



# I.P.L. USER MANUAL



## LASER S.O.S. AESTHETICS

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## SAFETY WARNINGS

### CAUTION

Do not try to operate the Sapphire Ultima IPL System until the User Manual has been read and fully understood.

Please read and understand the entire User Manual before you attempt to use the system. Furthermore, a total understanding of the biological effects and the interaction of light with tissue. This is a prerequisite prior to operating this system. A training course will be provided on this subject. When you are not using the system, remove the on-off key to prevent unauthorized use.

#### CAUTION. THIS SYSTEM IS AN INTENSE PULSE LIGHT (IPL) DEVICE!

DIRECT EXPOSURE TO THE INTENSE LIGHT OUTPUT MAYBE INJURIOUS TO THE SKIN AND EYES. NEVER POINT OR SHINE THIS LIGHT INTO THE EYES.

#### IT IS IMPERATIVE THAT BOTH THE CLIENT, THE THERAPIST, AND ANY OTHER PERSONS IN THE ROOM MUST WEAR THE PRESCRIBED PROTECTIVE EYEWEAR.

#### FURTHER WARNINGS

- High voltages are generated in this Sapphire Ultima IPL System are extremely dangerous and under certain circumstances could prove fatal.
- The following safety measures must be observed;
- The IPL System mains input cable's earth must be connected to the mains earth or another protective earth.
- After the Hand Piece (Applicator) has been connected, both the water and electrical connections are complete.
- Ensure adequate ventilation at the rear of the unit to prevent overheating.
- NEVER operate the IPL System with any of the protective panels/ covers removed.

#### **GENERAL INTRODUCTION**

The Sapphire Ultima IPL System operates from a universal mains supply and incorporates an active power factor correction capacitor charger. This charges the internal 27 F capacitor bank to a peak voltage of 380 volts. This is also the over voltage shutdown limit. The Sapphire Ultima IPL also contains low voltage power supplies for internal use, IGBT drivers, trigger supplies, control electronics and the display panel. The water cooling for the flash lamp, located in the Handpiece, comprises a water tank (reservoir), pump, flow switch and cooling radiator. The system uses de-ionized water as the coolant.

The Sapphire Ultima IPL System is designed to meet BS EN61010-1 with the following parameters being applicable:

- Pollution Degree 2
- Installation Category II
- Ambient temperature range 5°C to 40°C
- Altitude less than 2000 metres
- Indoor use only
- Mains Category Class 1. (Accessible metal parts are connected to the protective earth)
- Type B provides a very high degree of protection against electric shock due to low earth leakage and all panels are earthed.
- The system has an earth leakage current limit of 500  $\mu A.$

The Sapphire Ultima IPL System provides for hair removal by photodepilation and skin rejuvenation.

The user-controlled settings on the Sapphire Ultima IPL System include the following:

Fluence or Energy Density J/cm<sup>2</sup>

Number of pulses:	3, 5, or 7.
Duration of each pulse:	3, 5, or 7 mS.
Delay between pulses:	3, 5, 7, or 9 mS

The Sapphire Ultima IPL System is equipped with two shot counters:

- a) The first counter displays the total number of shots fired by the handpiece that is currently connected to the system.
- b) The second shot counter displays the number of shots fired during the current treatment.

The Sapphire Ultima IPL System is supplied standard with one hand piece fitted with a 610 nm (Red colour) Filter most suitable for photo depilation. A second hand piece is also available as an option. This is fitted with the 530 nm (Yellow colour) Filter and is only suitable for photorejuvenation.

## SAFETY INFORMATION GLOSSARY OF SYMBOLS







## ENVIRONMENT AND USE RESTRICTIONS - WARRANTY TERMS

Laser S.O.S. Aesthetics Ltd assumes responsibility for the safety and proper operation of the Sapphire Ultima IPL System, provided that the following items have been observed:

- The wiring in the area where it is used complies with the relevant CEI/(UNE) standards.
- The system is to be used only in accordance with the specifications included in the instruction manual.
- All products to be used with the procedure, Applicator Heads, Light Guides, Filters, Flash Lamps or Gels are supplied exclusively by Laser S.O.S. Aesthetics. This is to ensure the effectiveness of the treatment, the bio-compatibility of the materials and compliance with standards.
- The maintenance and repairs for the system are only to be performed by staff authorised by Laser S.O.S. Aesthetics. The user being responsible for controlling the timing of maintenance and calibration of the system. One (1) Year interval not to be exceeded
- Maximum room temperature of 40 °C must not be exceeded.
- The Flash Lamp is pre-programmed to operate up to 50, 000 shots and then must be replaced.
- The Ceramic Reflector must be replaced after 250 000 shots.
- The Optical Filter must also be replaced after 50, 000 shots.

NOTE: Laser S.O.S. Aesthetics is able to provide upon written request, the circuit wiring diagrams, components lists, technical descriptions and any other information required for the repair and calibration of the Sapphire Ultima IPL System by the users staff. This is provided that their staff are properly trained with specialist knowledge to adequately undertake repair to the units deemed repairable by Laser S.O.S. Aesthetics Ltd.

## WARNING:

TO REDUCE TO A MINIMUM THE EFFECTS OF HEAT BUILD-UP ON THE SKIN WITH THE RISKS INVOLVED (BURNING OF THE SKIN) THE AREA TO BE TREATED MUST BE COOLED OR CHILLED PRIOR TO STARTING THE PHOTO-DEPILATION TREATMENT. THROUGHOUT THE TREATMENT APPLY ADDITIONAL GEL OR FURTHER CHILL THE TREATMENT AREA AS OFTEN AS NECESSARY.

When depilating with the Sapphire Ultima IPL System we recommend the use of a cold gel which, as well as keeping the skin cold, decreases the risk of burns and preserves the optical integrity of the application.

During and after depilation, the Hand piece's waveguide must be examined from time to time to ensure that it is free from any hairs and other impurities where energy could concentrate.

Should the Waveguide not be kept clean there is a real risk of burns to the skin and damage to the Waveguide itself.

After completion of the treatment, we recommend that an Aloe Vera based cream or corticoid be applied to the treatment area to sooth the irritation.

THE HAND PIECE IS ONE OF THE MOST EXPENSIVE PARTS OF THE SAPPHIRE ULTIMA IPL SYSTEM. WE STRONGLY RECOMMEND THAT YOU HANDLE IT WITH EXTREME CARE.

THE WAVEGUIDE MUST BE CLEANED USING A LENS CLOTH TO ENSURE THAT ITS SUFACE DOES NOT BECOME SCRATCHED.

## SYSTEM LAYOUT

Descriptions of the principle elements of the Sapphire Ultima IPL System, that are important for the user to familiarise themselves with, are listed below. Please refer to Figures 1 & 2 to locate all the key components on the system.

- 4. Hand piece (Applicator)
- 5. Hand piece connector
- 6. Fill connector
- 7. Mains fuses

- 8. Hand piece support
- 9. Rear Panel Power Switch
- 10. IEC Mains Input Socket
- 11. Blue overflow with transit cap.





- 12. Energy Display in J/cm<sup>2</sup>
- 13. Number of pulses Display
- 14. Pulse width Display in mS.
- 15. Delay between pulses Display in mS.
- 16. Future use
- 17. Flash lamp charge Display
- 18. Total number of shots Display for the hand piece.
- 19. Increase Energy Button
- 20. Decrease Energy Button
- 21. Number of pulses Button
- 22. Pulse width Button in mS.
- 23. Delay between pulses Button
- 24. Start/Stop Button.

25. Partial shot counter reset Button

26. Partial shot Display. Error codes are also displayed here.

- 27. Handpiece (Applicator) Button
- 1. Face
- 2. Key switch
- 3. Emergency STOP button

#### FRONT PANEL PARAMETER SETTING CONTROLS

21. This button sets the Number of Pulses providing, 3, 5, or 7 pulses, as seen in the display 13 immediately above the button.

22. This button sets the On Time 3, 5 or 7 mS, as seen in the display 14.

23. This button sets the Delay Time between the pulses 3, 5, 7 or 9 mS.

After the required parameters have been entered, pressing the Start/Stop button (24) initiates the capacitor charger. The "Ring of six LED's (17) will flash, when the capacitors are fully charged, the LEDs will extinguish with a Beep. This indicates that the system is now fully charged to their predetermined voltage. The Trigger Button (27) on the Hand piece (Applicator) (8) can now be pressed to apply the light output to the patient.

Pressing the trigger button on the Hand piece prior to the Sapphire Ultima IPL System reaching its predetermined level, will have no effect. It must first reach the predetermined voltage as indicated by the beep sound.

Having fired a "shot" of light, the Number of Shots decreases by 1 and the Total Shot counter (26) increments by 1. You will also need to wait until the capacitors have recharged before the system can fire another shot.

Neither the treatment parameters nor the shot counter reset can be changed once the Sapphire Ultima IPL System has been started. However should it be found necessary that either the parameters or to reset the shot counter to zero, then the Sapphire Ultima IPL System must first be stopped; reprogrammed, and starting the system again once the changes have been implemented.

When the Sapphire Ultima IPL system is "Stopped" the internal bleed circuit discharges the 27F capacitor bank.

#### **INSTALLING THE SAPPHIRE ULTIMA IPL SYSTEM**

Plug the power cord supplied with the system into IEC socket (9) on the rear panel. Please ensure that the wall outlet is correctly earthed, and then plug the other end into the wall socket.

## PRIOR TO PLUGGING THE SYSTEM IN, CHECK THAT YOUR LOCAL LINE VOLTAGE MATCHES THAT SPECIFIED ON THE LABEL OF THE MACHINE

Remove the transit cap from the blue overflow outlet (11) on the rear panel, after the system has been placed in its correct working positioned. This is necessary to avoid an over pressure condition within the cooling system. Retain the transit cap and keep in a secure place. You will need this when you wish to move the system to another location.

Only move the system with the transit cap fitted so as to avoid spilling any of the coolant.

#### **CONNECTING THE UNIT**

For more information about starting the system, please refer to chapters 3 and 5 of the manual.

#### ACCESSORIES AND CONSUMABLES

To order any accessory, please contact your local authorised representative and fill in an order with the relevant code and quantity.

CODE	DESCRIPTION	QUANTITY
SPEC3PL/33	User Goggles (Passive)	1
IPLLIGHTSPEED	Therapist Goggles (Active)	4
CGEL250	Treatment Gel	1
SAPPAPP610/950	Handpiece 610 nm Red (Standard)	1
SAPPAPP530/950	Option Handpiece 530 nm Yellow	1

### WARNINGS AND SAFETY

#### **WARNINGS**

The Sapphire Ultima IPL System must NEVER be used on persons with skin conditions or inflammation, skin erosions, wounds or broken blisters that could come into contact with the waveguide of the Hand piece. Should you use the system under these conditions there is a very high risk of transmitting infections between patients.

Regardless of this, and as a general rule, the Sapphire Ultima IPL System must ALWAYS be appropriately cleaned prior to use on another patient. This will avoid any possible transmission of infections between patients. Please refer to section 10 for full Cleaning and Disinfection instructions.

The Sapphire Ultima IPL System's electrical connections MUST be supplied with the correct earth connection.

The Sapphire Ultima IPL System is NOT designed for use in explosive environments. i.e. enriched with oxygen or nitrous oxide, etc.

There are no potential risks involved regarding the disposal of consumables, but this must be done in accordance with local regulations.

The initial installation, repairs and maintenance of the Sapphire Ultima IPL System must be performed by an authorised service representative. Unauthorised repairs and modifications will INVALIDATE the warranty.

#### PRECAUTIONS

Some side effects may occur after using the Sapphire Ultima IPL System but can minimised after correct training. This leads to a better understanding of the systems features and operation. These effects include burns, blisters, swelling, skin eruption and in very serious cases, anaphylaxis.

#### PERSONALISING THE TREATMENT

The Sapphire Ultima IPL System can be configured to work within the parameters suitable for each individual client. The client must undergo a complete medical examination and must understand the possible side effects of the treatment. He or she must also sign an informed Consent Form prior to undergoing treatment.

#### SAFETY USAGE RESTRICTIONS

- This system is designed to be used solely and exclusively by suitably qualified personnel. The Sapphire Ultima IPL System must not be handled by any unauthorised personnel.
- Do not use the system unless you have been trained to do so.
- Do not eat or drink while you are using the system.
- Do not use the system if any operating errors exist.
- Do not try to operate the system without a Hand piece attached.
- Only use the system according to the recommendations as set out in the User Manual.
- Do not disassemble the body or panels of the system.

#### HANDPIECE (APPLICATOR)

Each Hand piece is a delicate piece of equipment. This produces the light emission that is used to treat the patient, when the light output is applied to the skin. Use it carefully. The Hand piece has a water cooled chamber that houses the flash lamp. Please be careful not to cause mechanical damage and do not disassemble it, or any of its parts. This is so that you avoid possible electric shock which could prove to be fatal. The Optical Waveguide is manufactured from special glass and can crack or break if subjected to mechanical shock or stress. Check that the optical Waveguide is in perfect condition prior to each treatment, preferable during the cleaning process. Comply with the following recommendations:

- Do not drop the Hand piece (Applicator)
- Do not knock or bang the Hand piece (Applicator)
- Always keep the Hand piece (Applicator) clean.
- Do not immerse the Hand piece in any liquids.
- Do not use any inflammable products for the purpose of cleaning the Hand piece either immediately before or after treatment.
- Do not use the Hand piece (Applicator) if you observe any water leaks.
- Do not attempt to disassemble the Hand piece (Applicator).

#### **OPTICAL SAFETY**

The Sapphire Ultima IPL System emits very intense light that can damage one's sight. It is imperative that both the patient and the THERAPIST's eyes are protected by utilising the recommended protective eyewear prior to starting treatment.

	Patient	Therapist
Type of eye protection	High Density Safety Goggles	Safety Goggles
Wavelength range:	Total optical protection	200 to 1800 nm
Colour	Dark Green or Black Green	IPL LIGHT
Reference:	SPEC3PL/33 (Passive)	SPEED (Active)

#### RECOMMENDED EYE PROTECTION.

ONLY use eye protection that has been authorised and supplied by the distributor. Failure to comply could lead to serious damage to both the THERAPIST's and the patients' eyesight.

- NEVER point the Hand piece (Applicator) directly at anybodies eyes.
- Do not look directly into the waveguide while the system is charging.
- Always ensure that all persons present in the treatment room are wearing protective goggles.

## INDICATIONS AND CONTRA-INDICATIONS

### **INDICATIONS**

The Sapphire Ultima IPL System is appropriate for the following procedures:

- Photodepilation
- Photorejuvenations

## **CONTRA-INDICATIONS**

#### ABSOLUTE GENERAL:

- Having used oral medication for acne during the past six(6) months, such as Accutane, Roacutane etc.
- Photosensitivity, porphyria, and xeroderma pigmentosum.
- Photosenstising medication.
- Pregnancy
- Epilepsy
- Kaposi's sarcoma
- Cancerous tissues or suspected malignancy
- A history of poorly healing wounds and keloid scarring
- Treatment with anticoagulants

#### ABSOLUTE IN THE DEPILATION AREA:

- Tattoos
- Sun spots, freckles, or lentigos
- Tanned skin
- Micro-pigmentation
- The areas around the eyes
- Skin Fitzpatrick V VI
- Wound or infected skin

#### RELATIVE:

- Herpes
- Diabetes mellitus

#### SIDE EFFECTS

It is very important to comply with all safety measures and operate within the appropriate parameters. Should these recommendations not be followed, side effects could be experienced, such as the following:

- Erythema
- Oedema
- Vesiculation or burns
- Hypo or Hyperpigmentation, with late onset effects. The most frequent is Hypopigmentation, which is usually transitory.
- It is very important NOT to sunbath before or after depilation.

This is why it is important to take the contra-indication into account and to conduct a patch test as described in the depilation section of this manual.

#### POTENTIAL INCIDENTS

It is essential to wear protective goggles, as the ocular system amplifies the effects of the energy transmitted by the pulsed light, which can damage different components of the eye; such as the cornea, crystalline lens or the retina. Remember that the retina is the one that cannot be repaired.

Burning is the most serious of the accidents capable of affecting the skin. This can be caused by not selecting a conservative time setting especially in the case of tanned skins (artificially or natural tanned skin). This should also not have been exposed to the sun for at least one (1) month or due to the incorrect parameter selection (on/off times) or Fluence. As a preventative measure, it is always a good idea to start depilating with a low Fluence. This can be adjusted upwards (increased).

In the case of a burn, send your patient to a Dermatologist who will then be able to provide the appropriate treatment.

## USING THE IPL SYSTEM

#### STARTING THE SYSTEM

For startup please follow the following steps:

The water overflow cap on the rear of the system MUST be removed before switching the system on. Please retain and keep in a safe place.

The water overflow outlet must be open during system operation.



Figure 3



The Handpiece is connected to the Sapphire Ultima IPL System's power unit via the connector on the front column.



Plug in the large rectangular connector of the Handpiece/Applicator, ensuring that it is latched in correctly.

Please ensure that the Handpiece that you have fitted is the correct one for the procedure that you require. (Photodepilation or Photorejuvenation).



Mains inlet: The Sapphire Ultima IPL System is designed for connection to a universal mains supply (100 to 240 Volts 50 Hz or 90 to 265 Volts 60 Hz) using a three (3) core mains cable with a minimum cross section area of 1 mm<sup>2</sup>. This must be connected to the IEC Mains Connector (10) situated on the rear panel of the system's power unit.

Re-check that all connections have been carried out correctly.

Switch on the system with the Mains Switch (9) located on the rear panel.

The Sapphire Ultima IPL System will start up and perform its self-test routine; during this time the ring of green LED's flash on the front panel.



The self-test routine test the Sapphire Ultima IPL System for various fault conditions including the following:

- Correct Hand Piece (Applicator) is fitted.
- The DI Water Level
- Water Flow /no flow
- The Output IGBT's are good
- Capacitor charger operation
- Capacitor bank leakage/bleed function
- "E" stop

Should a fault be present during the self-test routine, a fault code number will be displayed on the front panel. The Power Unit will shutdown. The system will then need to be switched off via the Mains Switch on the rear panel to reset the system once the fault has been rectified to clear the fault condition. The self-test error codes are displayed in the partial shot counter display (26).



After performing the self-test and assuming no faults are found the internal pump will run continuously cooling the flash lamp. The pump only switches off during the self-test or when the "E" Stop is activated.

With the Key Switch (2) in the OFF position, the Sapphire Ultima IPL System will display only the total number of shot left for the flash Lamp, located inside the Hand Piece (Applicator). All the other displays will be blank.

Switching the Key Switch (2) to the ON position allows the Sapphire Ultima IPL System to be programmed with the required treatment parameters. NOTE: The Key Switch (2) does not actually isolate the Sapphire Ultima IPL System from the mains power.



With the Sapphire Ultima IPL System switched ON via the Mains Switch on the rear panel and the Key Switch (2) on the front panel in the ON position. The front panel will display the shots remaining (18) for the connected Handpiece/Applicator. The shot counter display (26) will display '0000'. The default settings are as follows:

- The Energy level will be set to 12
- Number of pulses to 3
- On time to 3
- Delay time to 3

The Sapphire Ultima IPL System can now be programmed with the treatment parameters required. The Energy level can be increased or decreased in stages of 2 using the up/down buttons. Note the Energy level is relative to the output energy pulses from the Sapphire Ultima IPL Power Unit and not the actual output of the Hand Piece (Applicator). The Sapphire Ultima IPL System's Power Unit will have a tolerance of  $\pm$  20 %.



Turning OFF the System

The System should be switched when no treatment is being undertaken. To do this, switch off the System using the Main Switch (2) located on the rear panel.



Step by Step

1. The System is switched on as described above section 5.1 The System is now ready for programming. During the System boot, and after a delay, the Hand Piece is identified by the system:

- Either the 610 nm (Red) for Photo-depilation.
- Or the 530 nm (Yellow) for Photo Rejuvenation.

2. To program the Energy Density required by increasing or decreasing it, simply press the corresponding up/down buttons (19 & 20).

According to the number of pulses or pulse times programmed, the Sapphire Ultima IPL System has a maximum amount of energy, e.g. if the energy density cannot be increased sufficiently it will be necessary to increase either the number of pulses or increase the pulse duration.

To decide which parameter to change please consult the table in section 7.1, which provides the relevant information.

3. The number of pulses is entered by pressing the Number of Pulses button (21) as shown in the diagram below. The Sapphire Ultima IPL System allows this to be set at 3, 5, or 7 pulses.



4. The Sapphire Ultima IPL System allows the choice of pulse durations of 3, 5 or 7 mS (Time on) again by pressing the Pulse Width Button (22) as shown in the drawing above.



5. Between each pulse, in a set of pulses, there is no emission time (Off time or delay). This varies between 3, 5, 7 & 9 mS. to select, all you need to do is press the Delay Time button (23).

To program different parameters please refer to table in section 7.1 of this User Manual. This table set out suggested parameters for use with different skin and hair colours.



6. The Sapphire Ultima IPL System includes two shot counters. The top display shows the total number of shots that the current Hand Piece's flash lamp has fired. The lower display shows the number of shots fired during the current treatment session. This counter will always be at "0" after switch-on. Should you wish to reset the counter to "0" during a treatment session (because you have started depilating another area) or that you are now treating a different patient ; and because you did not switch the system off between sessions, then all you need to do is press the Counter Reset button (25). This will reset the counter to "0".



7. Once all the parameters have been programmed, the Start/Stop button (24) can be pressed.

Now all you will observe is ring of green LED Lights (17) around the Start/Stop (24) button flash on and off in ascending order showing that the capacitors charging. This charge is then discharged by the flash lamp in the Hand Piece.



The reset button (25) returns the display to zero. You can then start the new treatment area, at zero.



Once the capacitors are fully charged and the system is ready to fire, there will be an acoustic warning signal Beep. Now the Sapphire Ultima IPL System is ready to be fired.

8. Before you start to depilate, please ensure everyone in the treatment room is wearing the recommended appropriate eye protection. Apply the cooling gel and then place the Handpiece (Applicator) to the area to be depilated. Then press the button on the side of the Handpiece (Applicator). The system will then fire, depilation has begun.



After each shot, the capacitors will need to charge up again, so it is necessary to wait a few seconds for this to occur. When the system is ready to fire again, it will again give you an acoustic warning signal. Each new shot overlaps the previous one by 10%, so as not to leave out any areas from the depilation treatment.



9. If needed the system can be shut down immediately by simply pressing the "E" Stop button (3). To restore normal working, simple twist the Red Button in the direction of the arrows. After this the On/Off Key Switch (2) must be switched to OFF, and then back to the ON position. To recover all the parameters that were on the displays, such as the partial shots made until the time of the "E" Stop shutdown with the I/O key off, meaning that to resume the treatment session it will be necessary to press the Start/Stop button (24) and wait until the capacitors have recharged.

#### ERROR MESSAGES

If an event occurs outside the normal operation of the system, the Sapphire Ultima IPL System will report this condition. This provides accurate data for trouble shooting purposes. Firstly switch OFF the system. Please refer to the following table for a description and solution for the various Error Codes:

Error Code	When does it appear?	Solution
	At Switch ON and During Operation	
1	Faulty IGBT outlet	Notify the Factory
	Overheating	Examine the system to ensure that the ventilation ducts are not blocked. Allow to cool down.
	Over voltage	Notify the Factory
	Output with low impedance value	Check Handpiece connections/ Notify the Factory
2	Water at minimum level	Check for leaks. Fill.
		Refer to maintenance and cleaning instructions
3	Minimum Water Flow	Check water tubes
	Power connector not connected	Check power connector
4	Cannot charge the capacitors	Notify the Factory
5	The capacitors cannot discharge	Notify the Factory
6	Problems in the Handpiece (Applicator)	Ensure the small connector is installed correctly. Lamp has failed.
7	Emergency Button	Check the emergency button

Table 2

#### **DEPILATION FORMS**

#### PHOTODEPILATION PROTOCOL (610nm FILTER)

#### DIFFERENT PARAMETERS FOR PHOTODEPILATION WITH 610nm FILTER

The settings for depilation depend on the area of the body that is to be treated. Should there be different coloured hair in the area to be treated, then the darkest one must be chosen. This is to ensure the elimination of the darkest and most visible hair. Once the type of skin (Pigmentation) and thickness of the hair have been established, set the Fluence (Energy Level) and the On and Off Times. The table below sets out the parameters to provide guidance for the different skin and hair types. These parameters can be modified and can be adapted to each individual client. It is advisable to start at lowest Fluence and increase according to the results obtained. As you notice in the table below, the initial Fluence and the Off Time are lower.

Off is increased when the skin type is dark and there is more pigmentation. Increasing the Off time allows the surrounding tissue to be protective as it has longer to cool in comparison to the hair.

Fitzpatrick	Hair	Hair	Fluence	No.	Time	Time
or Phototype	Colour	Thickness	J/cm <sup>2</sup>	Pulses	On mS	Off mS
Fair Skin	Light	Fine Hair	30	3	7	3
( II – III)		Thick Hair	28	5	5	5
	Dark	Fine Hair Thick Hair	26 24	3 5	7 5	3 5
Dark Skin	Light	Fine Hair	24	5	5	7
(IV)		Thick Hair	24	7	5	9
	Dark	Fine Hair Thick Hair	22 22	5 7	5 5	7 9

Table 3

#### PHOTODEPILATION WORKING PROCEDURE

Shave before depilating the area to be treated. (To reduce the treatment time, you could ask the client to shave or depilate one to two days earlier)

Use creams but never tweezers, wax or other methods that involve pulling out the hair). It is very important to cleanse the area well. Using a white pencil, (never a dark-coloured pencil as this will absorb the light and burn the skin) mark out the areas to be treated and those to be avoided (such as moles, etc). Apply an appropriate amount of cold gel from the refrigerator onto the area to be treated. This should be at least 0.5 mm thick. The gel assists to even out the skin, protecting it and reducing the side effects. Before you start depilating, everyone in the treat room must put on the recommended protective eye wear. Once you have programmed the Sapphire Ultima IPL System, the Handpiece with the Waveguide (Lightguide) is applied to the area to be treated, shooting and overlapping by 10% each time to ensure that the entire area has been depilated.

#### TEST AREAS

It is highly recommended that the qualified IPL THERAPIST conduct a small test depilation, always on the area to be treated. For example, if you are going to depilate the upper lip, it is useless to carry out the test on the arm, as the results will be irrelevant.

The test areas must always be performed on clients with darker skin (Type III or Higher) as there is a risk of hypo/hyperpigmentation (change of the skin colour in the test area) or in cases where there are doubts regarding the efficacy of the treatment.

In any event, even in the absence of risk factors, such as dark skin, when you start work you must do some test shots and wait a few minutes to see how the skin reacts. Adjust the programmed parameters as necessary before continuing with the treatment.

#### NUMBER OF TREATMENT SESSION NEEDED

As a general rule, between three (3) and eight (8) photo-depilation sessions will be needed, although this does depend on the area to be treated. The results obtained from more than eight sessions are not usual any better, i.e. you can depilate, but it will not decrease the percentage of growth. As the photodepilation advances, the hair follicle shrinks indicating that the hair growing back is finer and has less pigmentation, thus making it more transparent to the photodepilation process. This is why it is impossible to depilate 100% of the body hair. The purpose of photodepilation is to substantially reduce the density of the hair until a level is achieved that the client finds satisfactory.

A larger number of sessions may be necessary when depilating darker skin or lighter hair, as in these cases, the percentage of hair removed during a session will be lower.

#### DELAYS BETWEEN SUCCESSIVE SESSIONS

Due to the nature of the hair growth cycles, a certain number of sessions will be required to guarantee that the photodepilation covers the growth cycles of all the follicles. It is only during the growth, stage when the hair is present that the follicles can be successfully depilated.

It is recommended that the sessions are performed once the next growth stage has commenced, varying this according to the area of the body and the person. The growth cycle varies according to the part of the body, meaning the time to wait for the next session will be different in each case. Furthermore, growth cycles can vary significantly from person to person and according to the number of photodepilation that have been done. This basically means that it is up to the client to inform you when he or she requires the next session

Note: You must repeat the safety steps that you took in the first session and at all the following sessions; this is to ensure the best results at all subsequent sessions. Your client must advise the THERAPIST of any changes to their skin pigmentation that may have taken place. These changes need to be evaluated one by one, but generally an increased quantity of melanin in the skin means lower power (Fluence) levels should be used.

#### AFTERCARE

Immediate after each session, and at regular intervals in the case of depilating large areas, you should apply a soothing gel to the area, which preferably should contain Aloe Vera. These gels refresh the area, protecting the skin and damaged follicles.

You must warn the client against using make-up, fragranced soaps and similar products for a period of 24 hours following their photodepilation treatment. Likewise they must avoid exposure to the sun for approximately one (1) month, unless they use a high factor sun screen to prevent the risk of pigment changes.

#### **RESPONSE TO PHOTODEPILATION**

The immediate effect is the reddening (Erythema) in the treated area, particularly around the hair. This Erythema normally disappears after a few hours at most (and normally in a few minutes) with the skin recovering its normal colour. Clients must be warned that the hair remains in the follicle, as photodepilation, in contrast to other depilation systems, does not immediately eliminate the hair.

During the following days, the hair will appear to be growing, although more slowly than it did before. What is really happening to the hair is that it is no longer viable, but is being pushed out through the epidermis, which is still in close contact with the root. Provided it is not touched, the depilated hair will fall out naturally within one to three weeks, according to the depth of the hair's root. Should a client not wish to wait for the hair to fall out naturally, it can be removed manually (using tweezers) after four (4) to seven (7) days. It is important to know if the hair has been efficiently depilated. After a few days it should come out easily. If the hair feels as though it is plucked out when tweezed (the skin is pulled and there is pinching sensation) you must wait a few days longer. If after three weeks, the hair is still not coming out easily when pulled, this means that the photodepilation session was not effective, and the parameters used for that session should be adjusted. In any event, it is important not to remove the depilated hair too soon, as it acts as a barrier against infection.

#### **CLIENT MANAGEMENT**

The initial phase of the hair removal process consists of a consultation regarding the state of health (Anamnesis) and an examination of the hair. This ensures that there are no under lying medical conditions that would indicate that this client is not suitable for photodepilation. The client must also sign the Informed Consent Form prior to undergoing treatment.

The THERAPIST must carefully inspect the area to be treated and make notes of any marks or irregular pigmentation prior to performing the tests or depilation.

Photographs should be taken using a camera with a macro lens (most modern digital cameras have this feature). Take the picture position and with the same lighting to ensure equality during the depilation review phase. The photographs to illustrate the following:

- To provide the clinic with a record of all existing marks and pigmentation.
- The client will have a visual record of the density of the hair prior to photodepilation treatment.

Clients see themselves every day, and they tend to forget how thick their hair was prior to treatment, so photographs give them an opportunity to see the area before and after depilation sessions.

Check that all clients understand about hair growth cycles and that, it is only the hairs in the growth stage (the antigenic stage) that can be successfully depilated. Ensure that the client has realistic expectations, as this is an essential element for satisfactory depilation.

After a set of sessions, it is a good idea to review the area and check the results and evaluate the effectiveness of the photodepilation process. During this stage you can take any corrective measures that may need to be addressed. It may be necessary to modify the protocol. As a general rule, this examination should take place between 10 to 14 weeks after the first session.

#### **GENERAL ADVICE**

Check that the skin is not tanned and also and has not been subjected to the use of any self-tanning products. When you are depilating, check that the Handpiece (Applicator) is held perpendicular (90°) to the area being treated. Should the skin react strongly immediately after treatment, cool the area with a ice pack or similar cooling product (a bag of frozen peas or towelettes).

#### WORKING PROCEDURE FOR PHOTOREJUVENATION.

#### DIFFERENT PARAMETER INDICATIONS FOR PIGMENTATION (530nm YELLOW FILTER)

Once the skin pigmentation has been determined, set the Fluence together with the on and off times. Please refer to the table below to provide a starting point for the treatment. In any case, these parameters can be modified and will need to be adjusted for each client. It is prudent to start with low Fluence levels, increasing as necessary for optimal results.

Fitzpatrick	No. of Pulses	Time On mS	Time Off mS	Fluence J/cm <sup>2</sup>
Ι	3	5	3	30
II	3	5	3	30
III	3	5	3	28
IV	3	5	3	24

Table 4

#### PHOTOREJUVENATION WORKING PROCEDURE

It is very important to sterilise the area to be depilated. Never use a dark coloured pencil, as it will absorb the light and burn the skin.

Apply an appropriate amount of cold gel on the area to be depilated. The gel layer should be 0.5 mm thick. The gel helps to even out the skin, protecting it and lessening the side effects. Prior to starting treatment, please ensure everyone in the treatment room has put on the recommended protection eyewear. Once you have programmed the system, the Waveguide (Lightguide) is applied to the area to be treated. The therapist must shoot continuously ensuring that you have a 10% overlap, so that the complete area has been covered, so as not to leave any untreated areas.

#### TEST AREAS

It is recommended that the therapist carry out small tests, always on the area to be depilated. For example, if you are going to depilate the upper lip. It is of no use to conduct the test on the arm as this will totally irrelevant.

Test Areas must always be performed on clients with dark skin (Type III or higher) as there is an increased risk of hypo/hyperpigmentation (change of colour in the test area), in cases where there are doubts regarding the efficacy of the treatment.

In any event, even the absence of risk factors, such as dark skin, when you start work you must undertake some test shot, waiting a few minutes to see how the skin reacts. Adjust the programmed parameters as necessary prior to continuing the treatment.

#### NUMBER OF SESSION REQUIRED

In the case of pigmentation treatment, a single session may be sufficient. However this will be dependent upon the darkness of the pigmentation. This may indicate that more sessions maybe required.

Between six (6) and twelve (12) session are needed to treat small wrinkles, but again this will be determined by the severity of the wrinkles.

#### DELAYS BETWEEN SUCCESSIVE SESSIONS

For small wrinkles, it is generally recommended to wait one (1) week between sessions.

For pigmentation treatment, sessions can be repeated after fifteen (15) to twenty (20) days.

Note: You must repeat the safety steps that you took during the first session and also all subsequent sessions. This is to ensure that optimal results are obtained for the following sessions. The client must advise the THERAPIST about any changes that may have taken place.

#### AFTERCARE

Immediately after each session moisturizing cream can be applied. The use of antioxidants should be avoided for at least forty eight (48) hours. Once that time is up, Aloe Vera can then be applied.

You must warn the client against using any make up, fragranced soaps and similar products during the twenty four (24) hour period following the treatment. Likewise they should avoid exposure to the sun for approximately one (1) month, unless a high factor sunscreen is used to prevent the risk of pigment changes.

#### **RESPONSE TO PHOTOREJUVENATION**

The immediate effect is a slight reddening (Erythema) in the treated area. This Erythema normally disappears in a few hours (and normally in a few minutes) with the skin recovering its normal colour.

Pigmentations will increase its intensity and will darken. After some days, they will descale, leaving a pinkish skin. This new skin runs the risk of being pigmented again. Therefore it is important to protect it from exposure to the sun, advise them to use sunscreen lotions.

#### **CLIENT MANAGEMENT**

Client management should be performed in the same way as described for Photo Depilation.

#### **GENERAL ADVICE**

Follow the same advice described for Photodepilation.

## **INFORMED CONSENT**

#### INFORMED CONSENT FOR PHOTODEPILATION WITH THE SAPPHIRE ULTIMA IPL SYSTEM

This document has been prepared to inform you about hair removal via Photodepilation techniques which utilises pulsed light, its method of application, possible risks, and alternative therapies.

It is very important that you read this information carefully and completely, in order that you understand it. Please ask any questions or doubts that you may have prior to finally signing this consent form for the proposed Photo-Depilation treatment using pulsed light as explained above.

Date	on	20
Mr./Mrs		
	has received this verbal as	nd written information from:
Mr./Mrs		
	On be	half of the Treatment Centre
		Company Stamp.

#### **INTRODUCTION**

Photo-depilation with pulsed light is a technique that has been used to achieve the progressive depilation of body areas with excess or unwanted hair.

Prior to starting the treatment, it is important to wait for period of time (15 to 25 days) during which time unwanted hair must not be removed by pulling (e.g. using wax, tweezers etc). During this period you may shave or cut the hair you wish to remove. After this waiting period, you may start treatment using Photo-Depilation.

Exposure to the sun, this also includes sun beds, and artificial tanning products must be avoided for a period of two (2) to four (4) weeks before and after depilation session with pulsed light. After depilating the area, the use of sun filter and sunscreens is recommended to protect the area treated.

The treatment consists of shaving the area and then applying shots of pulsed light covering the surface to be treated. The treatment area will be covered with cooling gel prior to applying the pulsed light.

The best hair for depilation with pulsed light is black or dark hair on a white or fair skin. In cases where the hair is lighter and/or darker skin, the qualified depilation THERAPIST will adjust the dosage accordingly to achieve a satisfactory result. Pulsed light is contra-indicated for clients with fair hair on dark skins, it just not worthwhile.

The time between two consecutive sessions changes based upon the body area, but the average time will be six (6) weeks.

The number of sessions required to complete the treatment changes substantially based on multiple factors (hair colour, skin colour, body area....), but on average it ranges from six (6) to eight (8) sessions.

Various benefits are obtained with this technique: after the first few sessions, it can be observed that the hair re-growth time becomes increasing longer. It is also seen that the percentage of re-growing hairs are increasing lower and that the new hairs become weaker and thinner. As an average, at the end of the treatment, a large percentage of hair can be removed with the remainder having been transformed into weaker, thinner hairs. However it is important to point out that in very few cases, hair growth can actually be stimulated.

#### ALTERNATIVE TREATMENT

There are many different alternative methods of treatment:

- Classic techniques such as shaving, tweezing, wax, depilatory creams
- Use of chemical products with weakening action used in combination with classic techniques to enhance their results.
- Electrical depilation techniques require patience, since this is hair by hair depilation.
- This technique is slightly more uncomfortable than others, but can result in complete removal of the hair from the area.

#### **RISKS OF DEPILATION WITH PULSED LIGHT**

Depilation with pulsed light is considered to be a safe procedure, with very few side effects, However as with any procedure, it does involve some degree of risk and it is important that you understand the risks associated with the photo-depilation procedure. The actual decision to receive treatment lies with you, the client and should be based on assessing the risk against the potential benefits. Complications do not occur in most people having undergone treatment. Please discuss the following list to assist with the client's better understanding:

**Pain:** The feeling of discomfort or possible pain varies a great deal, depending upon the individual and the area, but techniques such as applying cold compresses can be used to minimise this discomfort.

**Erythema:** It is quite common for the skin to redden slightly after exposure to pulsed light depilation. This is a transient stage that will disappear after a few hours.

**Vesicles or blisters:** The appearance of vesicles or blisters is not all common, but may occur in some types of skin or as an exaggerated skin response( with greater frequency in recently tanned people).

**Burns:** The appearance of burns is very rare and may be due to skin hypersensitivity or an excessive dose for this type of skin (although two skins may look the similar and a similar dose may be considered, sometimes the skin response is different).

**Pigmentation disorders:** Pigmentation changes either as hypochromias (light spots) or hyperchromias (dark spots) are uncommon events that may be related to the previous appearance of burns, during previous or subsequent exposure to son or personal inherent risks of pigmentation in some people. These events are generally transient and disappear of their own accord over time. To minimise the risk, it is recommended to avoid exposure to the sun or artificial tanning for at least two (2) to four (4) weeks before and after depilation.

IT IS IMPORTANT THAT YOU HAVE CAREFULLY READ THE ABOVE INFORMATION AND THAT ALL QUESTIONS HAVE BEEN ANSWERED BEFORE YOU SIGN THIS CONSENT FORM.

#### CONSENT TO DEPILATION WITH PULSED LIGHT

I hereby authorise\_\_\_\_\_

and/or his/her chosen assistants to apply the pulsed light depilation treatment using the Sapphire Ultima IPL System

I have read and understood the above information, and have been duly informed and that my doubts have been resolved, during the course of the personal interview held on Date\_\_\_\_\_\_20\_\_\_\_

I have been asked whether I need any more detailed information, but I am satisfied with the explanations and do not require any additional information. I personally accept each and every of the foregoing risks that could occur as a result of the application of the above treatment. I declare that I have not omitted or changed any data when providing my past medical or clinic-surgical history, particular with regard to allergies, diseases, medication or personal risks.

I hereby GIVE MY CONSENT to receive the photodepilation treatment with the Sapphire Ultima IPL System.

I understand that I may withdraw this consent at any time before this procedure has been completed.

For the record, I now sign this consent document.

Date\_

\_on\_

\_20\_

## INFORMED CONSENT FOR PHOTOREJUVENATION WITH THE SAPPHIRE ULTIMA IPL SYSTEM

This document has been prepared to inform you about Photorejuvenation (spots and wrinkles) with the Sapphire Ultima IPL System, variable pulsed light equipment, its method of application, possible risks, and alternative therapies.

It is very important that you read this information carefully and completely, in order that you understand it. Please ask any questions or doubts that you may have prior to finally signing this consent form for the proposed Photo-Rejuvenation with the Sapphire Ultima IPL System.

Date	on	20
Mr./Mrs		
	has received this verbal and written infor	rmation from:
Mr./Mrs		
	On behalf of Trea	atment Centre
	Con	npany Stamp.

#### **INTRODUCTION**

Prior to starting the treatment, exposure to the sun, this also includes sun beds, and artificial tanning products must be avoided for a period of two (2) to four (4) weeks before and after a session with the Sapphire Ultima IPL System using pulsed light. After the session it is recommended, the usage of sun block lotions and sunscreens which will protect the area treated,

Light interacts with the skin pigments, heating up excessive pigmentation accumulated in the hyper pigmented zones, destroying it and being expelled from the body or removed from the body or removed by the body's defense cells. Skin type as well as hyper pigmentation characteristics will guide the therapist when choosing the best suited parameters for the treatment. In wrinkle treatment, light stimulates collagen and elstin formation in the skin cells. Wrinkle treatments usually performed in six (6) to twelve (12) sessions, with frequency of two (2) sessions per week. In pigmentation treatment, it may be necessary to perform more than one (1) session, depending on the severity of the case.

The benefits obtained through this technique are several: this is a non-invasive and highly effective technique. Nevertheless, you should not forget that skin aging is speeded up by exposure to the sun.

Therefore it is necessary to take care of the skin, using sunscreen lotions or reducing ones exposure to the sun.

#### ALTERNATIVE TREATMENT

- There are many different alternative methods of treatment:
- Cosmetics
- Peeling (mechanical or chemical)
- Combination of previously mentioned methods.
- Surgery

#### RISKS OF PHOTOREJUVENTAION WITH SAPPHIRE ULTIMA IPL SYSTEM

Photo-rejuvenation with the Sapphire Ultima IPL System is considered to be a safe procedure, with very few side effects, However as with any procedure, it does involve some degree of risk and it is important that you understand the risks associated with the photorejuvenation procedure. The actual decision to receive treatment lies with the you, the client and should be based on assessing the risk against the potential benefits. Complications do not occur in most people having undergone treatment. Please discuss the following list to assist with the client's better understanding:

**Pain:** The feeling of discomfort or possible pain varies a great deal, depending upon the individual and the area, but techniques such as applying cold compresses can be used to minimise this discomfort.

**Erythema:** After a photo-rejuvenation session with the Sapphire Ultima IPL System, it is quite common for the treated spots turn a darker colour, indicating that the treatments effective. As time goes by, the spot descales leaving a visible pinkish skin. It is very important to protect this new skin from exposure to the sun, during this period runs the highest risk of presenting hyperpigmention.

**Vesicles or blisters:** The appearance of vesicles or blisters is not all common, but may occur in some types of skin or as an exaggerated skin response. It is important to note that their appearance will e much more likely to occur in persons recently tanned, and consequently you should inform the therapist about any recent exposure to sun or UVA.

**Burns:** The appearance of burns is very rare and may be due to skin hypersensitivity or an excessive dose for this type of skin (although two skins may look the similar and a similar dose may be considered, sometimes the skin response is different) and/ or a recent exposure to sun radiation or UVA.

**Pigmentation disorders:** Pigmentation changes either as hypochromias (light spots) or hyperchromias (dark spots) may occur, but will disappear after some time. However, they may last longer or even become permanent in cases where burns have appeared during previous or subsequent exposure to the sun or a personal inherent risk of pigmentation in some people. To minimise the risk, it is recommended to avoid exposure to the sun or artificial tanning (including sun beds)

**People taking medication:** It is very important to notify the therapist if you are taking any medication. Some drugs may produce photosensibilisation reactions when pulsed light is applied to the skin. As a result, it is not possible to perform any treatment with the Sapphire Ultima IPL System whilst taking certain types of drugs.

IT IS IMPORTANT THAT YOU HAVE CAREFULLY READ THE ABOVE INFORMATION AND THAT ALL QUESTIONS HAVE BEEN ANSWERED BEFORE YOU SIGN THIS CONSENT FORM.

#### <u>CONSENT FOR PHOTOREJUNVENATION</u> (SPOTS AND WRINKLES) WITH THE SAPPHIRE ULTIMA IPL SYSTEM

I hereby authorise\_

and/or his/her chosen assistants to apply the pulsed light photorejuvenation treatment using the Sapphire Ultima IPL System.

I have read and understood the above information, and have been duly informed and that my doubts have been resolved, during the course of the personal interview held on Date\_\_\_\_\_\_20\_\_\_\_

I have been asked whether I need any more detailed information, but I am satisfied with the explanations and do not require any additional information. I personally accept each and every of the foregoing risks that could occur as a result of the application of the above treatment. I declare that I have not omitted or changed any data when providing my past medical or clinic-surgical history, particular with regard to allergies, diseases, medication or personal risks.

I hereby GIVE MY CONSENT to receive the photorejuvenation treatment with the Sapphire Ultima IPL System.

I understand that I may withdraw this consent at any time before this procedure has been completed.

For the record, I now sign this consent document.

Date		on	_20
Signature of client	Signature of the	apist	

#### **CLEANING AND MAINTENANCE**

The cleaning and maintenance of the Sapphire Ultima IPL System is very important both to lengthen the life of the system and to avoid problem during depilation sessions.

#### **GENERAL CLEANING**

It is essential to clean the Hand Piece (Applicator) between sessions, as this reduces the danger of transmitting infections. The left over gel can also affect the integrity of the pulsed light.

- Any remains of the gel must be carefully removed from the Wave Guide (Light Guide), using a towelettes or some other disposable material.
- Then carefully clean the Wave Guide with a good quality lens tissue that does not have a silicon impregnation.
- DO NOT USE abrasive products.

#### MAINTENANCE

The therapist must visually examine the system before use. This inspection is to check that there are no signs of wear and tear, cracks or damage to the cabinet, the power cable, the Waveguide (Lightguide), the Handpiece (Applicator) or the Umbilical cord.



Figure 21

#### CHANGING FUSES

Should the Sapphire Ultima IPL System not switch on when you activate the Mains Switch on the rear panel, check that the fuses are in good order. Please proceed as follows:

- Disconnect the power cord from the wall socket.
- Using a small screwdriver to loosen the fuse holder caps (there are two)
- Check that they are in good condition.
- Should they be found to be deflective, REPLACE THEM WITH FUSES OF IDENTICAL RATINGS. ( 8 Amp Time delay fuses)
- Be careful to replace them correctly.

Switch on the system, should the Sapphire Ultima IPL System not switch on, contact Laser S.O.S. Aesthetics Ltd.



Figure 22

#### CONNECTING AND DISCONNECTING THE HANDPIECE (APPLICATOR)

Please ensure that you have switched off the Sapphire Ultima IPL System at the main's wall socket. When switching the system either ON or OFF, ALWAYS USE THE ON/OFF SWITCH MOUNTED ON THE REAR PANEL.



Figure 23

Figure 24

#### DISCONNECT THE SYSTEM AS FOLLOWS:

- Unlatch the clamp, and remove the large rectangular connector assembly.
- Now remove the two connectors for the cooling water by pressing gently on the metal election tabs and withdraw the connector.
- Just reverse the procedure when you wish to reconnect the Handpiece (Applicator)

#### FILLING THE COOLING SYSTEM

Should the system display an Error Code 2, this indicates that the DI Cooling Water level is very low and that the system must be topped up. To top up or refill the system, proceed as follows:

- Please ensure the cover of the drain has been removed.
- Connect the tube with the funnel to the fill (6) connector on rear panel.



Figure 26 • Top up or refill with Deionised Water (DI Water)

Figure 27

• Continue filling until water is visible at the Blue Overflow (11) on the rear panel

Please refer to the full filling instructions: "Filling instructions for the Sapphire Ultima IPL System" included with the filling kit.



After filling, reconnect the power etc. Switch on the system, so that the system can begin its test routine. Should Error Code 3 appear, switch the system On and Off three (3) or four (4) times to eradicate any air-locks.

Should the Error Code still persist, notify Laser S.O.S. Aesthetics Ltd.

#### TECHNICAL SPECIFICATIONS

#### <u>General:</u>

Manufacturer:	Laser S.O.S. Aesthetics Ltd
Model:	Sapphire
Classification:	Class II Type BF according to EN 61010-1
Electrical Voltage:	AC 100 to 230 Volts, 50/60 Hz
Fuses:	2 x 8 Amp Time Delay
Power:	800 VA

#### Mechanical:

Dimension of system without Handpiece:	450 mm (L) x 420 mm (W) x 220 mm (H)
Dimension of Transit Case:	510 mm (L) x 740 mm (W) x 320 mm (H)
Weight without Handpiece:	15.8 Kg
Weight with Case and Handpiece:	25.6 Kg

System Parameters:

Fluence (Energy Density):	530 nm Handpiece: 40 J/cm <sup>2</sup> (Yellow)
	610 nm Handpiece: 36 J/cm <sup>2</sup> (Red)
	Tolerance of ± 20%
Number of Pulses:	3 / 5 or 7
Pulse width:	3 / 5 or 7 mS
Duration between pulses:	3 / 5 / 7 or 9 mS
Spectral Output:	530 nm Handpiece: 530 to 1000 nm
	610 nm Handpiece: 610 to 1000 nm

## Environmental Specifications:

Operating Temperature:	5° C to 40 ° C
Storage Temperature:	5° C to 85° C
Relative Humidity:	75% non-condensing

## **GLOSSARY**

#### Biocompatibility:

The absence of allergic reactions, immune reactions, etc when coming into contact with body tissue and the materials to which they are applied.

#### Dermal Papilla:

A very small protrusion in the root of the hair that is thought to be one of the main objectives for permanent hair removal.

#### **Energy Density:**

More commonly referred to as Fluence. See below.

#### **Electromagnetic Spectrum:**

Covers the Ultra Violet (UVA, B & C) Wave, the Visible range, the Infra Red Spectrum (IR), X-rays, Radio Waves etc. The IPL primarily uses the Visible Spectrum (VIS).

#### Erythema:

Diffuse reddening or spots on the skin produced by capillary congestion, which disappears momentarily when pressure is applied.

#### Fluence:

This is the term used to measure the Energy Output of an IPL System It is measured at the output of the Waveguide of the Handpiece. The unit of measurement is J/cm<sup>2</sup> (Joules per square centimeter). This unit is also used for all pulsed laser systems. It is the same as Energy Density.

#### Follicle:

A crypt or sac in the form of a gloved finger in a mucosa or skin, generally with secretion functions.

#### Gel:

Dispersion of water composites that give particular, gelatinous consistency. In photodepilation, it is used to even out the surface of the skin to be depilated, cooling and protecting it; thus keeping side effects to an absolute minimum. This also ensures the integrity of the interface between the Quartz Crystal output of the Waveguide (Lightguide) and the skin. Should one not have a good interface here, it will be detrimental to the treatment.

#### Hair Follicle:

The structure of the skin in which the hair develops, grows and emerges to the exterior.

#### Hair growth cycle:

The hair grows through a series of cycles known as the Anagenic stage (growth stage), Catagenic stage (resting stage), Telogenic stage (inactive and subsequent fall)

#### Hyperpigmentation:

The darkening of the skin caused by melanocytes hyperactivity. These can be freckles caused by the sun or melasma.

#### Hyperpigmentation:

Whitening of the skin caused by the absence of melanocytes. Vitiligo is an example of hypopigmentation.

#### J/cm<sup>2</sup>:

Joules per square centimeter, this is the unit of Fluence or Energy Density see above under Fluence.

#### Joule:

The Unit of Energy. This is a measure of pulsed energy and is applicable the Intense Pulsed Light (IPL) output.

#### Lamp:

The Handpiece is fitted with the Flash Lamp. The lamp comprises a glass tube filled with an inert gas under high vacuum. When a current is passed through the lamp, the gas reacts and an intense pulse of light is emitted. This also has a wide spectral output bandwidth.

#### Light Pulse:

The bundle of light energy that is emitted from the pulsed light source. This normally only lasts for a few milliseconds (mS). The pulses can be subdivided into several sub-pulses. This is a typical scenario for pulsed light systems.

#### Melanin:

The natural pigment that gives colour to both the hair and the skin and acts as a chromophore. This is necessary for the efficacy of photo-depilation, as the molecule that absorbs and transforms the light energy into heat.

#### Mircopigmentation:

Permanent make-up techniques using tattooing or derma-pigmentation techniques.

#### mS.:

A millisecond is one millionth of a second, corresponding to the time during which the pulse or pulses of light are emitted during depilation.

#### nm:

The unit of wavelength for light is the nanometer. This determines the distance of the energy and colour of the light emission. Therefore a light of 400 nm (blue) is more energetic than the output at 600 nm (red).

#### Photodepilation:

The use of light to remove body hair, by using the Intensed Pulsed Light.

#### Photorejuvenation:

The use of light to combat the signs of ageing, such as age related spots or small wrinkles.

#### Photosensitisation:

Sensitivity of an organ to light, generally due to taking or applying a chemical substance. This manifests as an inflammatory reaction to zones exposed to light.

#### Photosensitising:

See below under Photosensitor.

#### Photosensitor:

This is a substance that increases the skin's sensitivity of light radiation.

#### Phototype:

This is the classification of the skin's colour according to its reaction to the radiation from the sun. The Fitzpatrick scale is the most frequently used for skin classification.

#### **Pulsed Light:**

The emission of a non-coherent source of light (not with pulsed light) with a wide bandwidth (large spectrum) in the form of short pulses with a typical duration of a few milliseconds (mS).

#### Power Meter:

This device is used to measure the Fluence/Energy density output of the IPL System. Power meters are able to measure light outputs either in continuous or pulsed modes. In continuous mode (CW), the unit of measurement is in Watts, whereas for pulsed systems, such as the IPL and some Lasers, the unit of measurement is in Joules per square centimeter (J/cm<sup>2</sup>).

## TROUBLE SHOOTING

The user can resolve the following malfunctions:

- The pilot light inside does not illuminate.
- Change the fuses.
- Replacement of the power cord.
- Refilling or topping up the cooling system.

When the system is started by the mains switch, mounted on the rear panel, and the pilot light does not illuminate, there is a high probability that either one of both fuses also mounted on the rear panel may have blown. To replace them proceed as follows:

- Isolate the system from the mains by unplugging the mains wall socket.
- Remove the cap from the fuse holder with screwdriver or similar tool.
- Examine the fuses, look inside the glass fuse, is there a wire inside? Should this be missing the fuse(s) need to be replaced. Sometimes the fuses will be totally black inside, this would indicate that they have blown. This very often indicates that a serious failure has occurred. The fuses are 8 Amps each with a Time Delay (8 AT).
- Replace the fuse holder by pressing them inwards.
- Reconnect the power cord and switch on. Check that the system is operating correctly.

NOTE: A fuse may blow for various reasons: one possibility is that a component failure has occurred. If, after replacing the fuses, the system does not work, contact Laser S.O.S Aesthetics Ltd.

Should the power cord be defective, the user can change it taking into account that the new power cord must have the same ratings as the original, 1 mm<sup>2</sup> cross section.

To fill the cooling system, please refer to the filling procedures described earlier under "Filling the cooling system".

## DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY				
Manufacturers Name:	Laser S.O.S. Aesthetics Ltd	Laser S.O.S. Aesthetics Ltd		
Manufacturers Addre	ss: Unit 3 Burrell Road, St Ives Indu	Unit 3 Burrell Road, St Ives Industrial Estate,		
	St Ives, PE27 3LE, Cambridgesh	St Ives, PE27 3LE, Cambridgeshire, UK.		
Declares that the product: Electro-cosmetic				
Name of product:	Sapphire Ultima IPL System	Sapphire Ultima IPL System		
Brand:	Laser S.O.S. Aesthetics Ltd	Laser S.O.S. Aesthetics Ltd		
It has been manufactured under the following technical specifications:				
Meets the intent of low voltage directive 2006/95/EC and EMC directive 2004/108/EC. Compliance is claimed by the application of the following specifications which have been published in the Official Journal of European Communities.				
Safety: EN 61010-1 (2010) Installation Category II, Pollution Degree 2				
Electromagnetic Compatibility:				
Emission: E	EN 55011 Radiated and Conducted	EN 61000.3.2 Harmonics		
I	EN 61000.3.3 Flicker			
Immunity: F	EN 61000.4.2 ESD EN 61000.4.4 Fast Transients EN 61000.4.6 Conducted RF EN 61000.4.8 Magnetic Field EN 61000.4.11 Voltage Dips.	EN 61000.4.3 Radiated EN 61000.4.5 Surges		
Signature				
Antoni Waldemar Koszykowski				