



LUMINA

Intense Pulsed Light (IPL) and
Laser Technology
**TREATMENT
PROTOCOL**

TP01 : Issue 14 : 15/08/19



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Treatment Protocols

Lynton LUMINA® System

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1. INTRODUCTION AND TECHNICAL SPECIFICATIONS

The object of this document is to supply an Expert Treatment Protocol for the use of the LUMINA® System in the treatment of unwanted hair, the removal of benign vascular and pigmented lesions, tattoo removal and photo-rejuvenation (including acne and Combination Facial Therapy treatments). It is not intended to be prescriptive, or in any way replace thorough training; rather it is intended to be used as a constant point of reference that will be updated periodically.

The standard LUMINA® System is an Intense Pulsed Light (IPL) source manufactured in the UK by Lynton Lasers Ltd. It emits non-coherent broadband light, delivered via a series of millisecond pulses separated by a variable pulse delay. The light is filtered to emit wavelengths which vary depending upon the attached handpiece. The most commonly supplied filters have wavelength bands of 550-1100nm and 625-1100nm.

In addition to the various intense pulsed light handpiece applications the LUMINA® System also has the option of being fitted with a Long-Pulsed Nd:YAG laser option, for treatment of deeper vascular lesions such as leg thread veins and a Q-Switched Nd:YAG laser for the treatment of tattoos and pigmented lesions. The treatment pen allows at least three different spot sizes to be utilised in treatment and a red aiming beam guides the user over the target region.

LUMINA® IPL Specifications

Pulse sequence duration	10 - 350ms
Pulse sequencing	1 – 6 pulses
Pulse Delay	10 – 50ms
Maximum Fluence	50J/cm ²
Repetition rate	0.4Hz
Spot sizes	5.0, 2.5, 1.0 cm ²

Long Pulsed Nd:YAG Laser Specifications

Wavelength	1064nm
Repetition rate	up to 2.0Hz
Spot sizes	3 to 8 mm (depending on model)
Maximum Fluence	400 J/cm ²
Delivery	Fibre Optic, articulated arm or handpiece attachment

Q-Switched Nd:YAG Laser Specifications

Wavelength	1064nm or 1064/532nm mixed
Pulse duration	7-10ns
Spot size	2mm to 5mm in 1mm intervals
Max Energy (1064nm)	500mJ
Max Energy (532nm)	250mJ (with 250mJ @ 1064nm)
Repetition rate	0.6 - 5Hz

Fractional Er:YAG Laser Specifications

Application	Gentle and Deep
Laser Type	Er:YAG (2940nm)
Pulse Duration	350 µs
Fluence	0.42J/cm ² (Gentle), 0.9J/cm ² (Deep)
Spot Size	10 mm
Rep Rate	1Hz

2. PRE-TREATMENT DOCUMENTATION AND TESTS

Each client should be provided with written information about the treatment and undergo a thorough consultation and test patch before treatment commences. During the consultation a full medical history will be taken and discussed in private. The treatment will be fully explained and any special circumstances applicable to the client will be noted. Ask the client about each contraindication individually and mark each one with the client's reply. If the client answers 'yes' to any of the listed contra-indications, document in full on the consultation form. Act on the directions listed for that condition (i.e., do not treat). After a medical history is obtained it is important to also:

- Reassure the patient of the high quality medical attention they will receive.
- Assess the condition to be treated. For example, hair thickness and colour will need to be assessed for hair removal treatments, whilst lesion type, colour and size will have to be noted for pigment and vascular treatments. In the case of tattoos this includes whether the tattoo is professional or amateur, what colour pigments are involved, and whether any existing scar tissue is present.
- Show examples to the patient of the likely results of treatment. Answer any questions the client has regarding treatment and make sure the client has *realistic expectations* of the outcome of the treatment. Explain that multiple treatments will often be required. The client should be informed that 100% clearance can not be guaranteed and the effectiveness of treatment is related to skin/hair type and/or tattoo pigment colour.
- Explain the treatment process to the client. Discuss pain control and aftercare. Possible side effects of treatment should be discussed in detail.
- Explain the hazards of Intense Pulsed Light / laser radiation and the need for appropriate goggles to be worn at all times.
- Carefully record the client's reaction to sun exposure and assign skin type using the Fitzpatrick Scale.
- Provide estimates of the total cost of treatment and methods of payment.
- Photograph the treatment site for the client's records.
- Answer any questions that the client might have and record client comments.
- Ask the client to read, sign and date the consent form if he/she has understood its contents. Countersign the consent form and give the client a copy if requested.

CONSENT POLICY

Informed consent is a legal and medically imperative document that must be obtained before commencing any physical examination, treatment or personal care for a patient. The practitioner providing the treatment shall be responsible for ensuring that the patient has given valid consent before treatment begins.

Patients need sufficient information concerning the benefits, risks, alternative treatments, expected outcomes and fees before they can decide whether to give their consent. If the patient is not offered as much information as they reasonably need to make their decision, and in language they can understand, their consent may not be valid. A Health Questionnaire and Contractual Agreement to LASER or ILS Skin Treatments / Consent Form is used for this purpose.

Prior to any examination, skin test patch or treatment, every adult patient is required to provide informed consent to LASER or ILS treatment. If, as the responsible therapist, you have doubts about their competence, the question to ask is: "Can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent but may indicate a need for further information or explanation.

Consent must be given voluntarily: not under any form of duress or undue influence from therapists, family or friends. Check your facility's policies and procedures concerning who can obtain the consent and the required documentation defined by your scope of practice. It is good practice to maintain contemporaneous hand-written notes to amplify advice. A signature on a consent form does not itself prove the consent is valid - the point of the form is to record the patient's decision - and also increasingly the discussions that have taken place.

Before examining, test patch procedure or treating a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. In other cases, someone with parental-responsibility must give consent on the child's behalf.

Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your treating them.

If the client is suitable for treatment continue with patch-testing. A patch test must be performed on or as near as possible to the area prior to any course of treatment.

3. PATCH TESTING

- Patch testing must be carried out on all patients before treatment commences. If a new condition or area is to be treated on someone who has had prior treatments, a patch test must still be carried out in the new treatment area.
- The test patch should always be carried out using the wavelength/handpiece that is to be used in treatment. If a client has previously been treated with one wavelength/handpiece (for example the 650 handpiece), but is about to commence treatment using a different wavelength/handpiece (for example the 585 or 650 advance handpiece), it is still necessary to re-test patch with the new wavelength/handpiece.
- The aim of the test patch is to determine the most effective fluence settings for the patient skin type and lesion type, without causing any adverse reactions.
- Treat a small area, in the area to be treated. The area to be treated needs to be clean and devoid of cosmetics and creams.
- Client, operator and anyone else in the room must ensure that appropriate eyewear is worn before treatment commences.
- The treatment block being used for the treatment should also be used for the IPL test patch. The light guide should be placed gently onto the area being treated. The Nd:YAG handpiece must be held perpendicular to the surface being treated with the appropriate spacer touching the skin.
- The patch test should be carried out at the fluence suggested by the LUMINA® Systems for a given skin type, and increased until the appropriate skin reaction occurs.
- Treatment should be ceased if contra-indications occur.
- Clients must be given clear instructions on post IPL/laser skin care, in particular, sun avoidance and avoidance of injury to the skin.
- Details of the treatments performed should be accurately recorded in the client's record. The entry should be signed and dated.
- If the area to be treated only requires one or two shots (for example, a small spider naevus), then treatment can go ahead without a test patch if desired.

4. CONTRA-INDICATIONS

Do not treat anyone who has:

- Tanned skin (real or artificial)
- Skin Pigmentation problems such as melasma (in or near the treatment area)
- A history of keloid scarring
- Pregnancy and Breastfeeding
- Severe photosensitive skin
- Epilepsy within the last 12 months
- Skin Cancer or other malignant disease
- Cancer in last 2 years

- Any active inflammatory skin condition e.g. eczema, psoriasis, Herpes Simplex in the treatment area
- Healing disorders such as those caused by Diabetes Mellitus, connective tissue disease (e.g. lupus), radiation therapy or chemotherapy
- Porphyria
- Patients with unrealistic expectations, or who are unlikely to follow post treatment guidelines
- Immune / lymphatic system disorders
- Do not treat over any tattoos, semi-permanent make-up or moles with the IPL or long pulsed Nd:YAG (these can be covered with a white pencil if required). Pay particular attention to the presence of eye-liner, lip-liner or other cosmetic tattoos in the area being treated which may not always be obvious.
- Only treat semi-permanent or cosmetic tattoos with the Q-Switched laser after careful test-patching. Be aware that there is a high risk of permanent colour change when treating these pigments
- Used St John's Wort, minocycline or amiodarone in the past month
- Used Isotretinoin (Roaccutane or Retin-A) or any drugs for Photodynamic Therapy (PDT) in the previous 6 months
- Used topical retinoids such as Tretinoin, (Retin-A, Aknemycin Plus,) Isotretinoin (Isotrexin), Adapalene (Differin) in the last two weeks on the area to be treated
- Used high dose systemic steroids in the past month
- Used topical steroids in the past week (in or near the treatment area)
- Has ever had a gold salt injection for the treatment of arthritis

Careful test patching should be carried out before treating anyone on any photo-sensitising medication in line with the British Medical Association Guidelines.

A GP letter should be requested before treating anyone where you are uncertain about any medical condition.

5. TREATMENT TECHNIQUE

Following consultation and having obtained written consent, it is important to follow a set routine at all treatment sessions. The regime advocated is as follows:

- Ask the patient if they have had any change in their health or medications since the last treatment or test patch. Ensure that the patient has not had any sun exposure in the area to be treated.
- Closely examine the area to be treated. Identify any signs of scarring, marks or underlying skin disorders such as eczema. If there are any broken areas or pustules the treatment should be delayed until the area has completely healed.

- The area to be treated needs to be thoroughly cleansed ensuring all make up, body lotions, deodorants and daily pollution is removed from the skin
- The area being treated can be marked with a white eyeliner pencil.
- It is recommended that the area to be treated is photographed together with the patient's identification number. Before and after photographs taken at each treatment session will allow progress to be demonstrated.
- Ensure the patient is comfortable and all safety precautions have been followed before commencing treatment.
- The patient and any visitors should be provided with suitable goggles for the wavelengths being used. Not all goggles offer protection at all wavelengths and it is essential therefore that the proper goggles are provided. The operator should put on his or her own appropriate goggles before commencing treatment.
- The operator should select the appropriate IPL handpiece or the laser and set the fluence, number of pulses, delay and spot size (for Nd:YAG treatments only). When using the Nd:YAG laser, ensure that the handpiece is set for the same spot size as the control panel.
- When treating tattoos, the wavelength is set according to the colour of the tattoo pigment being treated. Blue/Black tattoos will generally be treated using the 1064nm output, while red tattoos will be treated with the 532nm output. Yellow, orange and brown tattoos may also respond to this wavelength, although the results can be variable. For treatment of green tattoos, a Ruby laser will be required. The pigment used in the application of tattoos is not standard and therefore the above instructions should be used as a guideline only.
- The treatment area should be cooled before, during and after treatment to improve client comfort, reduce post-operative erythema and permit the use of higher fluences.
- The patient can now be treated, taking care to ensure that the patient remains comfortable at all times. If the patient cannot tolerate the treatment then the treatment should be stopped and methods of pain control discussed.
- Details of the treatments performed should be accurately recorded in the client's record. This should include wavelength, fluence, pulse sequencing, spot size and number of shots fired. The entry should be signed and dated.

6. HAIR REDUCTION WITH THE 650 AND 650 ADVANCE™ HANDPIECES

The object of hair removal treatment is to target the melanin of the hair and cause heating of the hair follicle, without excessive collateral damage to the surrounding tissues. The parameters should be set according to the hair and skin type of the client, with lighter skins being able to tolerate higher fluences than darker skin types. The LUMINA® System gives suggested starting parameters for different skin types and hair colours, and automatically increases the number of pulses and delay in-between pulses for darker skin types, in order to ensure that the light is delivered to the skin in a non-aggressive fashion. All clients should be test-patched before treatment

commences, but this is particularly important for the treatment of skin types IV and V, who should be treated at settings considerably lower than those used for fairer skins.

For hair reduction treatments with the LUMINA® System, the area to be treated should be shaved leaving stubble no longer than 1mm in length. A thin layer (1-2mm) of cold, clear gel applied to the skin before treatment. White, grey or very fair vellus hair will not respond and should not be treated

Observable end points may include mild patient discomfort (likened to an elastic band flicking of the skin), peri-follicular oedema and mild to moderate erythema of the area. This erythema response is transient and should resolve in all cases within 1-24 hours. Severe erythema or discomfort may suggest over-treatment. After treatment the area should be cooled and a soothing lotion (such as aloe vera) can be applied.

Multiple treatments are required for optimum results. Complete 100% hair loss is unlikely, although any hair that remains should grow back more slowly and be thinner and lighter in colour.

7. SKIN REJUVENATION (ALSO KNOWN AS COMBINATION FACIAL THERAPY (CFT)) WITH THE 650 HANDPIECE

Sun damaged or aging skin can become rough and dry, with fine lines occurring around the eyes and mouth. This is often accompanied by a 'dulling' of the skin and changes in skin texture. These symptoms can be treated using Intense Pulse Light, which will help promote collagenesis. Combining various cosmeceuticals and aesthetic procedures and are likely to bring about optimum results. For example, a superficial peel (maximum 40% glycolic acid) or microdermabrasion can be administered to the skin, followed several days later by a facial treatment with the Intense Pulsed Light in the usual manner. Subsequent facial treatments with the IPL can be administered on the same day as the mild peel or microdermabrasion once the skin's reaction is known. Prior to treatment with the IPL, the skin should be cooled thoroughly and a thin layer (1-2mm) of cold, clear gel applied to the skin. The peel or microdermabrasion helps to remove dead skin cells, which can reduce the penetration of light into the skin. After this exfoliation process, the light is absorbed more easily within the dermis, initiating a healing response, resulting in the formation of collagen and elastin within the deeper layers of the skin.

Maximum benefit to the client occurs over a course of four to six treatments, with top-ups as and when necessary. Skin rejuvenation with the 650 handpiece is a low level treatment, and as such the only skin reaction should be mild erythema.

8. VASCULAR LESION TREATMENTS WITH THE 585 HANDPIECE (Including thread veins, spider naevi and Port Wine Stains)

The target chromophore for these treatments is haemoglobin, and using the 585nm handpiece, the light emitted by the IPL is absorbed by blood, causing

heating and coagulation, in such a way that the vessel wall is damaged and goes into spasm and / or collapses, seals and later dissolves. The most common treatments include telangiectasia, spider naevi, rosacea, port wine stains and Campbell de Morgan spots.

A thin layer (1-2mm) of cold, clear gel should be applied before treatment. The lightguide should be placed on the skin with minimum pressure to ensure blanching of the vessel does not occur.

An instant change in the vessel should be present after treatment. Blanching or complete disappearance of the vessel may occur, whilst sometimes vessels may darken as coagulation takes place. If a vessel change does not occur, and the skin reaction is not too severe, it may be possible to repeat the treatment once only. Vessel changes are usually accompanied by mild to moderate erythema. Slight swelling can occur, especially if the cheeks are treated, but should resolve within 48 hours. Bruising of the area can arise on rare occasions but should resolve uneventfully in 1-2 weeks.

9. PIGMENTED LESION TREATMENTS WITH THE 585 HANDPIECE (including lentigines (age spots) and freckles).

Prolonged sun exposure can result in changes in skin pigmentation, and these benign, superficial pigmentation marks can be treated with the 585nm handpiece. The light emitted by the IPL is absorbed by the melanin contained within the pigmented lesion, causing heating and destroying the melanocytes in such a way that the excess pigment is expelled from the skin via the process of skin renewal. Only benign, superficial pigment can be treated such as freckles and lentigines (commonly known as age spots, liver spots or sun spots). Any deeper pigment, such as pigmented birthmarks, moles or melasma, should not be treated, nor should any pigmented lesions that look in anyway unusual, or that have recently changed in colour or size. Any suspicious lesions should always be examined by a dermatologist.

A thin layer (1-2mm) of cold, clear gel should be applied to the skin and the lightguide placed on the skin with slight pressure (this helps to evacuate any blood, a competing chromophore, from the area). Optional pre-cooling of the area may be carried out. A darkening or 'greying' of the lesion should become apparent after treatment – this can sometimes take several minutes to occur. If, after this time has elapsed, there is no change in the lesion, it can be treated again if no adverse skin reaction has been seen. General erythema may be seen in area after treatment, and over the following 1-2 weeks, the lesion will form 'micro-crusts' which will gradually fade or wash off to leave an area without excess pigmentation. This sun-induced pigmentation can recur with repeated exposure to the sun so it is important to advise your clients to use a high sun-protection factor in the future.

10. SKIN REJUVENATION TREATMENTS WITH THE 585 HANDPIECE

Sun-damaged facial skin which can present itself in many forms: wrinkles and fine lines are often accompanied by dry and rough skin, mottled skin tone and areas of abnormal pigmentation. Lentiginosities, (also known as age or sun spots) and ephelides (freckles) are common, superficial, pigmented lesions, and although benign, they can become an issue of cosmetic concern. Vascular irregularities such as telangiectasias and rosacea can also contribute to overall skin tone irregularities and up until recently, treatment options have been limited. Each of these issues can be addressed with a photo-rejuvenation treatment. The entire facial area can be treated with the 585nm handpiece in the usual manner, paying attention particularly to areas of excess pigmentation or vascular irregularity. As well as helping to improve overall skin tone, an improvement in skin texture and pore size should be observed, leaving the skin softer and more radiant. Side effects and skin reactions are the same as those described in the sections on pigmented and vascular lesions.

11.ACNE TREATMENTS WITH THE 585 HANDPIECE

It has been shown that the major cause of acne, *Propionibacterium Acnes* can be destroyed by the application of light. Blue light (wavelength ~400nm) is most efficient at destroying the bacteria, however, at these short wavelengths, skin penetration depths are very small and it is difficult for light to penetrate the skin sufficiently to target bacteria in deep blocked pores. Recent studies seem to indicate that yellow light (~585nm), which has a greater skin penetration depth than blue light, is more effective *in vivo* at targeting the bacteria that causes acne.

Infrared wavelengths (greater than ~750nm) have also been shown to combat acne. These long wavelengths can penetrate the skin to cause heating of the overactive sebaceous glands. It is thought that reversible thermal damage to sebaceous glands can result in long term remission from acne. Broadband light sources such as the LUMINA® System are the only systems that can offer shorter wavelengths for optimum surface bacterial destruction, whilst also getting to the deep-seated bacteria existing in pustules and papules and damaging the sebaceous glands themselves.

The entire facial area (not just individual lesions) should be treated with the 585nm handpiece in the usual manner. It is thought that double passing over the whole area with relatively low fluences may be more efficacious than a single pass at a high fluence. As well as helping to control the appearance of spots, an improvement in overall skin tone, texture and pore size should be observed. The only skin reaction observed should be mild to moderate erythema.

12.TREATMENTS WITH THE LONG PULSED Nd:YAG 1064nm LASER (including Vascular Treatments, Hair Removal and Skin Rejuvenation)

Nd:YAG lasers emit a wavelength of 1064nm. At this wavelength, there is a broad peak (approximately 800 to 1100nm) in the absorption spectrum of

blood. Skin penetration depths are relatively high (up to 8mm) as there is little absorption by melanin at these wavelengths, enabling safe treatment of darker skin types (up to and including skin type VI). These lasers have proved particularly effective in the treatment of larger (up to 4mm), blue/purple veins, and are especially useful for the treatment of leg veins. These blue/purple vessels tend to reside deeper within the skin than the superficial red vessels often found on the cheeks, and as such, require a more penetrating wavelength than the IPL, making them ideal for treatment with the long-pulsed Nd:YAG laser. It should be noted that the presence of multiple thread veins on the leg may indicate underlying problems with the venous system (such as varicose veins) and best results are obtained when these underlying problems are first addressed.

The Nd:YAG laser can also be used for skin rejuvenation, and the deeper penetration at 1064nm makes it useful for the treatment of fine lines and wrinkles, promoting collagen deposition and skin texture improvement. Combining Nd:YAG treatment with superficial peels (maximum 40% glycolic acid) or microdermabrasion can enhance results as with the 650 hand piece. (See Section 7, Combination Facial Therapy with the 650 handpiece). It is a low level treatment, and as such the only skin reaction should be mild erythema.

The Nd:YAG laser can also be used for hair removal. The decreased affinity for absorption in melanin at this wavelength means that the Nd:YAG laser does not result in as much skin heating as other hair removal laser systems and therefore has a lower associated risk of epidermal damage. These gentle treatments make the Nd:YAG laser ideal for hair removal in dark skin types.

- The Nd:YAG handpiece, or the blank handpiece (if using the fibre-optic or articulated arm Nd:YAG) should be connected to the LUMINA® System
- Skin cooling is essential before any treatment with the Nd:YAG laser.
- The correct spacer must be attached as required. **Ensure that you then select the corresponding spot size on the LUMINA® System software.** Failure to do so will result in a difference between the fluences being applied to the skin and those displayed by the LUMINA® System software.
- The starting parameters should have been determined in advance at the test patch session (see below). If the test patch showed no adverse effects, begin the treatment at those settings. Most vascular treatments will probably be carried out at a fluence of about 60-150 J/cm², whereas skin rejuvenation and hair removal treatments will typically be carried out at 30-80 J/cm²
- Place the laser spacer against the skin and depress the button or the footswitch (if using the articulated arm) to deliver the pulse of laser light. Ensure that the handpiece or pen is held perpendicular to the skin and not tilted at an angle.
- For hair removal treatments, the area should be close-shaved. Frazzling of the hair should be apparent during treatment.

- For vascular lesions, the vessel should blanch or disappear completely. In some cases, the vessel will darken as coagulation occurs. At this fluence, treat the whole vessel by tracing along the length of the vessel with the laser, taking care to not overlap shots.
- After treating the area, cool the skin and moisturise the area with a soothing ointment such as aloe vera gel
- Patients must be warned to keep the treated area out of the sun or to use high factor sunscreen for at least 2 weeks after treatment

For hair removal the end point is mild to moderate erythema and peri-follicular swelling. Eight to ten treatments are usually necessary for maximum hair reduction. For vascular treatments the end point is blanching or a darkening of the veins. The onset of surrounding erythema and oedema occurs in a few minutes and can last a few days, some smaller superficial vessels can form a cat scratch scab over the vein patch, and crusting and peri-vascular bruising can occur. Vessels may take up to 8 weeks to fade. One treatment is often all that is necessary, but subsequent treatments can take place 6-8 weeks after the initial treatment.

13. TREATMENTS WITH THE Q-SWITCHED Nd:YAG 1064/532nm LASER (including Pigmentation Treatments and Tattoo Removal of blue-black and red pigments)

Following consultation and having obtained written consent, it is important to follow a set routine at all treatment sessions. The regime advocated is as follows:

- The blank handpiece should be connected to the LUMINA® System.
- The client and any visitors should be provided with suitable goggles for the wavelength being used. Not all goggles offer protection at all wavelengths and it is essential therefore that the proper goggles are provided. The operator should put on his or her own appropriate goggles before commencing treatment.
- The operator should switch on the laser and set the wavelength, repetition rate, spot size and fluence required. The wavelength is set according to the colour of the tattoo pigment being treated. Blue/Black tattoos will generally be treated using the 1064nm output, while red tattoos will be treated with the 1064/532nm mixed output. Yellow, orange and brown tattoos may also respond to these wavelengths, although the results can be variable. For treatment of green tattoos a Ruby laser will be required. The pigment used in the application of tattoos is not standard and therefore the above instructions should be used as a guideline only.
- Ensure that the handpiece is set for the same spot size as the control panel.
- The treatment area can be cooled before, during and after treatment to improve client comfort, reduce post-operative erythema and permit the use of higher fluences.
- Ensure that the treatment pen is held at the correct distance from the skin by keeping the spacer in contact with the tissue throughout treatment.

- An initial whitening of the treated area is the first sign of a positive reaction. This blanched area will fade after approximately five to ten minutes, leaving the surrounding area red, raised and inflamed. The client should feel a 'ping' and some mild discomfort. Occasionally a small amount of bleeding may also be observed. After a number of treatments, it is less usual to observe blanching as the pigment should no longer be contained in the superficial region of the dermis. It is normal however, to still observe erythema of the treated area and again there is a possibility of slight bleeding.
- As the course of treatments proceeds, the tattoo pigment is gradually removed in layers, and the pigment which remains is to be found progressively deeper within the dermis. As some of the energy is scattered as the laser beam penetrates through the dermis, this requires that the surface energy density be increased as the course of treatment progresses. This ensures that the energy density actually reaching the pigment is sufficient to cause the explosive interaction required.
- Details of the treatments performed should be accurately recorded in the client's record. This should include laser type, wavelength, fluence, repetition rate, spot size and number of shots fired. The entry should be signed and dated.

14. TREATMENTS WITH THE FRACTIONAL 2940 ER:YAG LASER (INCLUDING REJUVENATION AND SCARRING TREATMENTS)

Clinical Applications

- Photo-damaged skin: Roughened, thickened skin, with uneven tone, large pores, excessive secretion of sebum, and loss of elasticity
- Congested skin
- Scarring: Acne scars, surgical scars, traumatic scars and stretchmarks
- Mild, static wrinkles
- Pigmented lesions: Dyschromia
- Total skin rejuvenation of facial and non-facial areas

Following consultation and having obtained written consent, it is important to follow a set routine at all treatment sessions. The regime advocated is as follows:

- The Fractional 2940 handpiece should be connected to the Lumina. Select the 'Gentle' or 'Deep' application, depending on the condition being treated and the client's skin type.
- If treating skin types III – V, pre-treatment with bleaching agents such as hydroquinone may help to minimise the risk of post-inflammatory hyperpigmentation.
- If the client has a history of cold sores, prophylactic anti-viral treatment should be considered.
- The patient and any visitors should be provided with suitable goggles for the wavelength being used. The operator should put on his or her own appropriate goggles before commencing treatment.

- Set the treatment parameters based on the patient's medical history, skin type and condition to be treated. Refer to the 'Parameter Selection' section below for further instruction.
- DO NOT use gel on the skin when using the 2940 handpiece.
- Ensure the skin is completely dry and free of product before commencing with treatment.
- Begin treatment, taking care to ensure the client remains comfortable at all times. Overlap each shot (or set of pulses/stacks) by about 10% to ensure an even coverage.
- Treatment is very bearable and anaesthetic is rarely needed. Cooling the skin prior to, and during treatment can help if there is any discomfort.
- Some plume may be produced during treatment. Using a smoke evacuator may be necessary if the treatment is carried out in a poorly-ventilated room.
- For each pass, 40 microspots/cm² will be produced, at a depth of 30-60 microns on single pulses.
- Generally, 2-3 passes should be carried out.
- Pulsing is recommended for deeper penetration. To do this, select the desired number of pulses on the software.
- Accurately record treatment parameters, including fluence, number of pulses (stacks), number of passes, observations and any other relevant information in the client's record. Sign and date the entry.
- Clients must be aware that a degree of 'downtime' is to be expected following treatment. The skin will look and feel intensely 'sunburnt' for up to 24 hours. Following that, it will be red/bronzed in appearance for up to 7 days. From day 2-3, the skin will start to feel rough and flaky as the epidermal debris sloughs off.

Fractional 2940 Treatment parameters

Indication	Mode	Number of Passes	Number of Pulses	Typical Number of Treatments	Treatment Interval
Skin Roughness	Gentle	2-3	1-2	3-5	2-4 weeks
Skin Brightening / Open Pores	Gentle	2-3	1-2	3-5	2-4 weeks
Dyschromia	Gentle	2-3	1-2	3-5	2-4 weeks
Mild to moderate wrinkles	Deep	1-3	2-3	4-6	4-6 weeks
Mild Acne Scarring	Deep	1-2	2-3	4-6	4-6 weeks
Stretchmarks	Deep	2-4	3-6	4-6	4-6 weeks

FRACTIONAL 2940 – POST-TREATMENT CARE

The parameters used, along with patient sensitivity will determine post-operative reactions. In general, for fractional laser treatments, the treated area may show strong erythema accompanied with slight oedema and flushing during and immediately after treatment and these symptoms may last for 1-3 days.

For about one week after a fractional laser treatment, the epidermal debris on the stratum corneum may give the treated skin area a bronzed, rough, dotted appearance. The epidermal debris naturally exfoliates as the reorganized epidermal skin replaces the dead tissue. Gradually the treated skin naturally flakes away and skin colour, tone and laxity will all improve and continue to improve over time as the recovery cycle continues.

Advice for patients following Fractional Laser Treatment

- Following treatment, the area will appear very red and may be swollen. It may feel hot and tender for several hours following treatment. The redness (similar to sunburn) and swelling may last a few days but can be minimised with the application of cold compresses. Facial swelling can be reduced by sleeping with your head raised on pillows.
- In order to minimise skin heating and to reduce the likelihood of skin reactions, the treatment area will be cooled after the procedure. Once you get home, you may like to apply a cold compress / wet flannels etc. If applying an ice pack at home, always put ice inside a clean plastic bag and wrap in a soft cloth. Do not allow ice packs or ice into direct contact with the skin.
- While redness remains on the skin after treatment, do not indulge in heavy drinking, going to a sauna or heavy exercise. Those activities may worsen the redness of your skin.
- The skin will also feel quite tight following treatment and using Vaseline, aloe vera gel or a gentle moisturiser for a day or two following treatment can help to relieve this.
- Starting on day 2-3 the skin will appear flaky and have a bronzed appearance as the epidermal debris comes to the surface; this generally lasts for about 5 days. This is a positive sign and indicates that the skin is regenerating. Do not try to peel off the epidermal debris by force; just leave it to flake off naturally. Keeping the skin well moisturised at this point will help reduce the risk of tightness.
- Avoid cosmetics for approximately 48hrs after treatment. However, we advise caution if the area is feeling sensitive. Remove make up carefully as rubbing the skin can cause irritation or infection. If the skin at the treatment area becomes broken, then make-up should be avoided.
- Avoid hot baths / showers for 24hrs
- Do not pick at any flaking or crusting that may form.
- The skin will usually return to normal by day 7 to 10.

- Use a sunscreen (SPF 30+) and protect the area from sunlight as much as possible between treatments and for at least 6 to 10 weeks after treatment ends. Failure to do this can lead to sunburn and hyper-pigmentation of the treated area. (Most cases of changes in pigmentation occur when the treated area has been exposed to sunlight or in people with darker skin types).

15. SETTING THE FLUENCE

The fluence should always be set as low as possible in order to achieve a satisfactory clinical response. Setting the fluence too high can result in excessive pain, blistering, skin pigmentation changes and possibly even scarring. Setting the energy density too low can result in no interaction and involve the patient undergoing further treatment.

Treatment cannot be purely prescriptive and as in all high-energy laser or IPL treatments, individual tissue reaction and observed clinical endpoints for successful outcomes are the primary determining factor in setting device parameters. It is the operator's responsibility to evaluate each patient and each lesion and to treat that patient accordingly. Nonetheless, it is possible to provide a framework of guidelines to assist the operator in their evaluation. Table 1 shows typical fluences used for a variety of skin types for several different IPL treatments (standard handpieces). It is important to note that these are TYPICAL treatment parameters. Test patches and initial treatments may have to be carried out at lower fluences than those stated here. These parameters may be too high for some patients, whereas others will require higher fluences for an effective treatment. Please consult the Training Manual for more information on treatment parameters.

	Skin Type 1	Skin Type 2	Skin Type 3	Skin Type 4	Skin Type 5
Hair Removal (650 handpiece)	F=22-36J/cm ² 3 pulses, 20ms delay	F=22-34J/cm ² 3 pulses, 30ms delay	F=20-30J/cm ² 4 pulses, 35ms delay	F=14-24J/cm ² 4 pulses, 40ms delay	F=12-22J/cm ² 5 pulses, 50ms delay
Hair Removal (650 Advance handpiece)	F=22-30J/cm ² 2 pulses, 15ms delay	F=20-28J/cm ² 2 pulses, 20ms delay	F=18-26J/cm ² 2 pulses, 20ms delay	-	-
Skin Rejuvenation (650 handpiece)	F=20-30J/cm ² 3 pulses, 20ms delay	F=18-28J/cm ² 3 pulses, 30ms delay	F=16-26J/cm ² 4 pulses, 40ms delay	F=14-20J/cm ² 4 pulses, 50ms delay	F=12-18J/cm ² 5 pulses, 50ms delay
Skin Rejuvenation (585 handpiece)	F=20-26J/cm ² 2 pulses, 20ms delay	F=20-24J/cm ² 2 pulses, 20ms delay	F=18-22J/cm ² 3 pulses, 20ms delay	-	-
Telangiectasia (585 handpiece)	F=24-34J/cm ² 2 pulses, 20ms delay	F=24-30J/cm ² 2 pulses, 20ms delay	F=20-28J/cm ² 3 pulses, 20ms delay	-	-
Rosacea (585 handpiece)	F=22-34J/cm ² 3 pulses, 25ms delay	F=20-32J/cm ² 3 pulses, 25ms delay	F=18-28J/cm ² 3 pulses, 25ms delay	-	-
Port Wine Stains (585 handpiece)	F=22-36J/cm ² 2 pulses, 15ms delay	F=20-34J/cm ² 2 pulses, 15ms delay	F=18-30J/cm ² 3 pulses, 15ms delay	-	-
Pigmented Lesions (585)	F=24-34J/cm ² 2 pulses, 15ms delay	F=22-32J/cm ² 2 pulses, 15ms delay	F=20-30J/cm ² 2 pulses, 15ms delay	-	-

handpiece)					
Acne (585 handpiece)	F=18-24J/cm ² 3 pulses, 20ms delay	F=16-24/cm ² 3 pulses, 30ms delay	F=14-22J/cm ² 4 pulses, 35ms delay	-	-

Table 1 Typical treatment parameters used for treatments with the LUMINA® Intense Pulsed Light Handpieces

Skin Type	Fluence (J/cm²)	Number of Pulses	Delay (ms)	Spot Size
1	50-70	2	15	Largest or Medium
2	50-60	2	20	Largest or Medium
3	40-60	3	25	Largest
4	30-50	4	35	Largest
5	20-40	5	40	Largest
6	15-35	5	45	Largest

Table 2 Typical treatment parameters used for hair removal with the LUMINA® long-pulsed Nd:YAG laser

Vessel Diameter	Fluence (J/cm²)	Number of Pulses	Delay (ms)	Spot Size
0-1mm	80-150	2	30	Smallest
1-2mm	70-120	3	40	Smallest
2-3mm	60-100	3	50	Smallest or Medium

Table 3 Typical treatment parameters used for vascular lesion removal with the LUMINA® long-pulsed Nd:YAG laser

Skin Type	Fluence (J/cm²)	Number of Pulses	Delay	Spot Size (mm)
1	40-60	2	20	Largest
2	40-60	2	20	Largest
3	30-60	3	20	Largest
4	25-50	3	30	Largest
5	20-40	4	40	Largest
6	10-30	4	40	Largest

Table 4 Typical treatment parameters used for skin rejuvenation with the LUMINA® long-pulsed Nd:YAG laser

	Fluence (J/cm ²)	Spot Size
1st & 2nd Treatment	1.0 - 2.5	5mm – 4mm
3rd & 4th Treatment	2.5 - 4.0	4mm – 3mm
5th Treatment	4.0 - 6.0	3mm
6th Treatment	6.0 - 8.0	2mm
7th Treatment	8.0 -10.0	2mm
and thereafter	10-12.7	2mm

Table 5 Typical treatment parameters used for tattoo removal with the Nd:YAG laser at 1064nm

It is possible that some small areas of pigment will not be removed even with the laser set at 12 J/cm² and higher energy density may be required after 6-8 treatments. Always exercise extreme caution using settings higher than 12J/cm² and only use these settings for small areas of stubborn pigment.

	Fluence (J/cm ²)	Spot Size
1st Treatment	1.0 – 2.5	4mm
2nd Treatment	2.5 – 4.0	3mm
3rd Treatment	4.0 – 6.0	2mm
4th Treatment	6.0 – 8.0	2mm
and thereafter	8.0 – 17.0	2mm - 1.5mm

Table 6 Typical treatment parameters used for tattoo removal with the Nd:YAG laser at 532nm

The same settings may be used for treatment of cafe au lait spots and other pigmented lesions however these lesions should always be assessed by the Consultant responsible for the clinic prior to treatment.

16. PERMITTED VARIATION ON MACHINE VARIABLES

The highest fluence most tolerable for the individual client should be used during the laser treatment to ensure the best results. The exact energies should be determined through patch testing. However, the standard requirement on medical products is for machine variables to be accurate to ±20%. Lynton regard this as being too broad a range and ensure that outputs stay accurate to ±10% between recommended service intervals. In the unlikely event that re-calibration during a service visit results in a machine variable change that is more than ±10%, the customer is formally notified.

17. TREATMENT INTERVALS

Acne and CFT treatments should be carried out every 2-3 weeks. Vascular, hair, pigmentation and photo-rejuvenation treatments should take place every 4-6 weeks. However, these spacings are only approximate and can be varied as necessary, for example, towards the end of a hair removal course it is advisable that the client only comes in when regrowth has occurred. This may take as long as 12 weeks for certain body areas. For tattoo removal

treatments, a minimum of 6 weeks should elapse between treatments. It is not unusual for blistering to occur after tattoo treatment at 532nm. It is important therefore to use a lower energy density and leave longer gaps (8-12 weeks) between treatments at 532nm. At subsequent visits, the results from the previous test patch or treatment should be discussed with the client. If the client has had a satisfactory outcome without adverse reactions then treatment can proceed using the same laser parameters, consideration being given to increasing the fluence as appropriate. Each time the fluence is increased, a test area must be performed at the new setting. Aim to reach maximum tolerated parameters as quickly as possible to maximise benefits without causing adverse reactions.

Treatment should not proceed if the area to be treated is inflamed, raised, broken, the skin is tanned or skin pigmentation has been disturbed in any way.

18. POST-TREATMENT CARE

Immediately after any treatment, the skin should be cooled. Cooling can improve patient comfort and reduce post-operative redness or swelling. Clients should be instructed in post-treatment care and should be provided with written take-home instructions recommending:

- Care should be taken to avoid trauma to the treated area for 4 or 5 days afterwards. Avoid strenuous activities, sauna and steam, excessively hot baths, massaging etc.
- If the area feels hot or swollen, the use of ice packs and / or aloe vera gel etc. can improve client comfort and reduce erythema and swelling.
- Wash and bathe as normal but take cool showers rather than hot baths. The skin should be patted dry and not rubbed.
- Make-up can be applied after several hours, if the skin is not sore or broken. However, we advise caution if the area is feeling sensitive. Remove make up carefully as rubbing the skin can cause irritation or infection. If the skin at the treatment area becomes broken, then make-up should be avoided.
- Following vascular treatments, a bruise may appear at the treated area. This may last up to 15 days and as the bruise fades there may be brown discolouration of the skin. This usually fades in 1-3 months. When larger vessels are treated they may take on a darker colour. Again, this may take up to four weeks to resolve as the body re-absorbs the damaged vessels.
- Use a sunscreen (SPF 30+) and protect the area from sunlight as much as possible between treatments and for at least one month after treatment ends. Failure to do this can lead to sunburn and hyper-pigmentation of the treated area. (Most cases of changes in pigmentation occur when the treated area has been exposed to sunlight or in people with darker skin types).
- If blistering or crusting occurs, do not pick or scratch the treated area as this could result in scar tissue formation.

- If pin-point bleeding has occurred (after tattoo removal), the area can be covered with a paraffin gauze dressing to avoid contact with clothing. Crusting may develop after a few days and this should be left to heal naturally.

19. RECOGNITION OF TREATMENT RELATED PROBLEMS

Improper use of the system may result in possible side effects. Although these effects are rare and expected to be transient, any serious adverse reaction should be reported to the client's own doctor. Side effects may be immediate or appear shortly post treatment (0-24hrs); in rare cases, there may be late emerging side effects (24-72hrs) and include:

IMMEDIATE

- Excessive pain: stop treatment and cool the skin. Review after 24 hours and re-start treatment at lower fluence (most common reasons, tanned skin, stress, menstruation and tiredness.)

POST-TREATMENT

- Excessive persistent heat and redness: Normally resolves in 24 hours. Cool the area regularly using ice packs or cooling gel and advise the client to use aloe vera gel and skin protection as for mild sunburn until the sensation disappears. If the reaction persists the client should consult their doctor.
- Damage to the natural skin texture (crust, blister, burn): Obvious signs that a burn has occurred include: the presence of blisters or raised skin (this may arise immediately but can also occur up to a period of 24 hours); a greyish discolouration of the skin; extreme discomfort; severe erythema or any mark/reddening of the skin that occurs in the actual shape of the block. If the burn is deep, pressing down on the skin will not result in the blanching effect seen in normal skin. Burns such as these will require urgent medical attention. As soon as the burn occurs cool area thoroughly for pain relief. Hold the burned area under cool running water for 20 minutes (ideal temperature is 15°C). If this is impractical, immerse the burn in cold water or cool it with cold compresses or covered ice packs changed frequently. **Do not use ice or iced water.**
- Excessive swelling (oedema) or bruising (purpura): Cool area immediately for effective pain relief.
- Pin-point bleeding is relatively common with the Nd:YAG Q-Switched laser, especially at high fluences. The area can be covered with a paraffin gauze dressing to avoid contact with clothing and the client informed not to pick any scabs that may form.

LATE EMERGING

- Change of pigmentation (hyper or hypo-pigmentation): Moisturise and protect from sun exposure. Contact GP if condition persists.
- Scarring and textural changes of the skin.

- Ineffective lesion removal: Re-assess client history and increase fluence dependant on skin reaction. Remind client that some people will not respond satisfactorily to laser removal procedures.
- Leucotrichia: Temporary appearance of pigment-free hair. May often be confused with pre-existing but previously unnoticed white hair.
- Increase in hair growth in the treated area (may be related to under treatment).

NB : Only re-treat an area where any problems have occurred after full healing and careful repeat test patching.

20. ACTION TO BE TAKEN IN THE EVENT OF AN ADVERSE REACTION

If anything goes wrong during treatment such as untoward skin reaction, excessive pain, client taken ill, etc., treatment should be abandoned immediately. (NB if necessary, the emergency stop button should be pressed to prevent any further emission of laser light. Also see section 'In the Event of Equipment Failure.' Appropriate information should be recorded in the client notes of extent of the partially completed treatment with details of any untoward side effects. An 'Untoward Incident Report' should be completed and the laser manufacturers informed.

Suspected eye damage or serious skin damage should be referred immediately to the A&E Department of the nearest hospital or via the client's GP to an appropriate medical specialist if necessary. The following action should be taken in result of a burn:

As Soon as a Burn has Occurred

- **Stop the burning process** (stop using the laser or IPL)
- **Cool the burn.** Hold the burned area under cool running water for 20 minutes (ideal temperature is 15°C). If this is impractical, immerse the burn in cold water or cool it with cold compresses or covered ice packs changed frequently. **Do not use ice or iced water.** Putting ice directly on a burn can cause frostbite, further damaging your skin.
- **Take an over-the-counter pain reliever** if required. These include aspirin, ibuprofen, or paracetamol.

Short Term Recommendations

- It is not necessary (or recommended) to use antiseptic creams or lotions.
- If the area has small, intact blisters, no dressing is required and exposure to the air is recommended. **Do not break small blisters.** Fluid-filled blisters are sterile and protect against infection. If large blisters form, seek medical attention.
- If the burnt area is open and moist looking, or if blisters have burst, cover the area in a paraffin gauze dressing such as Jelonet. Dry gauze dressings used with a layer of Vaseline may be substituted if paraffin gauze is not available. Change the dressings every 2-3 days.
- Elevation of the burnt area will help to reduce swelling.

- **Do not pick blisters or scabs.** This will drastically increase the risk of scarring.

Long Term Recommendations

- Massage moisturiser into the skin twice daily until the area has completely healed.
- Newly healed skin can be more sensitive to the sun and may be prone to pigment changes under sun exposure. For this reason, use high factor sun cream or avoid sun exposure on burns that are less than a year old.
- Deeper burns may result in the formation of a scar. If there is evidence of a raised or lumpy scar forming, consult a doctor immediately.

Minor burns usually heal in about 1 to 2 weeks without further treatment. Scarring is uncommon in superficial burns but pigment changes in the skin may occur. These changes may be permanent but will often resolve within 12 months. Watch for signs of infection such as increased pain, redness, fever, swelling or oozing. Infection will cause poor healing and further damage. If infection develops, get medical help immediately.

21. PROCEDURE TO BE FOLLOWED IN THE EVENT OF EQUIPMENT FAILURE

In the event of equipment failure, treatment should be abandoned IMMEDIATELY and the emergency stop button pressed and / or the key removed to prevent any risk of further treatments being carried out. Remove the mains plug. Details should be recorded in the client record sheet of the partially completed treatment and with details of any untoward side effects. A Lynton Lasers service engineer should be contacted immediately and informed of the circumstances of equipment failure, including any warning messages that may have been displayed. The equipment should not be used until passed for use by the appointed service engineer.

This protocol should be adopted in conjunction with the LUMINA® System User and Training manuals provided by the manufacturer and the 'Local Rules' provided by the certified Laser Protection Advisor, as these will contain important information to be followed by the operator in respect of;

- potential hazards associated with this type of laser
- controlled and safe access to the Controlled Area
- the authorised users' responsibilities
- methods of safe working and safety checks
- normal operating procedures
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedure
- further information on infection control and cleanliness

22. INFECTION CONTROL AND CLEANLINESS

In order to prevent cross contamination, potential infections and unwanted reactions, certain measures should be put into place that must be followed:

GENERAL PRINCIPALS

- Workplace, furniture, furnishings, telephones and fittings shall be kept clean and free from visible dirt. The whole of the premises is a non-smoking area.
- Where possible utilize appropriate single use, packaged items and discard them after each treatment. Follow protocols for the disposal of sharps, such as razors, which need to be discarded in designated sharp containers. No attempt should be made to recycle or reuse disposable equipment designed for single use.
- All lighting, heating and ventilation installations will be in accordance with the Health & Safety Commission Approved Code of Practice (Workplace – Health, Safety & Welfare Regulations 1992) [].
- It is good practice to have all electrical appliances safety tested annually (PAT – Portable Appliance Test) and evidence of testing (e.g. PAT labels) should be affixed to plugs and appliances. Make sure any local regulations about electrical safety testing of fixed and portable appliances are observed.

TREATMENT AREA CLEANING

- The treatment room should have a daily, weekly, and monthly environmental cleaning schedule.
- Depending on the surface material, floors should be vacuumed daily or mopped cleaned utilizing a general-purpose disinfectant. All horizontal surfaces should be cleaned with a hospital-grade disinfectant or a bleach solution (hypochlorite concentration 1000 ppm).
- Clean couches daily and change disposable couch roll between patients. Hair residue on working surfaces may be removed between patients using a lint roller. Empty waste receptacles daily.
- Toilet facilities with hot and cold running water are available and must be cleaned and disinfected daily. Liquid soap and disposable paper towels will be provided.
- Towels and washcloths used when washing the skin or used to maintain patient privacy and dignity when treating intimate body areas, should be changed or cleaned after every patient. Employment of a laundry service or machine-washing of these towels should be performed using in a dedicated washing machine at 90°C and dried using a high heat cycle.

LASER & IPL APPLICATOR HEAD CLEANING

- Before and after all treatments, goggles, laser handpieces and IPL lightguides must be disinfected using either alcohol or methanol wipes and dried thoroughly before use
- When using the AQS arm for tattoo removal and Fractional 2940nm Er:YAG for resurfacing, there can be a degree of plume and tissue spatter. It is advisable for practitioners to wear face masks when carrying out these treatments to prevent inhalation of said plume and tissue spatter.

HAND HYGIENE

- Use disposable paper towels or hot air hand dryer after hand washing whenever possible. Change reusable towels between patients. Wash reusable towels in a dedicated washing machine at 90°C.
- Good hand washing technique is an ESSENTIAL part of infection control as many infections are spread by hand contact. Hand washing should be performed routinely before and after contact with each patient and includes:
 - use of liquid antimicrobial soap and water for at least 15 seconds;
 - alcohol based hand rubs can be substituted when hands are not viably soiled;
 - before and after eating, after using the toilet.
- Staff developing skin reactions to hand disinfectant products or with pre-existing skin conditions should seek medical advice.
- Hand disinfection is necessary only in specific situations e.g. dealing with infected patient or inadvertent contamination of hands.
- Water based:
 - Wet hands and wrists before applying antimicrobial soap;
 - Apply cleanser;
 - Ensure all hand and wrist surfaces are well covered with lather;
 - Rinse off lather;
 - Dry hands thoroughly to avoid chapping.
- Alcohol based:
 - Antimicrobial and alcohol hand rub (e.g. 'Hibisol') should be used on unsoiled dry hands;
 - Ensure all hand and wrist surfaces are well covered with the hand rub, and then massage hands together until dry.
 - Use hand lotion (supplied in pump dispenser) regularly to avoid chapping of hands.

GLOVE POLICY

- The hands of laser operators are the most likely means of transmitting infection to others. The purpose of wearing gloves is to:
 - protect the hands from becoming contaminated with dirt and micro-organisms;
 - prevent the transfer of organisms already present on the skin of the hands and to minimize cross infection.
- Non-sterile gloves of appropriate quality should be used i.e. domestic type rubber for cleaning purposes and nitrile or vinyl examination gloves for patient procedures.
- Gloves must be made easily available for staff use, including the procedures described in this workbook. Standard precautions should be followed when working with LASER or IPL patients, which are the basic level of infection control measures in the care and treatment of patients. Gloves must be changed between performing each procedure. Hands should always be washed after wearing gloves.

- NITRILE or VINYL GLOVES MUST BE USED for handling blood stained items or contaminated with body fluids. Latex gloves are not recommended due to latex sensitivity.
- Disposal: Gloves are clinical waste and disposed of in the designated trash containers.

MRSA CONTROL

If a patient is identified as MRSA positive they should be referred to a clinic for treatment advice before an elective cosmetic procedure is performed.

BLOOD BORNE INFECTIONS

Where LASER treatments involve the possibility of puncture of the skin barrier e.g. Q-switched lasers, infection control procedures for blood-borne viruses or blood aerosol contaminants are particularly important e.g. use of gloves and N95 respirator mask.

23. FURTHER INFORMATION

This protocol is only to be used by registered persons or operators authorised and trained to use the LUMINA® System in conjunction with 'Local Rules' and within the confines of the 'Controlled Area' of the named establishment.

24. APPENDIX 1

The Equality Act 2010

Under the Equality Act 2010 several everyday situations encountered routinely in the LASER or ILS clinic have 'protected' status. These conditions automatically include, amongst others, pregnancy, cancer, HIV infection, multiple sclerosis, severe disfigurement (excluding tattoos), blind or partially sight-ed people. In the event of disinclination or refusal to treat a person with any of these conditions could imply a breach of the Act and expose the clinic, its staff and professional consultants to liability claims.

Several of these conditions are often identified by LASER and IPL manufacturers as contraindicated for light-based therapy so caution needs to be exercised when confronted with a request for treatment.

Reasonable adjustments that could be made, for example, in the case of HIV / AIDS are:

- Patient to provide current evidence from G.P. that the HIV viral load is undetectable;
- Operator to use single-use nitrile or vinyl examination gloves and single-use N95 respirator mask;
- Operator to avoid highest LASER or IPL settings to reduce risk of blister / burn;
- Treatment provision to be confirmed with appointed Expert Medical Practitioner (EMP).

25. APPENDIX 2

GUIDANCE ON PHOTOSENSITIVE MEDICATION

Drugs & Lasers/IPLs

Guidance provided by the British Medical Laser Association

Issued December 2009

Important

This advice relates to non-essential aesthetic laser applications and reflects the best data available at the time of this report. Caution should be exercised in interpretation; the results of future studies may require alteration of the recommendations in this document.

The following is a consensus opinion of interested parties from the laser and light source world in the UK and takes into account:

- a) Personal opinions
- b) Theoretical perspectives
- c) Evidence from practical use over very large numbers of clients/patients.
- d) Reporting of adverse events in clinical trials and in post marketing surveillance studies.

Background

There has been a general trend within the industry to provide end-users of laser devices with guidance on which drugs to avoid to minimise the possibility of drug induced photosensitivity reactions. This guidance has often, in the opinion of the authors, been largely based on an inappropriately rigid interpretation of what data exists.

Reports of photosensitivity reactions as a result of drug administration do occur, but we believe that these reactions have been reported to regulatory bodies with no indication of the wavelength of light that has been responsible. Accurate data are lacking generally.

Phototoxicity generally results from exposure to UVA (315-400 nm) radiation with some drugs showing sensitivity into the visible region of the spectrum up to about 460 nm. For laser/IPL devices emitting wavelengths above 500 nm there is very little likelihood of such a reaction for the vast majority of drugs

Other drugs may have an effect on the skin's healing ability without causing photosensitivity.

Practical Advice

Information regarding all drugs a patient / client is taking should be recorded including:

- a) over the counter drugs
- b) prescribed drugs
- c) herbal remedies.

1. Photosensitising drugs that are CONTRAINDICATIONS to laser therapy.

- a. Drugs causing marked whole-body sensitivity – wait 6 months

Drugs administered for systemic Photodynamic Therapy (PDT), e.g. Photofrin, Foscan.

- b. Drugs causing marked localised light sensitivity – wait 6 weeks

Drugs administered for localised PDT, e.g. ALA, Metvix.

2. Other drugs that may cause Photosensitivity

Any treatment should be performed with caution. Test carefully and treat small areas initially. If in doubt, do not treat.

If the client / patient wishes to proceed with treatment, the increased risk of hyperpigmentation / photosensitivity should be emphasised and documented.

- a. Amiodarone – risk of hyperpigmentation and photosensitivity.
- b. Minocycline (Minocin) – risk of hyperpigmentation. Recommend stopping 4 weeks prior to treatment or consider change to alternative.
- c. St John's Wort – risk of photosensitivity. Recommend stopping 4 weeks prior to treatment.
- d. If taking other medications or herbal remedies of any sort then careful initial test patch, wait 4-7 days in the case of hair reduction and 4-6 weeks in the case of vascular/pigmented treatments.
- e. If client starts a BNF named photosensitiser then repeat test patch.

3. Drugs which may affect the healing of treated areas.

Any treatment should be performed with caution. Test carefully and treat small areas initially. If in doubt, do not treat.

- a. Oral Retinoids – wait 6 months after completion of the drug course

Isotretinoin (Roaccutane), acitretin (Neotigason), alitretinoin (Toctino)

- b. Topical Retinoids – stop use 2 weeks prior to laser, recommence once area is healed.

Tretinoin (Retin-A, Aknemycin Plus), isotretinoin (Isotrexin), adapalene (Differin)

- c. Oral Steroids – Wound healing impairment is dependent on potency, dose and duration of use. It is advisable to check with the prescribing physician if laser treatment can proceed safely. When possible, wait 4

weeks off drug and avoid use immediately following laser therapy. Recommence use once treated area is healed.

Betamethasone, cortisone, deflazacort, dexamethasone, hydrocortisone, methyl prednisolone, prednisolone, triamcinolone.

d. Topical Steroids – Wound healing impairment is dependent on potency, dose and duration of use. It is advisable to check with the prescribing physician if laser treatment can proceed safe-ly. Wait 1 week prior to treatment and avoid use immediately following laser therapy. Re-commence use once treated area is healed.

Disclaimer

This should not be considered as an exclusive list of drugs that may interact with the laser treatment. It does not replace any advice or instruction issued by a registered medical practitioner, pharmacist or other registered health professional. The information provided is without any implied warranty of fitness for any purpose or use whatsoever.