	Fluence* (J/cm ²)	Pulse width (ms)
Settings		
1	19	100
2	20	60
3	20	40
4	21	20
5	26	20
6	33	20
a	11	10
b	14	10
c	16	10

Table 6.4-1 Button Settings

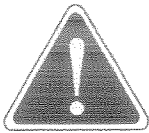
*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size range.

Performing Test Spots:

Benign Pigmented Lesions:

Treatment of benign pigmented lesions cannot be accomplished without producing some epidermal damage. Accordingly, test spots must be administered near the treatment site using buttons #4, 5 or 6, starting with button #4. The desired result (clinical end point) from the test spot and treatment should be the darkening of the pigmented lesion with minimal or no reaction in the normal skin. It is recommended to wait 30-45 minutes after administering test spots before assessing the epidermal response and effectiveness of the setting.

- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the test area using gauze.
- Pre-cool hand-piece according to the *"Instructions for Cooling Hand-Piece with the Palomar CoolSpray™"* (Chapter 6.1-10).
- Administer test spots beginning with lowest fluence and move up. If at any point immediate, severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #3 this consumer should be excluded from testing and treatment.



Vascular Lesions:

Treatment of vascular lesions cannot be accomplished without producing some epidermal damage. Accordingly, test spots using buttons # 4, 5, and 6 must be administered near the treatment site. The desired result (clinical end point) from the test spots should be the visible closure of the vessel with minimal reaction in the normal skin. In treating vascular lesions one must exercise special care not to apply pressure to the treatment site for fear of blanching vessels. Topical anesthetic cream for the treatment of vascular lesions is not recommended because it tends to blanch the vessels.

- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the area using gauze pads
- Pre-cool hand-piece according with the *"Instructions for Cooling Hand-Piece with the Palomar CoolSpray™"* (Chapter 6.1-10)
- Test spots are performed primarily to evaluate the effectiveness of selected setting in treating vascular condition. The desired result (end point) from the test spot treatment should be the visible closure of vessel.
- Administer test spots beginning with lower fluence and move up. If at any point immediate, severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #4 this consumer should be excluded for testing and treatment.



It is recommended to wait 15-20 minutes after administering test spot before assessing the epidermal response and effectiveness of setting.

Treatment Instructions

Treatment of benign pigmented lesions and vascular lesions cannot be accomplished without producing some epidermal damage. Best results in treating pigmented lesions are achieved with buttons #4,5,6 and vascular pathology with buttons 5, 6. Check and follow documentation of the test spot parameters.

- To minimize epidermal damage and consumer discomfort the hand-piece must be pre-cooled with cryogen spray prior to performing treatment (see Chapter 6.1-9 for *Instructions for Use of Palomar CoolSpray™*).
- The margin of safety is significantly reduced when treating with the hand-piece at room temperature.

Note: Treatment window must be clean and free from debris and lotion for effective cooling with cryogen spray.

Benign Pigmented Lesions:

Treatment of benign pigmented lesions cannot be accomplished without producing some epidermal damage. Accordingly, treat at the lowest setting based on the test spots. The desired result (clinical end point) from treatment should be the darkening of the pigmented lesion with minimal or no reaction in the normal skin.

Lesions may vary in size from a few millimeters to more than 1 cm across.

- 
- Decide on the treatment approach whether to:
 - Treat the entire area of skin containing the lesions **Caution:** suntan or solar bronzing will also be affected by the treatment and may result in lighter patches of skin in the shape of the treatment window.
 - or Treat the lesions only
 - If the entire area of the skin containing the lesions is going to be treated make sure the selected fluence is safe for surrounding non-pigmented skin.
 - If the lesions will be treated individually use the Palomar supplied test spot masks. You may need to modify the opening to slightly larger than the size of the lesion and apply it to the treatment window
 - The area should be cleansed thoroughly before treatment
 - Apply Palomar Lotion to the test area using CoolRoller or gauze pads.
 - Pre-cool hand-piece according to the *Instructions for Cooling Hand-Piece with Spray* Chapter 6.1-9
 - Check documentation of the test spot parameters. If at any point immediate severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue treatment because the fluence is too high for this particular skin type and dermatological condition.
 - Bring treatment window in contact with the skin applying gentle pressure and begin treatment.
 - Immediately after the treatment, there is a slight darkening of some lesions and melasma. In other cases (with lighter lesions), there may be no immediate reaction.
 - Within 2-3 minutes, usually there is mild to moderate redness around the lesions, suggesting a selective effect on focal areas of darker skin.
 - Some cases and/or conditions may require multiple treatments.

Vascular Lesions:

Treatment of vascular lesions cannot be accomplished without producing some epidermal damage. Accordingly, treat at the lowest setting based on the test spots. The desired result (clinical end point) from the treatment should be the visible closure of the vessel with minimal reaction in the normal skin. In treating vascular lesions exercise special care not to apply pressure to the treatment site for fear of blanching vessels. Topical anesthetic cream for the treatment of vascular lesions is not recommended because it tends to blanch the vessels. Treatment of vessels typically requires high fluences. Most frequently treatment will be performed at highest settings: buttons # 5 & 6.

- The area should be cleansed thoroughly before treatment
- Apply Palomar Lotion to the area using CoolRoller or gauze pads.
- Pre-cool hand-piece according with the *“Instructions for Use of Palomar CoolSpray™”* (Chapter 6.1-9).
- Bring treatment window in contact with the skin without applying any pressure and begin treatment.
- Vessels undergo immediate graying or blanching. In some cases, only a slight purplish change is noted. Vessels either fully or partially resolve in about 10–14 days; areas of diffuse flushing gradually fade leaving skin with normal appearance.
- Some cases and/or conditions may require multiple treatments.
- If at any point immediate severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #4 this consumer should be excluded from treatment.



Post-Treatment Instructions

Benign Pigmented Lesions

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed, to reduce discomfort and heat sensation.
- The treated area can be gently cleansed and topical bactericidal ointment can be applied if needed.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 14-21 days.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- The lesion is usually healed in 21-30 days. It will continue to fade over the next 6-8 weeks.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
- Avoid sun exposure to treated areas. Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin between treatments and 4-6 weeks after treatment.

Vascular Lesions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed, to reduce discomfort and heat sensation.
- The treated area can be gently cleansed and topical bactericidal ointment can be applied if needed.
- The vessels undergo immediate graying or blanching. In some cases, only a slight purplish change is noted. Vessels either fully or partially resolve in about 10-14 days areas of diffuse flushing gradually fade leaving skin with normal appearance.
- Repeat treatments may be performed every 7-10 days if skin has fully recovered.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
- Avoid sun exposure to treated areas.
- Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin.

Side Effects/Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and reduce the risk of complications and unwanted side effects.

Possible side effects or complications that may arise from use of the Palomar MediLux™ System may include, but are not limited to:



- **Blisters may sometimes occur.** If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced.
- **Pigmentary changes**, such as lightening or darkening of the skin may occur. In some consumers it may not be visible for 2 – 4 days after treatment and most color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment. This resolves in few hours or a couple of days.
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. They are intra-epidermal in nature, usually heal without scarring.
- **NOTE: These complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment. These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques.**

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. During treatment of pigmented lesions in hair bearing areas, there is a likelihood of hair removal in those areas treated. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.5 LuxRs HandPiece

LuxRs handpiece is recommended for hair removal and permanent hair reduction in consumers with skin type I-VI. For consumers with skin types V-VI, it is recommended that settings are limited to buttons 1,2,3 (and 4 with caution). The Lux Rs handpiece is designed to make hair removal from smaller body areas such as: axilla, face, bikini, etc. especially convenient and easier to operate.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples in Chapter 6.1)



It is required to use Palomar *CoolSpray™* when performing treatment with the LuxRs handpiece.

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes but is not limited to:

Physical assessment to establish hair color and skin type:

- The light is absorbed in hemoglobin, melanin and normal chromophores. Therefore it is important to assess the content of the melanin in the epidermis determine the consumer's skin type and hair before *any* treatment to insure proper treatment setting selections and to avoid potential thermal damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that is the consumer wore protective clothing or used a SPF-30 or higher sunscreen in the areas to be treated for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment. See Chapter 6.5-5 Test Spot Recommendations.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxRs handpiece is safe for use in skin types I-VI. The Skin type worksheet on page 6.1-9 should be used to assist in skin type determination

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

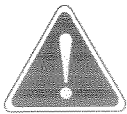
Relative consumer exclusion criteria to light therapy include but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If the consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method using the test spot tables and wait 24 hours before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** -less than 6 weeks prior to treatment for hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring.
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment.
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared.
- **Open lesions** - treatment should only be done on intact, healthy skin
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and for the entire course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the handpiece, per manual Chapter 2.



Warning:

During hair removal procedure avoid treating over darkly pigmented lesions and tattoos to avoid skin damage and color change.

Every consumer should have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area.

Do not use any cooling (CoolRoller, CoolSpray ice, gel packs, etc.) or topical anesthetics when performing test spots.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects.

Treatment parameters should be based on test spots appropriate to both the treatment site and skin type of the consumer to be treated.

Parameters of treatment should be determined by a trained operator based on the results of the test spots.

Pre-Treatment Instructions

Warning:



- Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Advise the consumer to:

- Discontinue use of sun-tanning bed and self-tanning cream 4 weeks before and throughout the treatment course is recommended. This will reduce the chance of skin color changes.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas, liberally reapply throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to treatment and during the entire treatment course.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- Shave or trim excess hair during the course of treatment.

Operator Considerations:

- The area should be cleansed thoroughly before test spot administration and treatment
- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

LuxRs Handpiece Fluence Chart

Button Label	Fluence (J/cm ²)	Pulse width (ms)
1	17	100
2	17	60
3	17	40
4	19	20
5	25	20
6	30	20
a	10	10
b	14	10
c	16	10

Table 6.5-2 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size range.

Performing Test Spots:

- Do not use any cooling (CoolRoller, CoolSpray, ice, gel packs, etc.) or topical anesthetics when performing test spots.
- The treatment area should be shaved or closely clipped prior to administering test spots.
- The area should be cleansed thoroughly before test spot administration and treatment
- The area should be free of makeup, ointment or hair clippings prior to treatment.
- Apply Palomar Lotion to treatment area using gauze.
- To perform test spots, place a provided pre-punched paper mask on the sapphire lens (treatment window) directly on the treatment window. The use of a mask limits exposing a large area for testing. Be certain that the hole in the mask is where you intend to place the test spot on the skin.
- Start spot tests with the lowest setting listed in the Table 6.5.1 (A&B) corresponding to the consumers skin type and increase slowly after checking for skin side effects. If there is evidence of darkening, blistering, deep reddening of the skin, or strong pain reduce the setting, and re-test.
- Treatment (with mask removed) may be performed at settings below the threshold for adverse skin reactions as determine by test spots.

Table 6.5.1 A. UN-TANNED Skin Test Spot Recommendations for LuxRs:

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spot	Evaluate Test Spot
I, II, III	a, 4, b, 5, c	6	30 min
IV	3, a, 4, b	c, 5	24-48 hrs
V	1, 2, 3, a	b, 4	24-48 hrs
VI	1, 2, 3, a	b, 4	24-48 hrs*

Table 6.5.1 B.

TANNED (Sun-exposed) Skin Test Spot Recommendations for LuxRs:

Skin Type	Starting settings for test spots in the following order	Maximum setting for test spot	Evaluate Test Spot
I, II, III	a, 4, b, 5, c	6	24-48 hrs
IV	a, 4, b	5	24-48 hrs*
V	1, 2, 3, a	b, 4	24-48 hrs
VI	1, 2, 3	a, 4	24-48 hrs*

Note:

The recommended maximum setting for treatment of any tanned consumer is 6.

*In rare instances darkening of skin can be delayed up to 72 hours after test spots are administered.

Treatment Instructions Hair Removal

- To minimize epidermal damage and consumer discomfort the handpiece must be pre-cooled with cryogen spray prior to performing test spots or treatment (see Chapter 6.1-9 for *Instructions for Use of Palomar CoolSpray™*).
- The handpiece is equipped with a temperature sensor that is located on both sides of the distal end near the treatment window. At a temperature above 20° C the sensors display a "bull's eye" GREEN dot with a GREEN concentric ring (Fig. 6.1-6). When temperature of the crystal in the handpiece drops below 20° C the sensor turns SOLID GREEN (Fig. 6.1-7). When sensor displays the "bull's eye" – it is time to re-cool the handpiece.
- It takes about 20 of 1-second sprays of CoolSpray to lower the LuxRs treatment window to 20° C. It lasts for 20-30 consecutive shots before the handpiece needs re-cooling.
- If there is a significant delay between shots (2-3 min) check color of the sensor and, if necessary, re-cool before resuming treatment.
- The margin of safety is significantly reduced when treating with a handpiece that is at room temperature.
- Check documentation of test spot treatment parameters.
- Check for recent sun or tanning exposure.
- Trim the area to be treated with a hair clipper, if necessary.
- If topical anesthetic is used apply after the hair is clipped, it should be washed off prior to treatment.
- Apply Palomar Lotion to treatment area using CoolRoller or gauze pads to spread the lotion over the treatment area immediately prior to administering treatment.
- Apply CoolSpray chilled treatment window to the skin
- When treating darker skin types and/or using higher fluence settings it is necessary to cool the treatment window more frequently, about every 10-20 shots with Palomar CoolSpray (see "Instruction for Cooling HandPiece" in the section 6.1 of this Chapter)

NOTE: Prolonged application of CoolRoller or cold packs may provide greater comfort but could reduce treatment efficacy due to overcooling. If consumer experiences discomfort, re-cool the treatment window with CoolSpray and apply CoolRoller to skin for additional cooling.

- Regularly clean the lens surface of the handpiece every 2-30 pulses using laser wipes or other soft moist cloth
- Follow Chapter 5 for system operation

NOTE: The system settings depend on skin type, hair color and test spot skin response. It is recommended that the pulses be overlapped (25-30%) to ensure that effective energy is delivered to the treatment site. The risk of injury to the skin from overlapping pulses is minimal. Use the imprint of the treatment window on the skin as a guide in lining up subsequent pulses.

- To assure delivery of the light energy to the proper depth apply light pressure to compress skin and to force the blood out of the skin during treatment. This improves light transmission and enhances delivery of light to the hair follicles.

NOTE: Skin cooling is necessary to lower the temperature in the epidermis and provide partial anesthesia. For this reason, it is imperative that the treatment window is chilled with CoolSpray immediately prior to the MediLux treatment.

- Maintenance of firm, constant pressure of the handpiece against the skin is essential to minimizing adverse effects.
- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. **For this reason, it is not advisable to use the Palomar MediLux™ System for shaping or sculpting precise hair-bearing areas such as the eyebrows, etc.**
- To help better visualize the treatment site and quickly look for areas that may have been missed during treatment, a direct light illumination is helpful.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that Palomar MediLux™ users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue.

Clinical Endpoints

There are no ideal clinical end points in hair removal with the MediLux System because pre- and post-cooling of skin significantly reduces perifollicular edema and erythema.



Although the likelihood of tissue damage is low, observe for epidermal damage, such as blistering, or whitening of the skin, if the fluence is too high the skin may look wrinkled or whitish/gray in color as if it were touched to a hot surface, similar to what you would see from a curling iron. If this occurs decrease preset power setting fluence. If blistering is encountered, the fluence should be decreased until this reaction is no longer present. If blistering occurs at even the lowest pulse width and fluence, that person should be excluded from treatment.

Post-Treatment Instructions Hair Removal

- Using ice, CoolRoller, cold packs and/or a steroid cream immediately after treatment has been found to minimize erythema and edema, and to provide comfort to the consumer.
- Provide the consumer with both verbal and written instructions including, but not limited to:
- Mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing and use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas. Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed 2-12 week intervals or within 1-2 weeks of new hair growth.
- Avoid shaving, waxing, swimming, hot tub/Jacuzzi, do not apply any cosmetics to the treated area, and excessive exercise for 7 days after treatment or until redness resolves.
- If blistering occurs, apply antibiotic ointment to the area 2 times a day until healed.
- Do not pick or remove scabs or crusting, this will help decrease the chance of infection or scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Side Effects/Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and **reduce the risk of complications and unwanted side effects.**

Possible side effects or complications that may arise from use of the Palomar MediLux™ System may include, but are not limited to:



- **Blisters may sometimes occur.** If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced. Be sure to maintain firm contact with the skin's surface before pulsing the MediLux.
- **Pigmentary changes**, such as lightening or darkening of the skin, may occur. In some consumers it may not be visible for 2 – 4 days after treatment. Most color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment. This resolves in few hours to a couple of days.
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment, but since they are intra-epidermal in nature, usually heal without scarring.

NOTE: These complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment.

These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques.

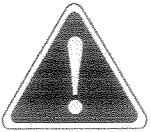
Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.6 LuxB HandPiece

LuxB handpiece is recommended for treatment of benign pigmented lesions and vascular lesions (e.g., telangiectasia, rosacea, port-wine stain, hemangioma, spider veins etc.) in consumers with skin type I-III only.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples in Chapter 6.1)



It is required to use Palomar cryogen *CoolSpray™* when treating with the LuxB handpiece.

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes, but is not limited to:

Physical assessment to establish skin type and nature of pigmented lesion:

- The light is absorbed in hemoglobin, melanin and other normal chromophores. Therefore it is important to assess the content of the melanin in the normal epidermis determine the consumer's skin type and in the benign pigmented lesion to insure proper treatment setting selections and to avoid unnecessary damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that is the consumer wore protective clothing or used a SPF-30 or greater sunscreen in the areas to be treated for the past 4 weeks. Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxB handpiece is safe for use in skin types I-IV. The Skin type worksheet on page 6.1-9 should be used to assist in skin type determination.

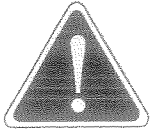


Prior to initiation of any treatment, the pigmented lesions in question must be correctly identified by a physician to be benign and be recommended for laser or lamp-based device treatment

It is very important to have an accurate diagnosis of the brown spots considered for treatment prior to actual treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to the delay in the consumer receiving proper medical care.

- **The mechanism of removal of benign pigmented lesions by the MediLux System is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which usually resolves within a one-to-two-week period.**
- The mechanism of removal of vascular lesions by the MediLux System is based on selective coagulation of abnormal vessels. Use of topical anesthetic cream is not recommended for treatment of vascular lesions because it may cause vasoconstriction (blanching of blood vessels) and minimize effectiveness of treatment.

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If the consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method by performing test spots before treating and waiting 24 hours before treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared.
- **Open lesions** - treatment should only be done on intact, healthy skin.
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated it is however known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only.
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the handpiece, per manual Chapter 2.

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or tanning delay follow-up treatment for a few weeks.

During treatments the LuxB handpiece will likely remove hair. Consumers should be cautioned of the possibility of coincidental hair loss when treating pigmented or vascular lesions in hair bearing areas.



Every consumer must have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

- Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects
- Treatment parameters should be based on test spots appropriate both the treatment site and skin type of the consumer to be treated
- Parameters of treatment should be determined by a trained operator based on the results of the test spots

Pre-Treatment Instructions

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!



Advise the consumer to:

- Discontinue sun tanning, use of sun-tanning beds and self-tanning cream 4 weeks before and throughout the treatment course is recommended. This will reduce the chance of skin color changes and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas; liberally re-apply throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to treatment.

Operator considerations:

- Shave or clip the treatment area if necessary prior to treatment.
- The area should be cleansed thoroughly before test spot administration and treatment
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Topical anesthetics are not recommended for treatment of vascular lesions because of potential vasoconstriction that renders treatment less effective.
- Test spots should be performed immediately prior to treatment.

LuxB Handpiece Fluence Chart

Button Label	Fluence* (J/cm ²)	Pulse width (ms)
Settings		
1	27	100
2	27	60
3	30	40
4	32	20
5	37	20
6	45	20
a	19	10
b	22	10
c	24	10

Table 6.6-1 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size range.

Performing Test Spots:

Benign Pigmented Lesions:

Treatment of benign pigmented lesions cannot be accomplished without producing some epidermal damage. Accordingly, test spots must be administered near the treatment site using buttons #4, 5 or 6, starting with button #4. The desired result (clinical end point) from the test spot and treatment should be the darkening of the pigmented lesion with minimal or no reaction in the normal skin. It is recommended to wait 30-45 minutes after administering test spots before assessing the epidermal response and effectiveness of the setting.

- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the test area using gauze.
- Pre-cool handpiece according to the *“Instructions for Cooling HandPiece with the Palomar cryogen CoolSpray™”* (Chapter 6.1-9).
- Administer test spots beginning with lowest fluence and move up. If at any point immediate, severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #4 this consumer should be excluded from testing and treatment.



Vascular Lesions:

Treatment of vascular lesions cannot be accomplished without producing some epidermal damage. Accordingly, test spots using buttons #5 and 6 must be administered near the treatment site. The desired result (clinical end point) from the test spots should be the closure of the visible vessel with minimal reaction in the normal skin. In treating vascular lesions one must exercise special care not to apply pressure to the treatment site for fear of blanching vessels. Topical anesthetic cream for the treatment of vascular lesions is not recommended because it tends to blanch the vessels.

- Shave or clip the treatment area if necessary prior to administering test spots.
- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the area.
- Pre-cool handpiece according with the *“Instructions for Cooling HandPiece with the Palomar cryogen CoolSpray™”* (Chapter 6.1-9)
- Test spots are performed primarily to evaluate the effectiveness of selected setting in treating vascular condition. The desired result (end point) from the test spot treatment should be the visible closure or distinct color change of vessel.
- Administer test spots beginning with lower fluence and move up. If at any point immediate, severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #5 this consumer should be excluded for testing and treatment.

It is recommended to wait 15-20 minutes after administering test spot before assessing the epidermal response and effectiveness of setting.



Treatment Recommendations (Benign pigmented and vascular lesions)

Treatment of benign pigmented lesions and vascular lesions cannot be accomplished without producing some epidermal damage. Best results in treating pigmented lesions are achieved with buttons 4-6 and vascular pathology with buttons 5-6. Test spots must be administered near the treatment site. The desired result (end point) from the test spot treatment should be the darkening of the pigmented lesion or visible closure or distinct color change of the vessel with minimal reaction in the normal skin. It is recommended to wait 15-45 minutes after administering test spots before assessing the epidermal response and effectiveness of the setting.

- To minimize epidermal damage and consumer discomfort the handpiece must be pre-cooled with cryogen spray prior to performing test spots or treatment (see Chapter 6.1-9 for ***Instructions for Use of Palomar cryogen CoolSpray™***).
- The handpiece is equipped with a temperature sensor that is located on both sides of the distal end near the treatment window. At room temperature the sensor displays a GREEN dot with a GREEN concentric ring (Fig. 6.1-6). When temperature of the crystal in the handpiece drops below 5° C the sensor turns SOLID GREEN (Fig. 6.1-7).
- It takes about 10 of 1-second sprays of cryogen to lower the LuxB treatment window to 5° C. It lasts for 5-7 consecutive shots before the handpiece needs re-cooling.
- If there is a significant delay between shots (2-3 min) check color of the sensor and, if necessary, re-cool before resuming treatment.
- The margin of safety is significantly reduced when treating with the handpiece at room temperature.

Note: Treatment window must be clean and free from debris and lotion for effective cooling with cryogen spray.

Benign Pigmented Lesions:

Treatment of benign pigmented lesions cannot be accomplished without producing some epidermal damage. Accordingly, treat at the lowest setting based on the test spots. The desired result (clinical end point) from treatment should be the darkening of the pigmented lesion with minimal or no reaction in the normal skin. It is recommended to wait 30-45 minutes after administering test spots before assessing the epidermal response and effectiveness of setting.

- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar LOTION to the test area.
- Pre-cool handpiece according to the ***“Instructions for Cooling HandPiece with CoolSpray”*** (Chapter 6.1-10).
- Administer test spots beginning with the lowest fluence and move up. If at any point immediate severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition.

It is recommended to wait 30-45 minutes after administering test spot before assessing the epidermal response and effectiveness of setting.

- Lesions may vary in size from a few millimeters to more than 1 cm across.



- Decide on the treatment approach whether to:
 - *Treat the entire area of skin containing the lesions* (**Caution:** suntan or solar bronzing will also be affected by the treatment and may result in lighter patches of skin in the shape of the treatment window.
 - *or Treat the lesions only*
- If the entire area of the skin containing the lesions is going to be treated make sure the selected fluence is safe for surrounding non-pigmented skin.
- If the lesions are to be treated individually use the Palomar test spot mask and apply directly over the lesion being sure the lesion is visible through the mask hole. Apply Palomar Lotion to the area, align the opening in the mask with the lesion and bring the treatment window in firm contact with the skin. For best results button #4 is recommended for dark brown/black lentigines and button #5 for all others.
- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the area using CoolRoller or gauze pads.
- Pre-cool handpiece according with the *“Instructions for Cooling HandPiece with CoolSpray”* (Chapter 6.1-10)
- Bring treatment window in contact with the skin applying gentle pressure and begin treatment.
- Immediately after the treatment, there is a slight darkening of some lesions and melasma. In other cases (with lighter lesions), there may be no immediate reaction at all. The area surrounding the lesion may turn red. The lesion may elevate and appear swollen. These are all expected outcomes and resolve in 14-21 days.
- Within 2-3 minutes, usually there is mild to moderate redness around the lesions, suggesting a selective effect on focal areas of darker skin.
- Some cases and/or conditions may require multiple treatments.

Vascular Lesions:

Treatment of vascular lesions cannot be accomplished without producing some epidermal damage. Accordingly, treat at the lowest setting based on the test spots. The desired result (clinical end point) from the treatment should be the visible closure of the vessel with minimal reaction in the normal skin. In treating vascular lesions exercise special care not to apply pressure to the treatment site for fear of branching vessels. Topical anesthetic cream is not recommended as for the treatment of vascular lesions because it tends to branch the vessels. Treatment of vessels typically requires high fluences. Most frequently treatment will be performed at highest settings: buttons # 5 & 6.

- The area should be cleansed thoroughly before test spot administration and treatment
- Apply Palomar Lotion to the area using CoolRoller or gauze pads.
- Pre-cool handpiece according with the *“Instructions for Use of Palomar cryogen CoolSpray™”* (Chapter 6.1-10).
- Test spots are performed primarily to evaluate the effectiveness of selected setting in treating vascular condition. The desired result (end point) from the test spot treatment should be the visible closure or distinct color change of vessel.

- It is recommended to wait 15-20 minutes after administering test spot before assessing the epidermal response and effectiveness of setting.
- Pre-cool handpiece according with the “*Instructions for Use of Palomar cryogen CoolSpray™*” (Chapter 6.1-10).
- Bring treatment window in contact with the skin without applying any pressure and begin treatment.
- Vessels undergo immediate graying or blanching. In some cases, only a slight purplish change is noted. Vessels either fully or partially resolve in about 10–14 days; areas of diffuse flushing gradually fade leaving skin with normal appearance.
- Some cases and/or conditions may require multiple treatments.
- If at any point immediate severe skin reaction is observed – blistering, graying, ablation, etc., – discontinue testing because the fluence is too high for this particular skin type and dermatological condition. If this occurs at button #5 this consumer should be excluded from treatment.



Post-Treatment Instructions

Benign Pigmented Lesions

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur.
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed.
- The treated area can be gently cleansed and topical bactericidal ointment may be applied if needed.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 14-21 days.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- The lesion is usually healed in 21-30 days. It will continue to fade over the next 6-8 weeks.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
 - Activities that cause excessive perspiration
- Avoid sun exposure to treated areas. Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin between treatments and 4-6 weeks after treatment.

Vascular Lesions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this, which usually resolves in 2-3 days. In some cases, prolonged redness, blistering or crusting may occur.
- Apply cool/ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed.
- The treated area can be gently cleansed and topical bactericidal ointment may be applied if needed.
- The vessels undergo immediate graying or blanching. In some cases, only a slight purplish change is noted. Vessels either fully or partially resolve in about 10-14 days. Areas of diffuse flushing gradually fade leaving skin with normal appearance.
- Repeat treatments may be performed every 7-10 days if skin condition warrants.
- Do not pick, scratch or removes scabs. This will prevent unwanted side effects.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas
 - Swimming, especially in pools with chemical/chlorine
 - Hot tubs and Jacuzzis
- Activities that cause excessive perspiration
- Avoid sun exposure to treated areas.
- Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin.

Side Effects/Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and **reduce the risk of complications and unwanted side effects.**

Possible side effects or complications that may arise from use of the Palomar MediLux™ System may include, but are not limited to:



- **Blisters may sometimes occur.** If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment if needed until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced.
- **Pigmentary changes**, such as lightening or darkening of the skin may occur. In some consumers it may not be visible for 2 – 4 days after treatment and most color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment. This resolves in few hours or a couple of days.
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. They are intra-epidermal in nature, usually heal without scarring.
- **NOTE: These complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment.**
These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques.

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. During treatment of pigmented lesions in hair bearing areas, there is a likelihood of hair removal in those areas treated. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 6.7 - LuxV Hand-Piece

LuxV hand-piece is recommended for treatment of benign pigmented lesions and hair removal in consumers with skin type I-III.

Prior to treatment you must have the consumer read and sign the Informed Consent Form, exclusion criteria and pre and post treatment instructions. (See samples Chapter 6.1)

It is required to use Palomar cryogen *CoolSpray™* when performing treatment with the LuxV hand-piece.

CoolRoller, Palomar Lotion and CoolSpray must be used when treating with buttons a,b,c, 4,5,6.

Consumer Selection

The practitioner must carefully screen all potential candidates for treatment. Screening includes, but is not limited to:

Physical assessment to establish hair color and skin type:

- The light is absorbed in hemoglobin, melanin and other normal chromophores. Therefore it is important to assess the content of the melanin in the epidermis determine the consumer's skin type and hair before **any** treatment to ensure proper treatment setting selections and to avoid potential thermal damage of the epidermis.
- Verify the consumer has had no unprotected sun exposure, that the consumer wore protective clothing or used a SPF-30 or higher sunscreen in the areas to be treated for the past 4 weeks . Suntan constitutes increased concentration of melanin in the skin and will get lighter from the treatment. See page 6.7-5 for Test Spot Recommendations.
- The Fitzpatrick Scale for skin typing or a modified Fitzpatrick Scale is most often used for skin type classification. The MediLux System with the LuxV hand-piece is safe for use in skin types I-III. The Skin type worksheet page 6.1-9 Chapter 6 should be used to assist in skin type determination.



Prior to initiation of treatment all pigmented lesions must be correctly identified by a physician to be benign and be recommended for laser or lamp-based device treatment.

It is very important to have an accurate diagnosis of the brown spots considered for treatment prior to actual treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the consumer receiving proper medical care.

- **The mechanism of pigmented lesion removal by the MediLux System is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which usually resolves within a one-to-two-week period.**

Medical History



After a consumer has met necessary criteria for treatment a pertinent medical history should be obtained to satisfy any exclusion criteria.

Consumer exclusion criteria to light therapy includes but is not limited to:

- **Unprotected sun exposure or use of tanning beds or creams.** If consumer has had unprotected sun exposure in the areas to be treated in the last 4 weeks you must determine appropriate treatment method using the test spot tables and wait 24 hours prior to treating. Protected sun exposure means wearing of protective clothing or use of a SPF # 30 or greater sunscreen.
- **Pregnancy-** there is no evidence at this time of fetal harm from a light-based system, the results of the treatment may be erratic/unreliable due to fluctuations in hormonal levels and changes in physiological conditions.
- **Menstrual dysfunction** – Consumers with menstrual dysfunction or known to have hyperandrogenism should be referred to an endocrinologist for evaluation and possible medical treatment. These consumers tend to have hirsutism secondary to their disease process that may respond to medical treatment.
- **Use of mechanical epilation** -less than 6 weeks prior to treatment for hair removal. This includes plucking, waxing, tweezing, electrolysis or sugaring
- **Allergies** – Confirm with consumer any allergies to medications, latex, foods or other substances.
- **History of seizures** –Flashing lights have been known to trigger a seizure.
- **Medications-** both prescription and non-prescription. Be sure to include herbal and natural remedies as some may cause photosensitivity. Consumer should not be taking Accutane, anti-coagulants or St. John's wort. For patients taking a photosensitizing medication perform test spots 24 hours before treatment
- **History of keloid and hypertrophic scar formation** - although scarring is rare, picking or pulling off of scabs or crusting can result in scarring. For this reason it is recommended to exclude from the treatment consumers with known tendency to form keloid or hypertrophic scars
- **Active infections/Immunosuppression** - Active infections and immunosuppression compromise the healing ability of the body. Reschedule the consumer when infection is cleared
- **Open lesions** - treatment should only be done on intact, healthy skin
- **Herpes I or II** - within the treatment area, consumer should consult their Primary Care Provider for medical evaluation and possible prophylaxis prior to treatment.
- **Tretinoin (Retin-A®, Renova®):** although tretinoin use in the area to be treated is not absolutely contraindicated, it is however, known to make skin more sensitive and prone to exfoliation. Consumer is better advised to discontinue use of tretinoin and other skin exfoliating products 2 weeks before and during the course of treatment.
- **Oral isotretinoin/Accutane** - within the preceding 6 months. Accutane changes the underlying structure of the skin, which may cause unreliable results. It may also increase skin sensitivity to light.

Warnings



- Palomar MediLux™ System is designed for treatment of intact skin only
- Take special precautions when treating near the eye area. Do not use any MediLux handpiece within the limits of bony orbital area. Always use eye protection, for yourself and the consumer, during treatments.
- Should bleeding occur during treatment, discontinue use immediately and clean/disinfect the hand-piece, per manual Chapter 2.

Warning:

During hair removal procedure avoid treating over darkly pigmented lesions and tattoos to avoid skin damage and color change.



Every consumer should have test spots performed prior to treatment to determine the appropriate treatment setting and to evaluate tissue response. Test spots should be performed in an area with skin pigment similar to that of the treatment area.

Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots.

Warning:

Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure or skin tanning re-administer test spots!

Test spots on dark skin must be administered a minimum of 24 hours prior to treatment.

- Performing test spots at recommended preset fluence/pulse width settings, and properly evaluating the tissue's response prior to initiating treatment will help to determine the proper treatment parameters for each site and reduce the risk of complications and undesirable side effects.
- Treatment parameters should be based on test spots appropriate to both the treatment site and skin type of the consumer to be treated.
- Parameters of treatment should be determined by a trained operator based on the results of the test spots.

PhotoEpilation: A fast and comfortable hair removal treatment method. This treatment method will provide long term to permanent reduction of hair.

PhotoWaxing: A high speed and virtually pain free alternative to waxing. This method of treatment will temporarily delay new hair growth from one to three months.

Pre-Treatment Recommendations

Hair Removal and Benign Pigmented Lesions



Warning:

- Prior to performing follow-up treatments verify that sun exposure or skin tanning conditions have not changed since the last treatment. If consumer experienced sun exposure, skin tanning, tanning beds, tanning creams or self-tanner re-administer test spots!

Inform the consumer to:

- Discontinue sun tanning and the use of tanning beds and self-tanning creams 4 weeks before and throughout the treatment course. This will reduce the chance of skin color changes, and development of new lesions.
- Always use a SPF-30 or greater sunscreen on all exposed treatment areas and re-apply every 2 hours throughout the day.
- Wear protective, light-occluding hats and clothing.
- Discontinue use of exfoliating creams such as Retin-A and other skin exfoliating products 2 weeks prior to and during the entire treatment course.
- Refrain from tweezing, waxing, sugaring, electrolysis or other epilation methods for at least 4 weeks prior to treatment and for the duration of treatments.
- Shave or trim excess hair during the course of treatment.

Operator considerations:

- The area should be cleansed thoroughly before test spot administration and treatment
- The treatment area should be shaved or closely clipped before the first and any subsequent treatments.
- Treatment areas prone to herpes outbreaks should not be treated until the consumer has been evaluated by his/her Primary Care Provider and has received a course of pre-treatment prophylactic antiviral therapy.
- Some consumers may require a topical anesthetic.

LuxV handpiece Fluence chart

Button Label	Fluence*(J/cm ²)	Pulse width (ms)
Photo Epilation™ Settings		
1	9	100
2	10	60
3	11	40
4	13	20
5	15	20
6	18	20
Photowaxing™ Settings		
a	8	10
b	9	10
c	10	10

Table 6.7-2 Button Settings

*The effective fluence may be higher due to photon recycling, the wavelength range and the spot size range.

Performing Test Spots:

- Do not use any cooling (CoolSpray, CoolRoller, ice, gel packs, etc.) or topical anesthetics when performing test spots
- The treatment area should be shaved or closely clipped prior to administering test spots.
- The area should be cleansed thoroughly before test spot administration and treatment.
- Apply Palomar Lotion to treatment area using gauze.
- To perform test spots, place a Palomar test spot paper mask on the sapphire lens (treatment window). The use of a mask limits exposing a large area for testing. Be certain that the hole in the mask is where you intend to place the test spot on the skin.
- Start spot tests with the lowest setting listed in the table 6.7.1(A) corresponding to the consumers skin type and increase slowly after checking for skin side effects. If there is evidence of darkening, blistering, deep reddening of the skin, or strong pain lower the setting, and re-test.
- Treatment (with the mask removed) may be performed at settings *below* the threshold for adverse skin reactions as determine by test spots.

Table 6.7.1 A. UN-TANNED Skin Spot Test Recommendations: LuxV

Skin Type	Starting settings for test spots In the following order	Maximum setting for test spots	Evaluate Test Spot
I, II,	a, b, c, 1, 2, 3, 4, 5	6	30 min
III	a, b, c, 1, 2, 3, 4	5	30 min
IV	Treatment not recommended	Not applicable	
V	Treatment not recommended	Not applicable	
VI	Treatment not recommended	Not applicable	

Treatment Instructions

Hair Removal:

- Check documentation of test spot treatment parameters.
- Check for recent sun or tanning exposure, and re-administer test spots, if necessary.
- Trim the area to be treated with a hair clipper, if necessary.
- If topical anesthetic is used apply after the hair is clipped, it should be washed off prior to treatment.
- To minimize epidermal damage and consumer discomfort the hand-piece must be pre-cooled with cryogen spray prior to treatment (see Chapter 6.1-9 for *Instructions for Use of Palomar cryogen CoolSpray™*).
 - Use CoolRoller for buttons 1,2,3 and CoolRoller and CoolSpray with buttons a,b,c and 4,5,6.
- Apply Palomar Lotion to treatment area. Use gauze or the CoolRoller to spread the lotion over the treatment site immediately prior to administering treatment.
- In addition to the CoolSpray apply CoolRoller over 2 x 8 inches, 4 x 4 inches or smaller area for 5-10 seconds when using buttons a,b,c, 4,5,6.

NOTE: Prolonged application of CoolRoller or cold packs may provide greater comfort but could reduce treatment efficacy due to overcooling. If consumer experiences discomfort, re-apply CoolRoller.

- Regularly clean the lens surface of the hand-piece (every 20-30 pulses) using Palomar wipes or other soft moist cloth.
- Follow Chapter 5 for system operation.

NOTE: The system settings depend on skin type, hair color and test spot skin response. It is recommended that the pulses be overlapped (25-30%) to ensure that effective energy is delivered to the treatment site. The risk of injury to the skin from overlapping pulses is minimal. Use the imprint of the treatment window on the skin as a guide in lining up subsequent pulses.

- To assure delivery of the light energy to the proper depth apply light pressure to compress the skin and to force the blood out of the skin during treatment. This improves light transmission and enhances delivery of light to the hair follicles.

NOTE: Skin cooling is necessary to lower the temperature in the epidermis and provide partial anesthesia. For this reason, it is imperative that the CoolRoller or ice pack is applied over the treatment site immediately prior to the MediLux treatment.

- Maintenance of firm, constant pressure of the hand-piece against the skin is essential to minimizing adverse effects.
- Since hair follicles typically grow at angles within the skin, it is possible to affect follicles that are not directly in the beam's apparent path at the skin surface. **For this reason, it is not advisable to use the Palomar MediLux™ System for shaping or sculpting precise hair-bearing areas such as the eyebrows, etc.**

- To help better visualize the treatment site and quickly look for areas that may have been missed during treatment, a direct light illumination is helpful.
- Treatment of large areas may be somewhat time consuming and tedious. For that reason, it is strongly recommended that Palomar MediLux users take frequent breaks or limit the length of each scheduled treatment session in order to minimize eye strain or fatigue.

Clinical Endpoints

There are no ideal clinical end points in hair removal with the MediLux System because pre- and post-cooling of skin significantly reduces perifollicular edema and erythema.



Although the likelihood of tissue damage is low, observe for epidermal damage, such as blistering or whitening of the skin. If the fluence is too high or improper technique is used the skin may look wrinkled or whitish/gray in color as if it were touched to a hot surface, similar to what you would see from a curling iron. If this occurs decrease preset power setting fluence and ensure firm constant pressure of the hand-piece against the skin. If blistering is encountered, the fluence should be decreased until this reaction is no longer present. If blistering occurs at even the lowest pulse width and fluence, that person should be excluded from treatment.

Benign Pigmented Lesions

- Benign pigmented lesions vary in size from a few millimeters to more than 1 cm across.
- The area should be cleansed thoroughly before test spot administration and treatment
- Decide on the treatment approach:
 - *Treat the entire area of skin containing lesions* (**Caution:** Suntan or solar bronzing will be affected by the treatment and may result in lighter patches of skin in the shape of the treatment window), or
 - *Treat the lesions only*
- If the entire area of the skin containing lesions is to be treated be sure the selected fluence does not exceed the recommendations for test spots on page 6.2-4 for surrounding non-pigmented skin
- If the lesions are to be treated individually place a provided pre punched paper mask slightly larger than the size of the lesion and apply it to the treatment window or use the plastic mask. Apply Palomar Lotion to the area, align the opening in the mask with the lesion and bring the treatment window in firm contact with the skin. For best results button #5 is recommended for dark brown/black lentigines and button #6 for all others. Immediately after treatment the lesions may turn darker in color. The area surrounding the lesion may turn red. The lesion may elevate and appear swollen. These are all expected outcomes and resolve in 7-10 days.

Post-Treatment Instructions

Hair Removal:

- Using ice, CoolRoller, cold packs and/or a steroid cream immediately after treatment has been found to minimize erythema and edema, and to provide comfort to the consumer.
- Provide the consumer with both verbal and written instructions including, but not limited to:
- Mild sunburn-like sensation is expected. This usually lasts 2-24 hours but can persist up to 72 hours.
- Apply cold gel packs or cool wet cloths to the treatment areas for 15 minutes every 2-4 hours until symptoms subside.
- Bathe or shower as usual. Treated areas may be temperature sensitive. Cool showers or baths will offer relief.
- Avoid aggressive scrubbing and use of exfoliants, scrub brushes and loofa sponges until the treatment area has returned to its pretreatment condition
- Avoid sun exposure to treated areas, as well as the use of sun tanning beds and self-tanning creams. Use a SPF-30 sunscreen if sun exposure is unavoidable. Sun avoidance will decrease likelihood of skin color changes
- Appearance of hair growth or stubble will continue for 7- 30 days post-treatment. This is not new hair growth, but the treated hairs being expunged/ purged from the skin.
- Hairs that were in the resting phase at the time of treatment may enter the active phase in 1 to 6 months depending on the body area.
- Follow-up treatment may be performed at 2-12 week intervals or within 1-2 weeks of new hair growth.
- Avoid, swimming, hot tubs/Jacuzzis, do not apply any cosmetics to the treated area and excessive exercise for 7 days after treatment or until redness resolves.
- If blisters occur, apply antibiotic ointment to the areas 2 times a day until healed.
- Do not pick or remove scabs or crusting; this will help decrease the chance of infection and scarring.
- A non-steroidal anti-inflammatory such as acetaminophen will help reduce discomfort. Take according to manufacturer's recommendations.

Benign Pigmented Lesions:

- A mild sunburn-like sensation is expected. This usually last 2-24 hours but can persist up to 72 hours. Mild swelling and/or redness may accompany this which usually resolves in 2-3 days. In some cases, prolonged redness or blistering may occur
- The lesion may initially look raised and/or darker with a reddened perimeter. Apply ice compresses to treatment areas for 10-15 minutes every hour for the next 4 hours, as needed.
- The treated area can be gently cleansed and topical bactericidal ointment may be applied if needed.
- The lesion will gradually turn darker over the next 24-48 hours. It may turn dark brown or even black
- The lesion will progress to scabs/crusting and will start flaking off in 14-21 days.
- Do not pick, scratch or remove scabs. This will prevent unwanted side effects.
- The lesion is usually healed in 14-21 days. It will continue to fade over the next 6-8 weeks.
- Until redness has completely resolved avoid all of the following:
 - Applying cosmetics on or near treated areas

- Swimming, especially in pools with chemical/chlorine
- Hot tubs and Jacuzzis
- Activities that cause excessive perspiration
- Avoid sun exposure to treated areas. Apply a sunscreen with SPF 30 or greater daily to sun-exposed skin between treatments and 4-6 weeks after treatment.

Side Effects /Risks

Performing tests spots at different preset fluence/pulse width settings and properly evaluating the tissue's response prior to initiating treatment will help determine the proper treatment setting for each site and reduce the risk of complications and unwanted side effects.

Possible side effects or complications that may arise from use of the Palomar MediLux™ System include, but are not limited to:



- **Blisters may sometimes occur.** If a blister should form, it is important to recognize that it is generally intra-epidermal and will usually heal without scarring. Blisters should be treated conservatively with gentle cleansing and application of a topical antibiotic ointment until they have completely healed. If blistering is encountered, the fluence/pulse width settings should be adjusted until this reaction is no longer produced. Be sure to maintain firm contact with the skin's surface before pulsing the MediLux.
- **Pigmentary changes** such as lightening or darkening of the skin may occur. In some consumers it may not be visible for 2 – 4 days after treatment. Most skin color changes will resolve within 3-12 months.
- **Discomfort** during treatment sometimes occurs. Good pre-cooling used immediately prior to treatment aids in minimizing consumer discomfort.
- **Prolonged redness and swelling.** Redness and swelling may occur immediately following treatment, this usually resolves in 2-72 hours.
- **Scarring.** Scarring is very rare. Blisters may occur during or sometime after treatment. The blisters are intra-epidermal in nature and usually heal without scarring.

NOTE: These side effects/complications have been rated as both transient and minor and appear to resolve spontaneously within several weeks or months after treatment

These side effects are rare and can be minimized by following established pre-treatment and post-treatment protocols and using proper techniques

Common side effects include temporary redness and mild "sunburn" like effects that may last a few hours to 3-4 days or longer. Pigment changes (light or dark spots on the skin) lasting 1-6 months or longer may occur. In addition, freckles may lighten and/or temporarily or permanently disappear in treated areas. During treatment of pigmented lesions in hair bearing areas, there is a likelihood of hair removal in those areas treated. Other potential risks include blistering, crusting, itching, pain, bruising, skin blanching, burns, infection, scabbing, scarring, swelling, and failure to achieve the desired result. Intense light can cause eye injury and protective eyewear must be worn during treatment. Serious complications are rare, but possible.

Be sure to observe all precautions described in Chapter 2: Safety, of this manual, and Chapter 5 system operation.

Chapter 7: Maintenance and Troubleshooting

Troubleshooting

Fault levels	7-2
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Maintenance

Routine Maintenance	7-5
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Adding Cooling fluid	7-5
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Filter Replacement	7-7
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Fuse Replacement	7-8
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GENERAL INFORMATION



Caution, do not attempt to install or use the system if the handpiece has been dropped or shows signs of physical damage. Contact Palomar Medical Service department.



No one other than Palomar Medical authorized personnel may service inside the protective covers of the MediLux System.

Do not remove the covers of the system. Dangerous and potentially lethal voltages are present inside the system.

Maintenance should only be performed by the operator 30 minutes after the system is shut down and disconnected from power. Performing maintenance procedures with the system while it is powered up or before 30 minutes from disconnecting the system may be hazardous to the operator and destructive to the system.

If system requires Service:

The MediLux system is designed to be depot serviced. Some trouble shooting or repair may be done in the field. This chapter will describe error levels and symptoms and possible solutions. In the event that these solutions do not cure the problem, the unit should be returned to Palomar for repair or replacement. Any service done should be performed only by a factory-trained technician or engineer.

If service is required, this product is to be returned to Palomar or authorized service center for repair. For warranty repair Palomar or authorized distributor will pay for the shipping charges. For systems returned for repair not covered by warranty the customer shall pay for all shipping charges.

All returns must be accompanied by a Return Authorization Number (RMA) contact Palomar by phone at 888-543-6700 or 781-993-2315, fax 781-993-2340 or email service@palmed.com to obtain the RMA number.

Any service performed should be in accordance with this manual or by the specific direction of the service department. If the laser is under warranty no service other than normal required maintenance should be performed without express written consent from Palomar Medical.

MediLux System Faults

Indication	Fault Condition/progression	Action to remedy fault
System not turning on	No power to the key switch Light next to the key switch not flashing	1. Turn main power switch on the rear panel to the up (on) position. 2. Verify the system is connected to AC power and the outlet is operational. 3. Release the emergency stop button by turning the button clockwise. 4. Check and/or replace the fuses in the AC in panel on the rear of the system. 5. Check to ensure the voltage selector matches your line voltage. 220VAC or 115VAC. 6. Internal fault, call Palomar Medical Service.
System not turning on Level one fault See figure 7-1	No power to internal components Light next to the key switch flashing when key switch off, no lights on when key turned on.	1. Check all connections to the handpiece, it must be connected to the system. Ensure Pins in the connector are not bent or pushed in. 2. Water leak in handpiece, check for water dripping from the air exhaust in the handpiece. 3. Replace the handpiece. 4. Internal fault, call Palomar Medical Service.
Only bottom row of lights on (a, b, c) Level two fault See figure 7-2		1. Coolant level in the reservoir, fill the reservoir (see page 7-5) 2. Water line to handpiece pinched or not connected. 3. The water filter in the rear access panel may need to be replaced and /or installed. 4. All connections to the handpiece connected. 5. Replace the handpiece. 6. Internal fault, call Palomar Medical Service.
Bottom two rows of lights on (a,b,c and 4,5,6) Level three fault See figure 7-3		1. Water line to handpiece pinched or not connected. 2. The water filter in the rear access panel may need to be replaced and /or installed. 3. Coolant temperature on handpiece too high 4. Replace the handpiece 5. Internal fault, call Palomar Medical Service.
All three rows of lights are on See figure 7-4	System does not go to default start button (#1) Flashlamp not simmering.	1. Check to see that holster is completely inserted against the side of the console. 2. The handpiece needs to be 'docked' into the holster. 3. Replace the handpiece. 4. Replace the holster. 5. Internal fault, call Palomar Medical Service.

Indication	Fault Condition/progression	Action to remedy fault
The ready lamp does not come on when the footswitch pressed	There are two ready lights, one on the console and one on the handpiece.	1. Check that the remote door interlock by pass is installed on the back of the system. 2. Footswitch must be connected to the rear panel of the console. 3. Replace footswitch. 4. If the remote interlock is connected to a door, check to see the door is closed. 5. Internal fault, call Palomar Medical Service.
The system does not fire when the handpiece trigger button depressed	The ready lights must be on to fire the system.	1. Handpiece trigger button broken/stuck. 2. Install a new handpiece, if new handpiece does not work call Palomar Medical Service. 3. Internal fault, call Palomar Medical Service.

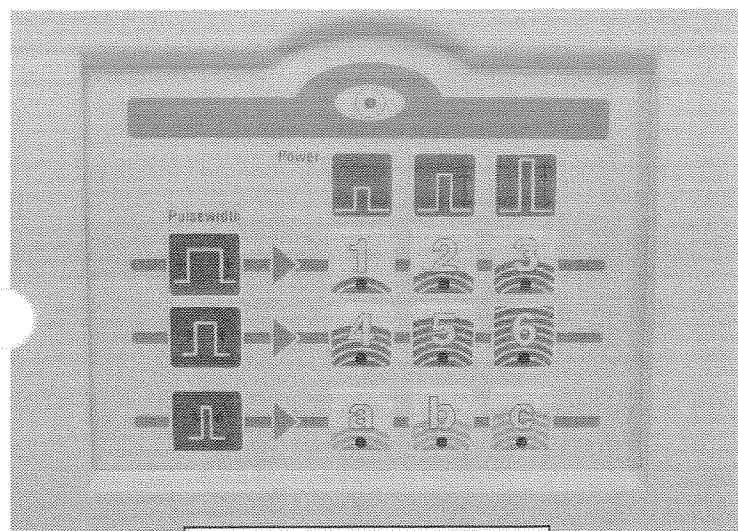


Figure 7-1 Level one fault

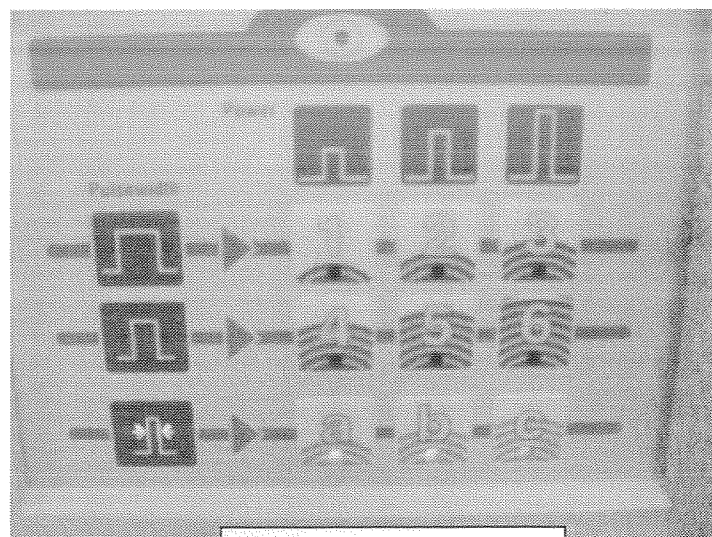


Figure 7-2 Level two fault

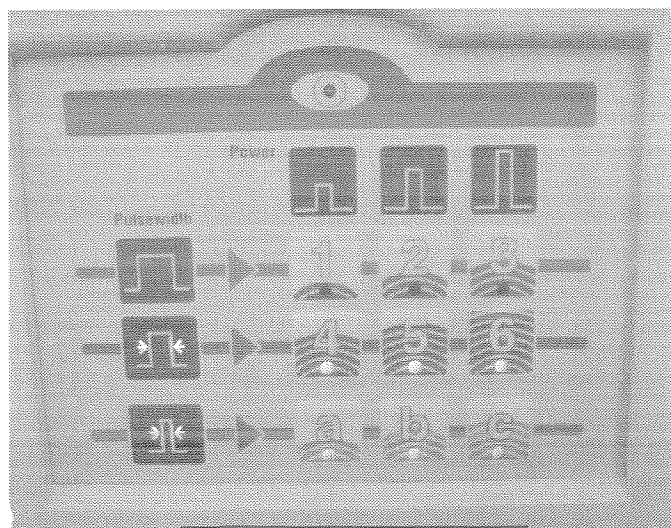


Figure 7-3 Level three fault

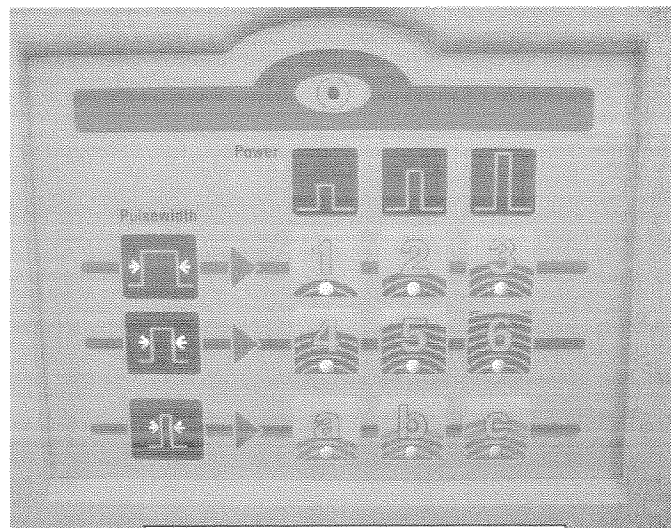


Figure 7-4 Lamp not simmering

Routine Maintenance

Adding chiller fluid:

The reservoir level light is located under the shot counter on the rear panel. When the light is ON the fluid level is usually OK. If the lamp is off when the key switch is on the fluid level is low.

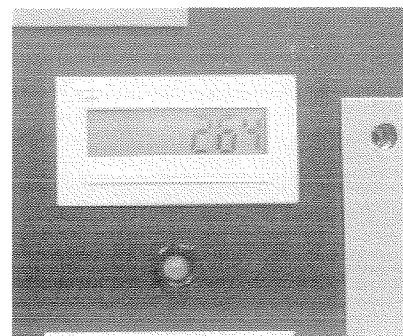


Figure 7-5 Fluid Level lamp

Procedure to add fluid:

1. Turn the system off and disconnect the power cord.
2. Loosen the two screws holding the filter panel to the chassis.
3. The hinged cover will tilt down to allow access to the fill port and filters.

Remove these screws to open access panel for filters and coolant fill connections

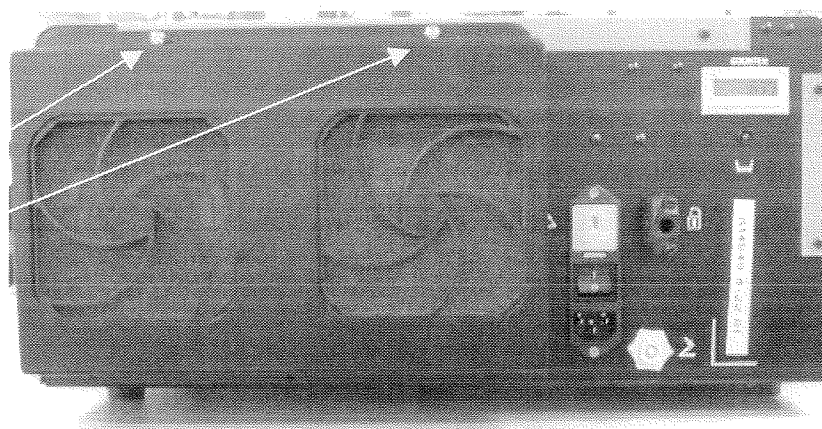


Figure 7-6 MediLux Rear panel

- 4 The bottle of 10% methanol syringe with Hose, and vent hose are needed to fill the cooling reservoir

Bottle of chiller fluid
10% Methanol
Re-order Part
#1812-0002

Vent hose with
quick connector

Fill syringe and
tubing with quick
connector

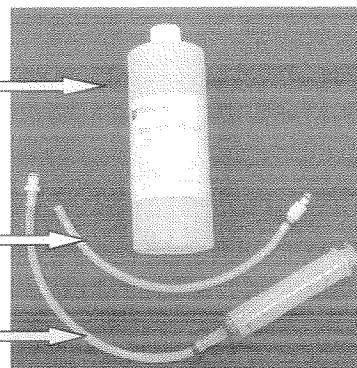
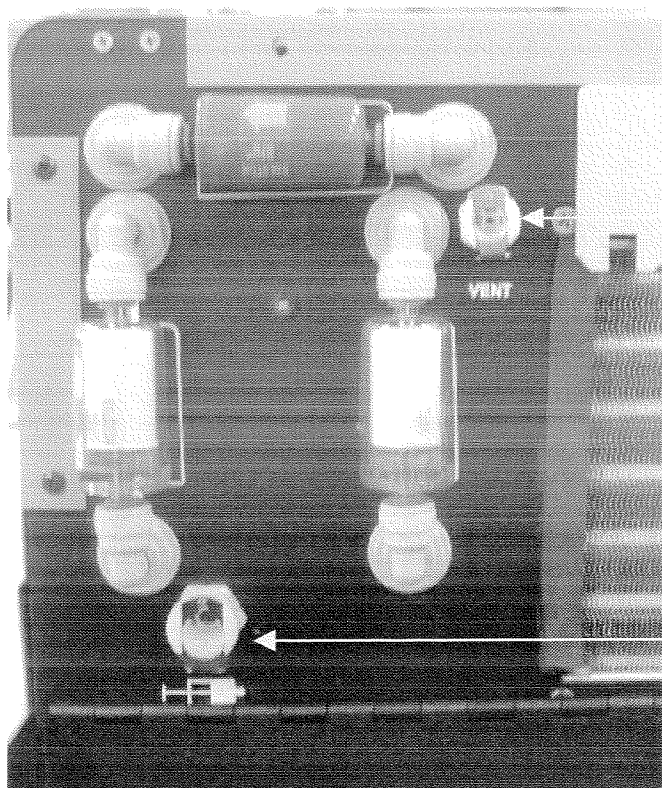


Figure 7-7 Fill kit components

5. Attach the vent hose using the quick connect fitting to the vent connector.
6. Fill the syringe by inserting the quick connector into the fluid bottle and pulling the plunger up. When the syringe is full of fluid remove from the bottle.



Attach the vent hose with connector here.

Attach the fill hose with full syringe here

Figure 7-8 Fill location

7. Attach the syringe to the fill port on the MediLux™ system, place the open end of the vent hose into the bottle to catch overflow.
8. Depress the plunger on the syringe until:
 - a. The fluid flows out the vent hose into the bottle. Stop pressing the plunger and remove the vent hose and fill hose.
 - b. The syringe is empty. Remove the fill hose from the fill port and refill the syringe. Repeat step 7.
9. When the reservoir is full remove the fill hose and the vent hose. Close the filter cover and resume operation of the MediLux™ system

Changing the filters:

The coolant fluid and the water filter should be changed every 6 months.

The air filters should be changed every 6 months.

The filters and coolant fluid can be ordered as a kit: Part number 1320-0025.

1. Turn the system off and disconnect the power cord.
2. Lower the rear access panel to expose the filters and the fill and vent connections.
3. Using the filter tool remove the water filter: this is the solid blue filter mounted on the top in a horizontal position. Discard the filter.
4. Install the new filter from the kit with the flow arrow pointing to the left.

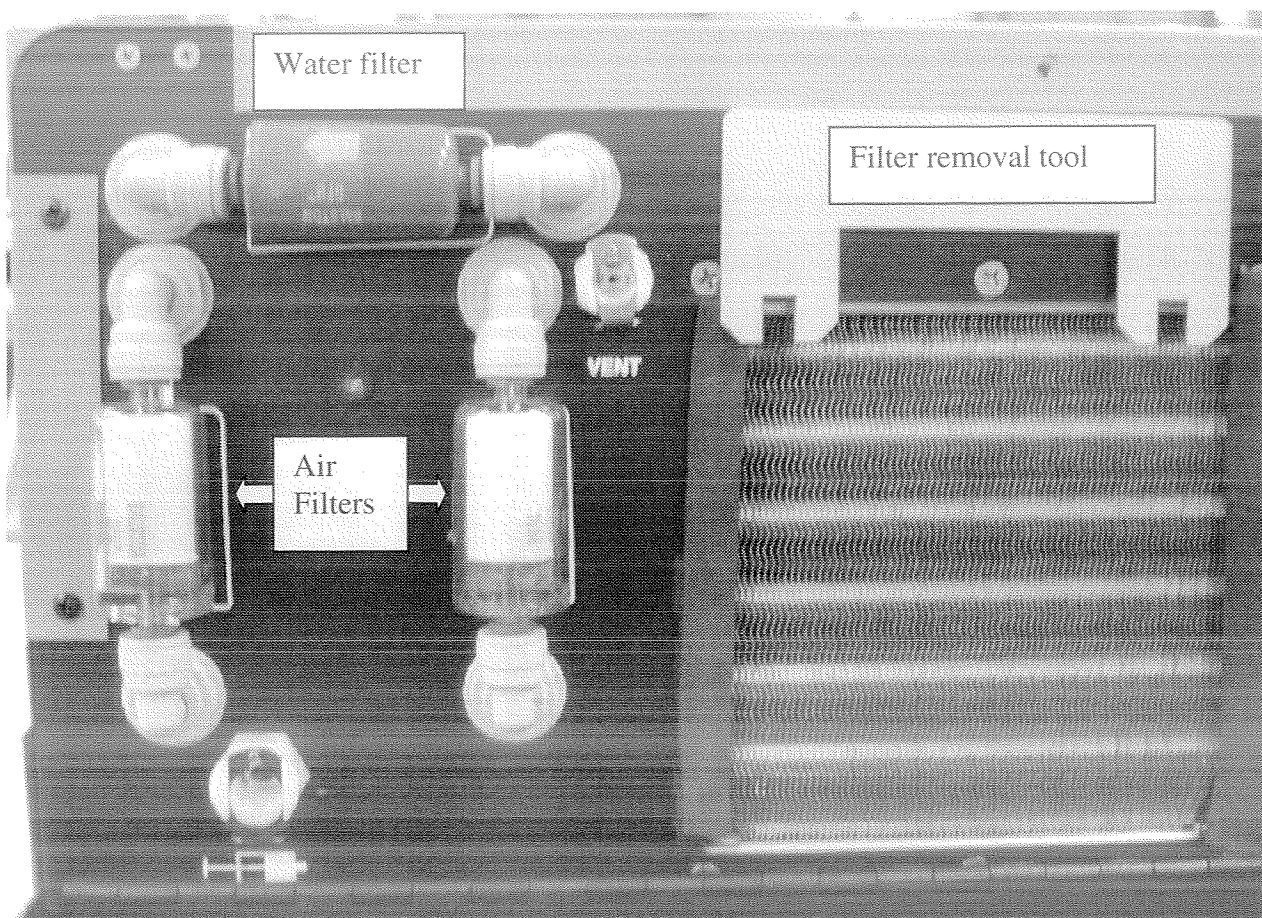


Figure 7-9 Filter locations

5. Using the filter tool, remove and replace the 2 air filters with the arrow pointing down.
6. Discard the old filters.

Changing the fuses:

1. Remove the power cord from the power cord connection
2. Using a small blade screw driver press the tab on the fuse holder/ voltage indicator, pull out the fuse holder.
3. Identify the defective fuse(s) and replace with the same type (5A 250VAC SB for 115V installations and 2.5A 250V for 230V installations)
4. Re-install the fuse holder, connect the power cord. Resume operation of the MediLux™ system.

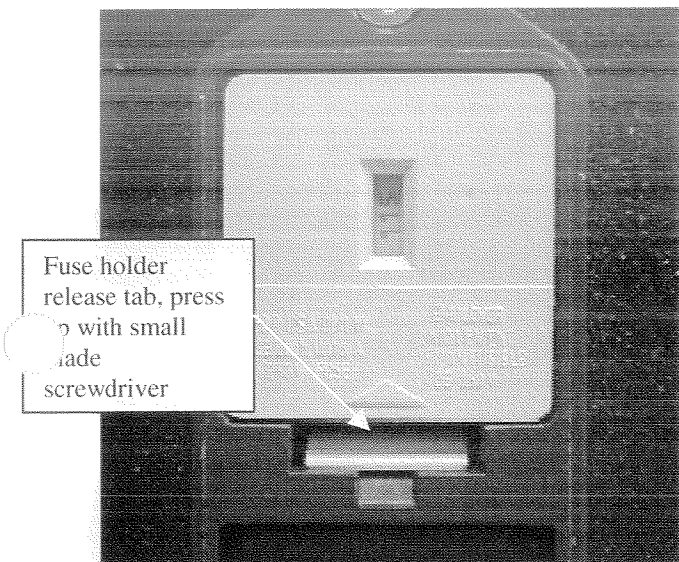


Figure 7-10 Fuse panel

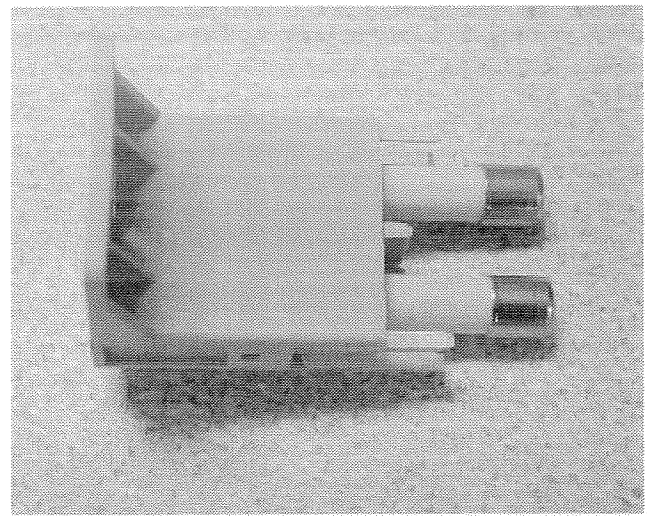


Figure 7-11 Fuse holder

Chapter 8: Customer Support

Customer Service	8-2
System Accessories	8-2

Customer Support

Contacting Palomar Medical Products, Inc.

In the United States:

Palomar Medical Products, Inc.
82 Cambridge Street
Burlington, MA 01803 USA

(781) 993-2300 Main Telephone Line
(781) 993-2330 Main Facsimile
(781) 993-2340 Service Facsimile
(781) 993-2315 Service Direct Line
(800) PALOMAR (725-6627)
Email to service@palmed.com

made June 2001
Serial # 11-0656

System Accessories

To order additional accessories, please contact Palomar at (800) PALOMAR. Palomar accepts VISA, MasterCard or company purchase order. International customers contact Palomar for the name and number of your local representative/distributor.

Palomar Lotion™, bottle

Palomar Lotion, case of 9 bottles

Order P/N: 1620-0163

Order P/N: 1620-0162

Palomar LuxWipes

Order P/N: 52-0101-00

Operator's Manual

Order P/N 1100-0001

LuxY Handpiece

Order P/N 1120-Y006

LuxG Handpiece

Order P/N: 1120-G006

LuxR Handpiece

Order P/N: 1120-R006

LuxRs Handpiece

Order P/N: 1120-RS06

LuxB Handpiece

Order P/N: 1120-B006

LuxV Handpiece

Order P/N: 1120-V006

Safety Glasses *Order P/N: 52-0308-00*

Eye Shields *Order P/N: 52-0309-00*

Key Ring *Order P/N: 52-0325-00*

CoolRoller™ Applicator *Order P/N: 1320-0017*

Roller Freezer *Order P/N: 52-0296-00*

The freezer is not an approved medical device therefore should not be kept or used in the treatment area.

Cart *Order P/N: 2120-0027*

Replacement Fuses
5A Fuse for use on 100-120VAC systems *Order P/N: 62-0000-40*

2.5A Fuse for use on 220-240VAC systems *Order P/N: 62-0000-37*

Fill Kit *Order P/N: 1320-0023*

The fill kit is needed to refill the 9% methanol cooling fluid for the handpiece.

Fill Kit components:

Chiller fluid, 9% Methanol, 91% Distilled Water *Order P/N: 1812-0002*

Vent Tube Assembly. *Order P/N: 1820-0031*

Fill Syringe Assembly. *Order P/N: 1820-0032*

Preventative Maintenance Kit *Order P/N: 1320-0025*

This kit contains the water and air filters.

Air Filter *Order P/N: 1320-0023*

There are two air filters, they should be replaced every 6 months.

Water Filter *Order P/N: 1320-0024*

The water filter should be replaced every 6 months

Filter Tool *Order P/N: 1321-0015*

The filter tool aids in removal of the filters.