TREATMENT GUIDELINES FOR THE USE OF LASER AND INTENSE PULSED LIGHT DEVICES FOR HAIR REDUCTION AND TREATMENT OF SUPERFICIAL VASCULAR AND BENIGN PIGMENTED LESIONS

March 2019
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>General Description and technical specifications</td>
<td>4</td>
</tr>
<tr>
<td>Cleanliness and Infection Control</td>
<td>4</td>
</tr>
<tr>
<td>Obtaining Patient Consent Prior to Treatment</td>
<td>6</td>
</tr>
<tr>
<td>Record Keeping Requirements</td>
<td>9</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>9</td>
</tr>
<tr>
<td>Contra-indications and Conditions that Require Special Consideration</td>
<td>10</td>
</tr>
<tr>
<td>Treatment Process (step-by-step guidance)</td>
<td>16</td>
</tr>
<tr>
<td>Recognition of Treatment-Related Problems and Skin Reactions</td>
<td>17</td>
</tr>
<tr>
<td>Procedure if Anything Goes Wrong During Treatment</td>
<td>19</td>
</tr>
<tr>
<td>Permitted Variation on Machine Variables</td>
<td>20</td>
</tr>
<tr>
<td>Audit</td>
<td>20</td>
</tr>
<tr>
<td>Procedure in the Event of Equipment Failure</td>
<td>21</td>
</tr>
<tr>
<td>Emergency Procedures</td>
<td>21</td>
</tr>
<tr>
<td>Further Information</td>
<td>22</td>
</tr>
<tr>
<td>Disclaimer</td>
<td>22</td>
</tr>
<tr>
<td>Appendix I The Equality Act (2010)</td>
<td>23</td>
</tr>
<tr>
<td>Appendix II Drugs and Lasers/IPLs (2017)</td>
<td>25</td>
</tr>
<tr>
<td>Appendix III Acknowledgements</td>
<td>27</td>
</tr>
<tr>
<td>Appendix IV Bibliography</td>
<td>28</td>
</tr>
</tbody>
</table>
TREATMENT GUIDELINES FOR THE USE OF LASER AND INTENSE PULSED LIGHT DEVICES FOR HAIR REDUCTION AND TREATMENT OF SUPERFICIAL VASCULAR AND BENIGN PIGMENTED LESIONS

Introduction

In the United Kingdom, the use of Class 3B or 4 lasers and intense pulsed light (IPL) devices, is subject to standards and regulatory controls because of the unique potential hazards they pose to tissues of the eye and skin, including the risk of blindness and skin burns [1, 2, 3]. In addition, UK law requires employers to effectively manage hazards through appropriate selection and maintenance of equipment (including personal protective equipment, PPE), staff training and information, and protection of staff and the public from exposure to hazards [Health & Safety at Work act, Management of Health and Safety at Work Regulations, Provision and Use of Work Equipment Regulations, Medical Device Regulations, The Personal Protective Equipment at Work Regulations]. The Artificial Optical Radiation Regulations specifies exposure limit values for staff and requires equipment to meet industry standards.

The Care Standards Act 2000, which was withdrawn in England in October 2010, covered ‘Prescribed Techniques and Prescribed Technologies’ or ‘P’ standards for LASER and IPL therapies. The ‘P’ standards provided the basis for the IHAS Essential Standards, which were updated in 2015/16 and relaunched by the British Medical Laser Association (BMLA) in October 2016 [4].

Devolved government powers to Wales and Northern Ireland, resulted in the provisions of the ‘P’ standards remaining in force in these jurisdictions and including the use of LASER and IPL devices by both Healthcare Practitioners (HCPs) and non-HCP therapists. They are administered by the Health Inspectorate Wales (HIW) and the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland. From April 1, 2011, Healthcare Improvement Scotland (HIS) took over the regulation of independent healthcare services in Scotland from the Care Commission and since April 1st 2016 registers independent clinics as well as hospitals. HIS guidelines require clinics to consider MHRA guidelines on safe use of lasers as best practice.

In certain regions of England, namely the London boroughs, Nottingham and some Essex boroughs, a licensing scheme exists for providers of ‘special treatments’, which include LASER and IPL therapies. In London, this licensing scheme is delivered under provisions of the London Local Authorities Act 1991.

These standards indicate measures for safety and quality and provide a template for facility audit by clinic management and regulatory bodies. In particular, they include a requirement for a TREATMENT PROTOCOL produced by an Expert Registered Healthcare Professional (ERHP) or Expert Medical Practitioner (EMP) which sets out the necessary pre-treatment checks and tests, the manner in which the procedure is to be applied, the acceptable variations in the settings used, and when to abort a treatment [4]. The ERHP is an expert doctor, dentist, clinical scientist or registered nurse with verifiable clinical expertise in using laser/IPLs to treat patients/clients and who can demonstrate that they have the necessary knowledge and experience to produce a protocol [4]. The ERHP must also be registered with their appropriate professional body and must ensure that any protocols written are within their area of expertise. These guidelines are intended to assist ERHPs or EMPs, Laser Protection Advisers (LPAs) and users of LASER and IPL devices, in meeting the requirements of the relevant regulatory and standards requirements and to serve as ‘best practice’.

These BMLA guidelines encompass the following sections required by regional regulations:

- General provisions and technical specifications
- Cleanliness and infection control within the treatment environment
- Obtaining patient consent prior to treatment
- Record keeping requirements
- Contraindications and conditions that require special consideration
- Treatment process (step by step guidance)
  - Pre-treatment tests
  - Post-treatment care
  - Recognition of treatment related problems and skin reactions
  - Procedure if anything goes wrong during treatment
Permitted variation on machine variables and procedure in the event of equipment failure
Emergency procedures
Technique - treatment procedure for the specific LASER or IPL system.

All laser/IPL treatment operators must attend a laser/IPL Core of Knowledge safety training course of a minimum of three hours duration as described in the joint BMLA/IPEM/SRP approved Core of Knowledge syllabus or the MHRA September 2015 Guidance [1,4]. Core of Knowledge training must be repeated periodically at least every 5 years. Evidence of training attendance certificates, including who provided the training and its contents, should be held within the establishment. Typical course content:

- Basic principles of laser generation and review of laser/IPL technology
- Laser hazard classification
- Meaning of associated warning labels
- Principles of quality assurance
- Emission characteristics of different types of equipment
- Laser-tissue interaction mechanisms
- Penetration of light of different wavelengths through skin and eye
- Dangers of central versus peripheral retinal damage
- Hazards to eye and skin from accidental exposure
- The concept of Maximum Permissible Exposure and Nominal Ocular Hazard Distance
- Principles of risk assessment
- Laser safety management including the role of the Laser Protection Adviser, Laser Protection Supervisor, Local Rules and Controlled Area
- Risks associated with accidental reflections
- Personal protection measures including eye protection
- Hazards to the patient, e.g. endotracheal tube ignition
- Incidental hazards, including electrical, fire explosion and plume emission
- Relevant legislation, standards and guidelines
- How to deal with an adverse event or accidental exposure

In November 2015, Health Education England (HEE) published a recommended qualification framework for delivery of cosmetic procedures in two parts [5, 6]. This publication provided the indicative content and knowledge elements of training and education for practitioners delivering a range of non-surgical interventions and hair restoration surgery. The recommended framework developed by HEE has been adopted and is now owned by the newly formed Joint Council for Cosmetic Practitioners (JCCP) [7]. The JCCP remit is to develop and implement credible training frameworks and competencies, supported by registers of practitioners and training providers that are open to public scrutiny. However, the JCCP recognises that the registers will be voluntary for non-surgical cosmetic interventions and will therefore not be a legal requirement.

**General Provisions and Technical Specifications**

A full description of the LASER or IPL system being used must be provided, including as a minimum: supplier’s name, model, class of LASER or IPL lamp class, wavelength(s), maximum output energy, pulse duration, spot size, repetition rate, delivery system used and system serial number. Service providers should also have available for inspection evidence of installation, servicing and calibration, details of a Laser Protection Adviser site audit including device risk assessment(s) and if available, details of conformity of LASER and IPL equipment to CE standards.

**Cleanliness and Infection Control**

**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.
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) [8]. 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 treatment couches daily and if applicable, change disposable couch roll between patients/clients. Hair residue on working surfaces must be removed between patients/clients. Empty waste receptacles daily. Toilet facilities with hot and cold running water must be 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. Wash in line with national requirements for medical laundry services.

LASER & IPL APPLICATOR HEAD CLEANING
The LASER and IPL handpiece are optical components and must be kept clean and free from debris at all times. Unless the manufacturer’s guidelines specify otherwise, the handpiece should be cleaned and disinfected between patients using a soft, lint-free tissue or wipe moistened with 90% isopropyl alcohol and dried thoroughly before use.

HAND HYGIENE
Use disposable paper towels or hot air hand dryer after hand washing whenever possible. Change reusable towels between patients/clients. Wash reusable towels in line with national requirements for medical laundry services. 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 for unsoiled hands;
- 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 patients/clients 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.
• An antimicrobial hand disinfectant containing chlorhexidine or equivalent 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.

HAND CARE
Use hand lotion (supplied in pump dispenser) regularly to avoid chapping of hands.

GLOVE POLICY
The hands of laser practitioners 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/clients, which are the basic level of infection control measures in the care and treatment of patients/clients. 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.

BLOOD BORNE INFECTIONS
Where LASER treatments involve the possibility of puncture of the skin barrier e.g. Q-switched or picosecond lasers, infection control procedures for blood-borne viruses or blood aerosol contaminants are particularly important e.g. use of gloves and mask. If a patient is identified as MRSA positive they should be referred to a clinic with the necessary expertise and infection control procedures for treatment before an elective cosmetic procedure is performed.

INSTRUMENT CLEANING
Cleaning and disinfection of the LASER or IPL handpiece along with regular washing of safety eyewear and cooling gel packs should be conducted under the protocols recommended by the manufacturer. Other supplies routinely used in the laser clinic are single-use items and should be disposed of after each patient.

Obtaining Patient Consent Prior to Treatment

CONSENT POLICY (To be used for all LASER and IPL treatments)
Informed consent is a legal and medically imperative process 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/clients 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 Consent Form agreeing to LASER or IPL Skin Treatments / 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 IPL treatment. If, as the responsible practitioner, 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 patient’s/client’s, 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 handwritten 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 i.e. under 18yrs, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. As a rule, someone with parental-responsibility must give consent on the child's behalf. However, it should be noted that, following a decision of the House of Lords in 1985, children under the age of 16 can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what’s involved in their treatment, (known as Gillick competent).

Giving and obtaining consent is a process, not a one-off event. Patients/clients 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.

Note: The following examples of procedure for hair reduction, skin rejuvenation and vascular and pigmented blemish treatments may require further adaptation for the particular equipment and / or procedure envisaged.

**CONSENT PROCEDURE – Hair Reduction**

Explain the purpose of the patient consultation. Provide information about the treatments offered and details of any specific procedure requested by the patient. This may include details of the skin test patch procedure and an explanation of how LASER and IPL therapy works and the reasons for possible side effects and adverse incidents.

Answer any questions the patient has regarding treatment and make sure the patient has REALISTIC EXPECTATIONS of the outcome of the treatment. Explain to the patient what other forms of treatment are available. Exclude any unsuitable candidates from treatment.

**RISKS & COMPLICATIONS**

The following key points must be communicated:

- LASER or IPL hair removal may not be permanent and some hair may re-grow, also results vary from person to person;
- The treatment may not be effective;
- Multiple treatments are normally required because hair grows in cycles and can only be treated effectively in the growing phase;
- Eye protection is required during treatment and this may be fully occlusive;
- Treatment efficacy is related to patient skin and hair colour. In hair reduction, dark hair with light skin responds best, blonde hair and dark skin worst and white and red hair rarely responds at all;
- After LASER or IPL treatment, the skin may experience temporary textural changes such as dry texture and scaling which will normally settle over time;
- Blistering and scabbing, scarring, hypo- and hyper-pigmentation or mottling can occur;
• Occasionally, an increase in hair growth can be seen after LASER or IPL treatment. This may be due to induction of catagen and synchronisation of hair regrowth following one or more LASER or IPL treatments where more hair enters the next anagen phase than usual. The patient should be reassured that the next LASER or IPL treatment will remove this anagen hair;

• Folliculitis and/or histamine reaction can occur and can be reduced by increased personal hygiene (new razor, fresh towels and face cloths) and by using anti-inflammatory / antibacterial and skin-calming lotions;

• Very rarely an increase in hair growth can occur on, or several centimetres away from, the LASER or IPL treatment site. This is called ‘paradoxical hair growth’. The exact cause of this is unknown but clinical studies indicate that this may be due to a thermally-induced inflammatory response where severe erythema, hyperpigmentation or crusting is observed following LASER or IPL treatment [9]. The incidence of this rare effect has been reported in the literature [10] to be more prevalent in darker skin types and in patients/clients suffering from underlying hormonal conditions such as PCOS [11, 12]. The increased hair growth can be treated with LASER or IPL but more visits may be required;

• Alternative methods of hair removal include waxing, threading and depilatory creams.

Patients/clients should be made aware of likely effects following treatment including:

• Redness and/or tenderness of the treatment area;
• Itchiness, mild irritation, swelling or “tingling” which normally disappears within 48 hours;
• Superficial bruising / purpura, blistering;
• Hair will continue to “exfoliate” and fall out for up to 21 days;
• Some hair may regrow thinner and lighter than before;
• Shaving of the area may be restarted after 4 days.

Discuss the benefits and risks of the proposed treatments including details of costs and treatment course options. Establish with the patient their specific treatment interest and obtain comprehensive answers to the Health Questionnaire.

Leave the patient alone for a few minutes to consider the Consent Form before asking if they have any further questions and if they are ready to sign it. A Health Questionnaire and Consent Form agreeing to LASER or IPL Skin Treatments should be completed and signed by each patient and countersigned by the responsible practitioner.

**CONSENT PROCEDURE— Skin Rejuvenation, pigmented and vascular blemishes**

Explain the purpose of the patient consultation. Provide information about the treatments offered and detail of any specific procedure requested by the patient. This may include details of the skin test patch procedure and an explanation of how light-based therapy for skin rejuvenation works and the reasons for possible side effects and adverse incidents.

Alternative methods for vascular lesion removal include sclerotherapy where a detergent solution such as aethoxysclerol is injected into the target vessel to cause it to collapse or go into spasm and thermo-coagulation of the vessels or by using microwave or RF energy;

Alternative methods for skin rejuvenation treatment include strong chemical peels (e.g. TCA or Glycolic), ablative or non-ablative fractional resurfacing and full laser skin resurfacing;

Alternative methods for pigmented lesion removal include chemical peels and hydroquinone.

**RISKS & COMPLICATIONS**

The following key points must be communicated:

• Vascular or pigmented lesion treatment may not be permanent;
• Complete clearance of vascular or pigmented lesions may not be possible;
• Multiple treatments may be required;
• Fine thread veins and epidermal pigmented lesions respond best to treatment;
• Blistering and scabbing, scarring, hypo-hyper-pigmentation or mottling are a possibility;
• Eye protection is required and this may be fully occlusive.

Patients/clients should be made aware of likely effects following treatment including:
• Redness, swelling, blistering and/or tenderness of the treatment area;
• Itchiness, mild irritation or “tingling” which normally disappears within 48 hours;
• Superficial bruising / purpura;
• Immediate darkening of a pigmented blemish which will slough-off the skin in 7-10 days following treatment.

Discuss the benefits and risks of the proposed treatments including details of costs and treatment course options. Establish with the patient their specific treatment interest and obtain comprehensive answers to the medical and health history questionnaire.

Leave the patient alone for a few minutes to consider the Consent Form before asking if they have any further questions and if they are ready to sign it. A Health Questionnaire and Consent Form agreeing to LASER or IPL Skin Treatments should be completed and signed by each patient and countersigned by the responsible practitioner.

**Record Keeping Requirements**

A treatment register must be maintained every time a LASER or IPL is operated, including:
• the name of the person treated (including a second means of identification, such as a date of birth);
• the date and time of treatment
• the name and signature of the LASER or IPL operator;
• the nature of the LASER or IPL treatment given;
• the treatment parameters, and
• any accidents or adverse effects

**Quality Assurance**

Any organisation delivering laser or IPL treatments is required to ensure that the equipment is maintained appropriately and the laser output remains within tolerance to avoid unexpected adverse outcomes. This is achieved through a quality assurance programme which includes commissioning when the machine arrives in the organisation followed by regular checks.

These checks may be done within the organisation or could be performed by an external contractor (e.g. original equipment manufacturer service engineers). In either case, it is the organisation that takes responsibility for any equipment faults and the effects these might have.

**LASER or IPL CHECK LIST**

At the start of each day, the LASER or IPL device to be used must be inspected for physical damage or faults. The LASER or IPL unit must be calibrated. This is usually performed by the LASER or IPL’s internal system check.

If any damage to the LASER or IPL equipment is observed:
• this needs to be noted on the check list;
• any fault or damage must be reported to the Laser Protection Supervisor (LPS) and/or Responsible Person;
• if the machine is out of use, a dated “NOT TO BE USED” notice must be placed on the machine.

**Contra-indications and Conditions that Require Special Consideration**
**POLICY – to be used for all laser & IPL treatments**

It is the policy of the clinic to provide safe and effective treatments to all patients/clients who are suitable to undergo LASER or IPL procedures within the competence of its trained staff.

A contra-indication refers to a health related condition, congenital condition or medication which may cause the treatment to be unsuitable for the patient.

A condition that requires special consideration is when a condition or medication raises doubt in the practitioner’s mind that should be explored further prior to commencing any treatment.

**PROCEDURE – to be used for all laser & IPL treatments**

All patients/clients being considered for any treatment must undergo a full assessment by a trained practitioner and completion of a full Health Questionnaire including personal details, past medical history, medication being taken and details of previous treatments including recent sun exposure and use of skin peeling agents.

Ask the patient about each contraindication and conditions that require special consideration individually and mark each one with the patient’s/client’s reply. If they answer “yes” to any of the listed contraindicated conditions, document in full on the Consent Form. Act on the directions listed for that condition e.g. obtain a G.P. or specialist’s letter on that medical condition in relation to light-based therapy. This process permits detection of any potential contraindications or conditions that require special consideration. Existing patients will be risk assessed using the review part of a Health Questionnaire prior to each treatment.

Below, is a list of conditions and circumstances that are either contra-indicated for LASER or IPL treatment or require special consideration before deciding to treat. If in doubt about any medical or health conditions presented by a patient at consultation, obtain advice or refer on. If in doubt, do not treat. See also further information in APPENDIX I.

Under NO circumstances should patients /clients with any of the following conditions be treated with LASER or IPL for the purpose of hair reduction, skin rejuvenation or the removal of vascular or pigmented blemishes associated with sun-induced skin dyschromia:

- **Active skin infection/disease including: cold sores, impetigo, scabies, fungal, shingles, eczema, psoriasis, and tumours (e.g. basal cell, basal cell carcinoma, melanoma), etc. on involved skin in the intended treatment area:**

  For reasons of hygiene, prevention of cross infection and to avoid aggravating the condition, any active skin infections are contra-indicated for treatment on or near that area. Other more localised infections such as active cold sores around the mouth or genitals will contra-indicate any facial or bikini treatment but could be indicated to have LASER or IPL treatment on other unaffected body areas – check what medication they are taking for this. If the patient feels they may be about to develop a cold sore then treatment in that area should also be delayed. If you are unsure whether to proceed or not seek advice. If in doubt, do not treat. Never treat over irritated or inflamed skin. If the area is small and localised you may be able to avoid the area with a 2 cm perimeter depending on the condition. Also consider what creams/medications they may be taking for the condition. Find out what tends to aggravate the patient’s/client’s condition e.g. urticaria can be due to heat, cold, sun and the patient may be taking anti histamines. Another unaffected body area may be treated but assess each case individually. If you are unsure then seek advice.

- **Use of Roaccutane or oral Retin A within 6 months:**

  These are strong medications that often have a significant effect on the skin by increasing sensitivity, particularly UV photo sensitivity and thinning the skin. See BMLA guidance on lasers and drugs (APPENDIX II).
• Recent ultra violet (UV) exposure of the area to be treated where the skin is still recovering from the inflammatory effects of sun, tanning beds, UV-curing lamps for nails, etc., or PUVA therapy:

UV exposure stimulates melanocyte activity and therefore creates greater levels of melanin in the skin. Recently sun-tanned skin is at much greater risk of adverse effects such as excessive erythema, blisters, hyper and hypo pigmentation and burns following LASER or IPL treatment. It is advisable not to treat a tanned area of skin for up to 4 weeks following exposure, (10 days for fake tan).

**Extreme caution must be exercised if LASER or IPL treatment is being considered in the following areas:**

- Below the eyebrow or within the orbital rim of the eye socket (using opaque intra-ocular corneal shields)
- Over moles (may be covered with white cardboard)
- Over the pink part of the lips or the vermillion border
- Over open cuts or wounds
- Over unsightly vasculature on or around a hypertrophic or keloid scar
- Over tattoos or semi-permanent makeup (5 mm perimeter) – except for tattoo removal
- Inside the nasal passage
- Inside the oral cavity
- Inside the ear canal
- Over the areola (pigmented part of the nipple)
- External genitalia (e.g. male testicles)
- Genital/labial mucosa

**Serious consideration should be given before treating patients with any of the following:**

- **Psoriasis:**
  The Koebner phenomenon describes the appearance of new skin lesions on areas of cutaneous injury in otherwise healthy skin. There is a risk that it may be induced by laser treatment. Skin conditions that manifest Koebner’s phenomenon include psoriasis, vitiligo and lichen planus.

- **Pregnancy and breastfeeding:**
  Although there is no evidence to link LASER or IPL treatment to problems arising during pregnancy, it is advisable not to treat as hormonal changes may negatively influence the efficacy of treatment (e.g. hair reduction) thereby requiring more treatments; and to avoid any medico-legal claims made by the patient. See further information in APPENDIX I. Hormonal changes during pregnancy and breast feeding and the period afterwards can affect hormonal hair growth and may negatively influence the efficacy of treatment. Certain ingredients in skin care products must not be used during breastfeeding (Retin A / Retinol, salicylates, EMLA) and these must be avoided during this period. Check individual product guidance and do not proceed if you are unsure.

- **Known photosensitivity e.g. porphyria or xeroderma:**

  LASER and IPL treatments involve the use of visible and near infrared wavelengths that do not normally cause a light sensitivity reaction. However, extreme caution is required when treating such patients/clients. If in doubt do not treat. See BMLA guidance on lasers and drugs (APPENDIX II). Often patients/clients with autoimmune conditions are on high doses of steroids or other strong medication to control the immune system’s attack on their bodies and these medications can also be contraindications to treatment due to light sensitivity. Patients/clients with other conditions e.g. discoid lupus which can be exacerbated by UV wavelengths, should not be treated with light sources with wavelengths below 500 nm.

- **Cancer:**
There is no medical evidence that having either any LASER or IPL treatment will cause a malignant condition, nor cause a recurrence of a past cancer [13, 14]. However, equipment manufacturers like to cover all eventualities and some include this as a contraindication. In the unlikely, regrettable event that a cancer may recur in an individual, there is always a chance that a patient may wrongly attribute that to an unrelated treatment such as LASER or IPL, which would cause difficulty for the LASER or IPL provider. One approach might be to explain in detail that there is no medical evidence that having any LASER or IPL treatment will cause a malignant condition, nor cause a recurrence of a past cancer. The patient can then decide whether to proceed and be invited to complete the appropriate consent forms.

See further information in APPENDIX I.

- **Pacemaker / Angina / Severe cardiovascular problems:**
  If the patient has a heart pacemaker it is advisable to check first with the LASER / IPL manufacturer whether this is likely to be problematic;
  If the person is generally fit and well and their heart condition is under good control, then treatment can proceed. Always check if they are taking any medication for these conditions and assess each case individually.

- **Keloid scarring anywhere on the patient’s body:**
  This is a rare form of scar that forms a thick lumpy raised layer of scar tissue generally outside the original boundary of an injury and can form quite unpredictably and remain raised. It is important to differentiate this type of scar from hypertrophic scars (which are often isolated, smoother and tend to form inside a wound boundary and regress in time). If you are unsure ask the patient the following questions:
  - Do they form lumpy scars from vaccinations, small cuts with a razor, ear piercing, spots or insect bites?
  - What causes the scar?
  - How old is the scar?
  - Have they had the scar treated or injected at any time to make it smoother and flatter?
  - Has a doctor told them it is a keloid scar?
  - Check how many of these scars they have and inspect them.

  If it is clear from patient responses that they have been predisposed to keloid scar formation anywhere on the patient’s body, then the patient must be advised that the LASER or IPL treatment carries a risk of scarring and in such cases, this could result in a keloid scar.

  Where it can be demonstrated that no further keloid scarring has occurred in the last 5 years LASER or IPL treatment may be performed e.g. where patient has had surgery where the skin and has been compromised and subsequently healed well. If you are unsure take a picture with the patient’s/client’s permission and request further advice.

- **Scarring – atrophic, hypertrophic and general scarring:**
  ATROPHIC SCARRING normally appears as depressed or sunken scar tissue. These scars are caused when underlying structures supporting the skin, such as fat or muscle, are lost. They are most commonly seen following moderate to severe acne scarring.
  HYPERTROPHIC OR KEOID SCARRING is often the result of surgery. This also appears as raised scar tissue. These patients/clients will not necessarily always form hypertrophic or keloid scars. However, the patient should be advised of the risk of forming a hypertrophic or keloid scar following LASER or IPL treatment. Unless treatment is being performed to remove the scar, the scar should be avoided with a 2 cm perimeter. Body areas that do not have hypertrophic scars can be treated with LASER or IPL but a history of keloid scarring indicates a predisposition to further keloid formation and care should be exercised when setting treatment parameters.

  There are various types of scar tissue, such as acne scars, surgery scars (not necessarily hypertrophic), injuries etc. If a scar is less than six months old and is still healing, you should avoid it when treating with LASER or IPL. If the scar is mature, white and flat such as a neat surgery scar, or pitting from acne, it can be considered safe to treat over these scars. If the erythematous component is the target, then this may be treated early using a vascular laser.
• **Bleeding or clotting disorders and anti-coagulant therapy (e.g. Heparin, Warfarin, Aspirin):**
  Patients/clients with any blood disorders or are taking medication that affects the blood, are more likely to bruise easily and they may have a slower healing rate. The LASER or IPL treatment can sometimes cause bruising and irritation to the skin which is a normal effect of the treatment; they may be more sensitive to the LASER or IPL and may take longer to heal. The risk of secondary infection is also higher. In some cases, such as haemophilia, consult with the patient’s physician regarding prophylactic treatment, such as the use of factor eight, prior to laser treatment. Examine their medications against the check list and why they are taking them and assess each case individually. If you are unsure, do not treat.

• **Blood borne infections e.g. hepatitis B or C, or HIV / AIDS:**
  Patients/clients with conditions such as hepatitis B or C, or HIV / AIDS may be treated safely providing that the risks are understood and appropriate precautions are instituted. However, awareness of the special provisions of the Equality Act 2010 detailed in APPENDIX I which relate to treatments with HIV/AIDs is also necessary where reasonable adjustments to procedure may be made such as use of gloves and N95 respirator mask and requesting evidence from the patient’s/client’s GP or specialist that the HIV viral load is undetectable. Lower settings of the LASER or IPL may also be selected to reduce the risk of blisters. If, after considering APPENDIX I below, you may wish to discuss special precautions with your EMP / ERHP, training provider or supplier.

• **Autoimmune collagen / vascular diseases:**
  Discuss any special precautions with your EMP / ERHP, training provider or supplier.

• **Tanned skin:**
  UV exposure stimulates melanocyte activity and therefore creates greater levels of melanin in the skin. Sun-tanned skin is at greater risk of adverse effects such as excessive erythema, blisters, hyper and hypo pigmentation and burns following LASER or IPL treatment. It is advisable not to treat a tanned area of skin for up to 4 weeks following exposure.

• **Patients on other medication with known sensitivity to visible and infrared light:**
  Special consideration is necessary if a patient is taking medications. Ask for details of the name of the medication and dose / how often do they take it? See BMLA guidance on lasers and drugs (APPENDIX II below).

• **Diabetes:**
  If a diabetic patient has their condition under control and does not have a history of recurring skin infections, leg ulcers and health problems (kidneys, heart, eyes) then LASER or IPL treatment can be applied with caution. (It is advisable to ask them to shave the area themselves before coming for hair removal treatment). Check their medications for light sensitivity and assess each case individually. If you are unsure then seek advice. If in doubt, do not treat.

• **Pigmented lesions, skin lesions or blemishes – lentigines, age spots, moles, birthmarks, etc:**
  If a patient presents with a pigmented lesion and you are unsure of the diagnosis, do not treat. Refer the patient to a specialist who will carry out the necessary diagnostic investigation and take a biopsy if required.
  **If any suspicious looking lesions are observed, do not treat and advise the patient to have the lesions checked by their GP or a specialist.**

• **Pigmentation disorders – Melasma / Chloasma / Vitiligo / hypo/hyperpigmentation**
  Because melanin is a chromophore for the LASER or IPL and because the LASER or IPL treatment is a mild trauma to the skin, pigmentation disorders could be aggravated by the treatment. **MELASMA / CHLOASMA**
  If a patient has Melasma or Chloasma on the face, then this could be made darker or enhanced if a LASER or IPL is passed over the affected area. This is most likely to occur if the pigmentation has a dermal
component. Treatment protocols do exist for treating melasma. Also, diagnostic techniques are available to ensure that the lesion is epidermal. Seek advice. If in doubt, do not treat.

**VITILIGO**

Vitiligo is a systemic autoimmune problem that can randomly affect almost any body area and is quite unpredictable. It is unknown if the trauma of LASER or IPL treatment could aggravate this condition, therefore special consideration is required. If the patient wishes to proceed with treatment after being informed of the unknown factors, then the discussion must be fully documented in their notes.

**HYPO-PIGMENTATION**

Hypo-pigmentation is caused by a localised skin injury is not likely to be aggravated by the LASER or IPL and can safely be treated, although the presence of hypo pigmentation may indicate a genetic tendency and so may be more susceptible to this if the skin is over traumatised by the LASER or IPL.

**HYPER-PIGMENTATION**

If it is recent and/or extremely dark compared to the natural skin colour, should be contraindicated until it has reduced significantly.

Hyper pigmented skin that has persisted for some time can be treated with the LASER or IPL depending on the nature and the cause of it. The settings may need to be adjusted when treating over darker skin areas.

If any suspicious looking lesions are observed, do not treat and advise the patient to have the lesions checked by their GP or a specialist - see section on pigmented lesions above.

- **Currently suffering from any infection-flu, cold, etc:**
  
  Generally, it is not advisable to treat patients who are actively infectious to avoid transmission risk to operators and cross infection. If a patient is generally unwell, it means their immune system is stressed, their healing responses may not be as effective and the effects of LASER or IPL treatment may be unpredictable. Their pain threshold may also be very low.

  **Rosacea:**

  Rosacea is an inflammatory condition that can be improved and managed but not eradicated. Light-based treatments can be used to treat the vascular element of rosacea. However, the patient should be warned that the light and heat from the treatment may cause a flare up of their condition in the days following the treatment.

- **Recent major / minor operations:**

  **LOCAL ANAESTHETIC**

  Following minor surgery (such as benign mole removal under local anaesthetic), LASER or IPL treatment may follow after 2-3 weeks.

  Do not treat facial areas on the same day as dental treatment.

  The severity and nature of the condition requiring surgery will dictate the length of time to wait before proceeding with LASER or IPL treatment. Assess each case individually. Some situations may require advice or a letter from the patient’s GP or specialist before proceeding.

  **GENERAL ANAESTHETIC**

  If a patient has recently undergone major surgery or hospital treatment under general anaesthetic, they may still be recovering from the condition that was treated and their healing responses may be compromised.

- **Allergies:**

  Treatment suitability will depend on the type and severity of allergy. Certain products may need to be avoided. Ensure you ask them what they are allergic to and what kind of reaction they have in response to this stimulus (urticaria, rash, anaphylaxis, do they carry an EpiPen etc.). Assess each case individually and check their medications.

- **Pustular / Cystic Acne:**

  If a patient requests LASER or IPL treatment within an area of skin that is affected by acne, consideration needs to be given to the fact that the treatment may exacerbate the acne problem. Consideration and discussion with the patient is necessary to address the fact that the LASER or IPL treatment may irritate
the acne and that the outcome regarding the appearance and health of the skin after treatment is unpredictable. A patient that suffers with acne can have a different unaffected body area treated but always check the medication they may be taking or using for their acne.

- **Varicose veins:**
  A patient suffering with varicose veins can have LASER or IPL treatment, however, special care needs to be taken if treating the affected areas. Any area with large twisted varicose veins must not be treated directly with LASER or IPL to avoid rupturing the varicose veins. Smaller red and blue leg veins can be treated using LASER or IPL. Refer the patient to a vascular specialist for treatment of varicose veins.

- **Bruised or mottled skin:**
  If bruises are already present, they must be avoided with the LASER or IPL with a 2 cm perimeter. If extensive bruising is present, do not treat at all. Some patients have a naturally mottled appearance to the skin especially on the arms and legs. This type of skin must be treated with caution to avoid enhancing the mottled appearance (e.g. erythema ab igne) of the skin. The patient will be made aware of this at consultation and close observation of the skin should be maintained.

- **Severe Raynaud’s disease:**
  Raynaud’s disease is a condition that results in very cold extremities (fingers and toes) and patients that suffer with this condition often suffer with poor circulation and can be susceptible to bruise easily. These patients could also be more at risk of experiencing vascular mottling (Livedo Reticularis) as a result of LASER or IPL treatment. In severe Raynaud’s disease where the blood supply can be markedly poorer in the extremities (hands and feet) - avoid treating these areas due to the risk of poor wound healing and infection.

- **Patients over the age of 65yrs:**
  Older people may have a slower healing rate following skin injury, may not respond as well to treatment (i.e. poorer, slower collagen synthesis in rejuvenation treatments) and may be more likely to have health issues or be on medication. As with all other age groups, age should not be highlighted and it is not a contraindication to treatment if they are healthy. Realistic expectations as to outcome should be given at all times. The following questions should be covered for all individuals in the Health Questionnaire at the consultation stage but check:
  - Do they have any current health issues?
  - Do they have any past history of health issues?
  - Do they take any medications?

- **Polycystic Ovarian Syndrome (PCOS)**
  This is a common condition affecting 1 in 10 women in the UK. People with PCOS can certainly have LASER or IPL treatment if there are no other contraindications, however, they must also be given realistic expectations, especially when treating hair removal and acne. Treatment will be effective but on-going maintenance treatments will be required compared with someone without PCOS, due to the hormonal drive behind the excessive hair growth.
  If someone presents with the following symptoms and they have NOT been assessed by their GP or had further testing, it is advisable to recommend they see their GP:
  - Excess facial or body hair
  - Acne and oily skin
  - Irregular or infrequent periods
  - Thinning hair or hair loss
  - Weight gain
  - Depression and mood swings
  Presence of these symptoms does not mean they definitely have PCOS but it is important that it is investigated further by their GP.

**Treatment Process (step-by-step guidance)**

**Pre-treatment tests:**
All patients being considered for LASER or IPL treatment must undergo a full assessment by a trained practitioner and a full patient registration form completed including personal details, relevant medical history, and any prescribed medication being taken.

- Patients should be given written information on what to expect during and after treatment and on suitable aftercare. Consider sending out information to the patient prior to their attendance for LASER or IPL treatment to facilitate informed discussion.
- All patients being treated must be counselled regarding the risks, benefits and possible complications of treatment; they should be informed of the alternatives to treatment and be given realistic expectations as to potential outcome. The anticipated cost of treatment should also be discussed.
- Patients must read and sign the patient consent form that relates to the procedure they wish to undergo.
- It is advisable to take photographs of the area to be treated prior to treatment. Ensure consent has been obtained for the photographs.
- Patients must be given a skin patch test prior to treatment.
- Normally, the skin test patch is valid for 24 months unless circumstances change (tan, medications, medical conditions) or different LASER or IPL technology or settings are envisaged.
- Skin typing and assessment should be performed using the Fitzpatrick Scale to facilitate appropriate choice of treatment parameters.
- Skin test patches should be performed on the least conspicuous part of the area being treated.
- Each body area requiring treatment must have a separate test patch performed.
- The number of LASER or IPL shots sufficient for test patch will vary depending on body area and the risk factor to the skin, but typically will comprise of 2 to 6 individual LASER or IPL shots.
- For assistance when selecting appropriate treatment parameters for test patching, refer to the manufacturer’s guide. If in doubt, confer with the Clinic Manager or EMP / ERHP to confirm your treatment parameters.
- Normally, the patient must wait a minimum of 24 to 72 hrs after skin test patches depending on manufacturer’s or EMP / ERHP guidance.
- Treatment may only proceed fully if no adverse skin reactions are observed.

**HEALTH REVIEW**

Each time a patient visits for LASER or IPL treatment, the patient must be risk-assessed prior to each procedure. To do this, a Health Review must be completed prior to treatment. The Health Review contains questions relating to any changes in circumstances since the last consultation or treatment. Key factors to assess are any medications that may have been prescribed since their last treatment or consultation or any UV exposure the patient may have had to the intended treatment area. The practitioner must use the document to check for any factors that may affect the safety of the proposed treatment.

The practitioner must verbally check through the questions on the checklist with the patient. The practitioner must pursue further questions with the patient if it is suspected that the treatment area may have been exposed to any sunlight, UV or had fake tan products applied.

Prior to any treatment the practitioner must ask the patient what products they have applied to the skin, and the skin must be cleansed and free from any makeup prior to treatment.

**Treatment Procedure**

The TREATMENT PROTOCOL used may include reference to the manufacturer’s user manual and/or clinical applications guide. Special considerations and precautions for particular treatments or treatment methods including details of test patch procedure and waiting times before full treatment, should be highlighted in the TREATMENT PROTOCOL produced by the EMP / ERHP.

**Post-Treatment Care:**
Immediately post treatment, the skin must be cleansed of gels and any pencil markings. A soothing lotion (such as Aloe Vera) may be applied to the skin. Additional skin cooling using forced-air convection cooling, cold compresses or cooling gel packs may be applied if required. Packs of crushed ice or refrigerator ice may be used but frozen ice packs from a freezer should not be applied directly to the skin to avoid freezer burns.

All patients should receive written information about aftercare following LASER or IPL treatment, and home care verbally reiterated:

- Avoid rough handling of the treated area;
- Do not use hot water, only lukewarm water to shower for up to 72 hrs post treatment.
- Keep the area clean and dry and avoid wearing tight clothing;
- Leave any skin responses alone, these are temporary and will subside;
- Don’t pick or scratch the treated area and don’t intentionally burst blisters; large blisters may need to be managed by a healthcare professional;
- Avoid游泳 in strong chlorinated water, steam/sauna, vigorous exercise or any activity that makes you sweat profusely for up to 48 hrs post treatment.
- Always wear sun protection of at least SPF 30+ on the treatment areas especially for body areas that cannot avoid sun exposure (such as the face, forearms, etc.). Post-treatment, mineral make up (i.e. zinc or titanium oxide based) is recommended to block the skin from UV exposure.
- Avoid exposing the treated body areas to strong sunlight (beach holidays or sun beds) for the duration of the LASER or IPL treatment course and for at least two weeks after treatment.
- Avoid the use of normal makeup for 4-5 days if possible while the skin is sensitive;
- Avoid shaving the treated area until completely healed (5-10 days);
- Maintain high standards of hygiene in the skin area for several days following treatment, and
- Hydrate the body by drinking plenty of water;
- Apply professionally recommended soothing agents (e.g. Aloe Vera gel) to the treated area. Do not use any product containing perfume or chemicals e.g. alpha-hydroxy fruit acid peels (AHAs) for at least 72 hrs post treatment.
- If the patient does not have soothing products at home, provide advice about the most suitable product available. If redness or a heat sensation persists, advise the patient to apply a cold compress to the area at home. Advise them NOT TO USE frozen ice packs.

NB. Hot and humid weather conditions can aggravate skin in the period immediately following treatment. Some treatments will have specific aftercare instructions and the correct aftercare sheet must be given for each treatment.

**Recognition of Treatment-Related Problems and Skin Reactions:**

- **Recognise end points**
  An ‘end point’ is where a sufficient skin or hair reaction has been observed that is likely to achieve a satisfactory treatment outcome but without causing excessive skin reaction. Patient pain tolerance must also be considered.

- **Satisfactory end points during the treatment include:**
  - In LASER or IPL hair removal, carbonising of the hair stubble. Ejecting of hair from the follicle may indicate over-treatment;
  - Moderate erythema / redness of the skin (although some patients may display a more pronounced erythema if they are more sensitive to heat.);
  - Moderate peri-follicular oedema that is patchy and not confluent (merged together);
  - Mild puffiness to the treatment area;
  - In vascular treatments, darkening or immediate disappearance of the vessels after the LASER or IPL pulse with mild/moderate erythema in the surrounding skin. Some pulsed dye laser treatments will induce a purpuric response immediately following treatment;
In IPL treatments, darkening of pigmentation with mild/moderate erythema in the surrounding skin; Whitened ‘popcorn’ effect is the end point when Q-switched laser is used.

**Skin reactions beyond the end point, that may be observed during the treatment:**
If any of the following observations are made during treatment, the treatment must be aborted and appropriate action must then be implemented to minimise the reaction of the skin:
- Skin colour changing to a whitish, grey or darker shade;
- Erythema appearing on the skin in the shape of the LASER or IPL beam or applicator head;
- Generalised extreme / confluent (merging) erythema;
- Bruising, other than with some pulsed dye laser treatments;
- Excessive discomfort expressed by the patient. (Too much heat/warmth from the LASER or IPL that is unbearable for the patient.) Lowering settings may be appropriate if this occurs in the absence of any adverse skin reaction;
- Merging perifollicular oedema or generalised swelling.

Most immediate skin reactions are a reaction to heat, therefore cooling the skin with a cold compress is appropriate in all cases.

A detailed description of events must be entered in the patient’s notes and recorded in the adverse incidents log.

**Skin reactions beyond the end point that may occur as a late emerging reaction:**

Typically, 2 to 4 hrs post treatment, these reactions may also occur:
- Excessive or prolonged erythema;
- Blistering of the skin;
- Excessive swelling;
- Inflammation and itching.

Adverse skin reactions that can become apparent from one to several days after the treatment include the following:
- Blisters which appear as a raised fluid filled pocket. Initially the reaction can appear as a localised swelling or hive. This is more likely to occur during treatment if the skin is tanned, or if too high energy is used. Sometimes blistering will occur several hours after treatment;
- Scabbing / scaling may be observed between 12 to 24 hrs after LASER or IPL treatment;
- Hyperpigmentation may be observed several days to weeks after treatment if the skin has an adverse reaction following treatment;
- Hypopigmentation may be observed several days to weeks after treatment if the skin has an adverse reaction following treatment;
- Bruising may be observed at the time of the treatment. It is also possible that the patient reports bruising that has appeared sometime after LASER or IPL treatment;
- Excessive and / or prolonged swelling is a very unusual side effect that can occur and could take several days to return to normal;
- Infection / cellulitis may be observed within the treated area typically 2 to 4 days after treatment. Symptoms include sore, itching skin with redness, puffy or swollen skin.
- Scarring is rare but can be permanent and is the result of an adverse skin reaction where either blistering or heavy scaling has occurred, usually followed by infection and scabbing.

An excessive or undesirable skin reaction that is recognised as more than expected, treatment related skin reactions, must be treated as an ‘adverse reaction’ and recorded following adverse reaction procedure.

---

**Procedure if Anything Goes Wrong During Treatment:**

**IMMEDIATE**
If an adverse skin reaction or reaction beyond the end point is observed while a procedure is in progress or you experience a user error fault which may result in a reaction beyond the end point:

- Excessive discomfort: Stop the treatment immediately;
- Ensure skin remains clean. Give honest and calm reassurance to the patient;
- Cool the skin for at least 10 to 20 minutes;
- Do not apply any Aloe Vera Gel or any other topical agents;
- Observe the skin reaction after some time to evaluate the skin;
- With the patient’s consent, take a photograph now – document if they refuse a photograph;
- After 10 to 20 minutes if necessary, apply a burns dressing;
- Contact the patient regularly after they have returned home.

POST TREATMENT

- Cool the area regularly using ice packs or cooling gel and advise patient to use pure Aloe Vera, or equivalent, and skin protection as for mild sunburn until the sensation disappears. If the reaction persists the patient should consult their doctor.
- In the event of severe, confluent and persistent erythema, recommend topical steroid anti-inflammatory cream with instructions to apply it every 3 hours and at least 3 times a day for no longer than 72hrs;
- In the event of a superficial (first-degree) burn developing (crust, blister, burn), follow adverse reaction procedure and consider onward referral for prescription burn medication. The patient should also consider taking over-the-counter pain medication;
- In the event of excessive swelling (oedema), fragile skin, bruising (purpura): Cool area for immediate pain relief; instruct patient to consult with GP; follow establishment adverse incident procedures and the Laser Protection Adviser (LPA) should be advised;
- Complete accident log and notify the Clinic Manager;
- Arrange follow up with the clinic ideally within 48 hours if possible;
- If the patient cannot attend request that they email current pictures of the area if they are happy to do so;
- Send any photographs taken and adverse incident documentation within 24 hrs to the Clinic Manager;
- Document everything in the patient notes;
- Re-evaluate the parameters used;
- Check the LASER or IPL device for any sign of fault.

LATE EMERGING

If a patient phones or attends presenting a late emerging reaction you should advise the following:

- Change of pigmentation (hyper- and hypo-pigmentation): Moisturise and protect from sun exposure and further skin insult (i.e. leave alone and do not rub), patient should consult with treating practitioner (and GP if condition persists);
- Excessive hypo-pigmentation or scarring: Instruct patient to consult with GP; follow establishment adverse incident procedures. Avoid sun exposure and use a sun block for six months;
- Prolonged itching on the treatment area: Keep the area cool and apply pure Aloe Vera gel. If itching persists instruct the patient to consult with their doctor;
- Excessive and / or prolonged swelling may require the assistance of anti-histamine or anti-inflammatory medication. Instruct patient to consult with GP; follow establishment adverse incident procedures;
- Infection: Antibiotic creams and / or tablets may be prescribed. If a patient reports these symptoms, they should visit their GP as soon as possible;
- Ineffective hair removal: Reassess patient history and consider increasing energy density depending on skin type and patch test reaction;
- Leucotrichia: Temporary appearance of pigment-free hair. May often be confused with pre-existing, but previously unnoticed, white hair. Often resolves spontaneously. No treatment;
• Apparent increase in hair growth in the treated area: May be related to under-treatment or synchronisation of hair growth;
• Apparent increase in hair growth adjacent to the treated area – usually on the lateral face: Seen in a small percentage of middle-aged, obese women of Middle Eastern or South Asian origin usually with PCOS. Stop long-pulse LASER / IPL treatment for six months, restart using ultra-short pulse QS Nd:YAG laser or other conventional epilation treatments to achieve hair reduction.

Only retreat an area where any problems or adverse skin responses have healed fully and always repeat patch testing.

**In the event of LASER or IPL exposure to the eye the following action must be taken:**

• Arrange for the affected person to visit an ophthalmologist for an eye examination. This should be carried out within 24-48 hours so that, if there is a lesion evident in the retina, it can be determined if it is of recent origin;
• The affected person must be accompanied when visiting the hospital;
• The procedures must be recorded following procedure for incidents;
• The procedure must be reported to the local regulatory / licensing authority (area specific), Clinic Manager, Laser Protection Supervisor and Laser Protection Advisor.

**Permitted Variation on Machine Variables**

Using the chosen LASER or IPL, the practitioner is able to choose from a range of permitted machine variables (fluence, pulse duration and pulse frequency) to facilitate the optimal treatment parameters to achieve the specified end-points as described above and in the manufacturer’s User Manual.

Treatment cannot be purely prescriptive and as in all high-energy light-based treatments, individual tissue interaction and observed clinical end-points for successful outcomes are the primary determining factor in setting device parameters.

**Audit**

Regular audit of treatment outcomes and unexpected or unwanted side-effects is important to ensure improvement, and to identify any areas of concern. Audits should be carried out after the introduction of a new protocol, piece of equipment or staff member. Regular audit, carried out at least annually, may include a selection of patient feedback, recorded outcomes, recorded treatment settings and a consideration of up-to-date practice elsewhere. This can be useful for informing continuous professional development for practitioners and highlighting discrepancies between practitioners. Clinical audit will be supported by other audits, such as laser safety and hygiene.

**Procedure in the Event of Equipment Failure**

A system **WARNING** message typically occurs due to a problem that the operator can, in most cases, easily correct by following the procedure in the “troubleshooting” guide found in the manufacturer’s User Manual.

A system **FAULT** message typically occurs due to a system malfunction and generally necessitates quitting and restarting the system and attempting to perform another calibration and enter the treatment screen. If the fault recurs, contact the appointed Service Engineer for assistance.

Equipment faults should be reported in the designated fault record including the date and nature of the error / fault. The Responsible Person / Clinic Manager or LPS should then inform the Service Engineer. The keys should be removed from circulation and a pre-printed warning sign “NOT TO BE USED” fixed to the system. The system should not be used until passed for use by the appointed Service Engineer.
In the event of equipment failure, treatment should be abandoned IMMEDIATELY. Remove the mains plug if it is safe to do so. Details should be recorded in the Patient Record Sheet of the partially completed treatment with details of any untoward side effects. The appointed LASER or IPL service engineer should be informed immediately of the circumstances of the equipment failure and an Incident Report completed. Only in the case of a false alarm should treatments be restarted.

- Stop treatment (explain to patient).
- Make a note of any error code displayed on the machine screen and any damage reported to the LPS. Switch off and unplug the system;
- Consider whether the patient needs to be monitored for any adverse skin reactions before leaving the clinic;
- Advise the receptionist, the manager and the LPS about the error immediately so that any bookings for that particular machine can be reorganized;
- If the LASER or IPL has to be put out of action, then a visible “NOT TO BE USED” notice must be attached to it;
- In the event that the fault is rectified by the service engineer, the engineer must sign the appropriate section on the fault sheet and the service report must be filled in the LPS Equipment log book.

Treatment should only be restarted if the event was a false alarm. Otherwise, the system should not be used until passed for use by the service engineer.

After an engineer has serviced or repaired a LASER or IPL machine

Attention must be paid to any advice that has been given by the engineer. This may include important information such as:

- To reduce treatment parameters after a lamp has been replaced or the device recalibrated;
- To act on advice such as a lamp needing to be replaced or that any repairs are needed;
- To ensure the laser remains out of use if necessary.

If treatment settings need to be adjusted after an engineer visit, a legible notice must be placed on the machine, stating the advised adjustment(s). Other methods of informing users of any adjustments must also be used such as circulating a memo and / or verbal reiteration either to each individual or in a group meeting.

Emergency Procedures

The safety precautions, which you have in place, should prevent any serious incidents from occurring. The risk assessments should have identified all possible hazards and reduced either the outcome or the frequency. However, in the event of the following:

- Smoke or fire coming from the LASER or IPL;
- Explosion;
- Electric shock.

Immediately press the Emergency Stop Button (red button on front panel of LASER or IPL), which cuts all power to the LASER or IPL system, raise the alarm, check any casualties, remove patient from treatment room and follow emergency procedures.

If possible:

- Switch off the LASER or IPL;
- Unplug the LASER or IPL at the mains;
- Fix a notice to the LASER or IPL warning other people not to use it;
- Contact the LPS and the LPA – IMMEDIATELY;
• If a person has received an over exposure to the eye – A full ophthalmic examination must be carried out as soon as possible and, in any case, within 24 hours;
• If a person has received a serious skin burn, they should be referred without delay to a medical practitioner together with details of the laser/IPL treatment given.

Further Information

This guideline is only to be used by registered persons or operators authorised and trained to use the LASER or IPL device in conjunction with ‘Local Rules’ and within the confines of the ‘Controlled Area’ of the Establishment clinic.

Disclaimer

THESE GUIDELINES ARE INTENDED TO PROVIDE HELPFUL INFORMATION ON THE SUBJECTS DISCUSSED. THE INFORMATION PROVIDED IS WITHOUT ANY IMPLIED WARRANTY OF FITNESS FOR ANY PURPOSE OR USE WHATSOEVER.
APPENDIX I

The Equality Act 2010 [15]

Under the Equality Act 2010 several everyday situations encountered routinely in the LASER or IPL clinic have ‘protected’ status. These conditions automatically include, amongst others, pregnancy, cancer, HIV infection, multiple sclerosis, severe disfigurement (excluding tattoos), blind or partially sighted 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 in the case of hepatitis B or C, HIV / AIDS

HIV infection’ is a ‘protected characteristic’ under the Equality Act 2010 and treatment with laser or intense pulsed light (IPL) cannot be considered a contraindication, as refusal to treat may expose the laser/IPL service provider to potential litigation. Clients with conditions such as hepatitis B or C, or HIV / AIDS may be treated safely providing that the risks are understood and appropriate precautions are instituted. “Reasonable adjustments” to procedure may be made such as:

- Practitioner to use single-use nitrile or vinyl examination gloves and single-use N95 respirator mask;
- Patient to provide current evidence from G.P. that the HIV viral load is undetectable;
- Practitioner to avoid highest LASER or IPL settings to reduce risk of fluid-filled blister / burn;
- Lower settings of the laser or IPL may also be selected to reduce the risk of fluid-filled blisters that might burst exposing the practitioner to contact with the virus
- Treatment provision to be confirmed with appointed Expert Medical Practitioner (EMP/ERHP).

“Reasonable adjustments” that could be made in the case of cancer

Cancer is a ‘protected disability under the Equality Act 2010 and treatment with laser or IPL cannot be considered a contraindication, as refusal to treat may expose the laser/IPL service provider to potential litigation. However, tumours (e.g. basal cell, basal cell carcinoma, melanoma, etc.) on involved skin in the intended treatment area remain a contraindication.

There is no medical evidence that having either any laser or IPL treatment will cause a malignant condition, nor cause a recurrence of a past cancer. One approach might be to explain in detail the facts that the laser or IPL IS safe, that there is no medical evidence that having any laser or IPL treatment will cause a malignant condition, nor cause a recurrence of a past cancer. The client can then decide whether to proceed and be invited to complete the appropriate consent forms.

“Reasonable adjustments” that could be made in the case of pregnancy and maternity

Pregnancy and maternity are ‘protected characteristics’ under the Equality Act 2010 and treatment with laser or IPL cannot be considered a contraindication, as refusal to treat may expose the laser/IPL service provider to potential litigation. Although there is no evidence to link laser or IPL treatment to problems arising during pregnancy, it is advisable not to treat to avoid any medico-legal claims made by the client. One approach might be to explain that:

- Natural hormonal changes during pregnancy may negatively impact the efficacy of treatment (e.g. hair reduction) thereby requiring more treatments - this is a reason to consider delaying laser or IPL hair removal treatment until the end of breast feeding and commencement of normal periods;
- there is no published clinical evidence to prove that laser or IPL treatment during pregnancy does NOT have any detrimental effect on the developing foetus;
• in the case of laser or IPL treatment on breast tissue during breast feeding, there is no published clinical evidence to prove that laser or IPL treatment does not negatively affect breast tissue during breast feeding.
APPENDIX II

Drugs & Lasers/IPLs

Guidance provided by the British Medical Laser Association

Issued November 2017

Important

This advice relates to non-essential aesthetic laser applications and reflects the best data available at the time of this report. It updates earlier advice issued in December 2009 [16]. 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 patients/clients.
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 often lacking [17].

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 (intense pulsed light) devices emitting wavelengths above 500 nm there is very little likelihood of such a reaction for the vast majority of drugs. Despite this, some centres continue to deny treatment to a client who is on any medication with a known photosensitivity [18]. This is not at all in accord with the original BMLA guidelines nor with the current revision which sets out the evidence on which the guidance is based.

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

Practical Advice

Information regarding all drugs a client / 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) [19], e.g. Photofrin, Foscan.

b. Drugs causing marked localised light sensitivity – wait 6 weeks
Drugs administered for localised PDT [20], e.g. Ameluz, 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 patient / client wishes to proceed with treatment, the increased risk of hyperpigmentation / photosensitivity should be emphasised and documented.

a. Amiodarone – risk of hyperpigmentation and photosensitivity [21, 22].
b. Minocycline (Minocin) – risk of hyperpigmentation [23]. Recommend stopping 4 weeks prior to treatment or consider change to alternative. It may be noted that lasers have been used successfully to treat minocycline-induced hyperpigmentation [24].
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/client starts a BNF-named photosensitiser during a course of treatment then repeat test patch. It is likely, however, that the wavelength of laser / IPL will not induce a photosensitive response.

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 – There is some controversy around this. The British National Formulary (BNF) states that clients should be told to avoid laser skin treatments for 6 months, although it has been reported that many laser clinicians have treated within this time period without seeing any adverse effects [26]. Examples include: isotretinoin (Roaccutane), acitretin (Neotigason), alitretinoin (Toctino)
b. Topical Retinoids – stop use 2 weeks prior to laser, recommence once area is healed. Examples include: 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. Examples include: 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 safely. Wait 1 week prior to treatment and avoid use immediately following laser therapy. Recommence 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.

‘Drugs and lasers/IPLs – Guidance provided by the British Medical Laser Association’ reprinted by kind permission of the British Medical Laser Association.
APPENDIX III

Acknowledgements

Dr Godfrey Town Ph.D.          RPA2000 Certificated Laser Protection Adviser
Dr Ross Martin MB., ChB.       Expert Registered Healthcare Practitioner
Prof Harry Moseley            British Medical Laser Association & Expert Registered Healthcare Practitioner
Dr Paul Meyers               Expert Registered Healthcare Practitioner & Doctors Appraisal Consultancy
Dr Jon Exley Ph.D.            Lynton Lasers & British Medical Laser Association
Dr Vishal Madan              British Medical Laser Association
Dr Tom Lister                 British Medical Laser Association
APPENDIX IV

Bibliography

[16] http://www.bmla.co.uk/resources/ downloaded 10/04/2017