LIPLED Standards

Box 1. Identified risk level and cooling off	

Risks to patient	According to the British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – As per *Standard 1* [1].
	
	Device and modality stratified risk with appropriate operator support and work environment as per Health and Safety Work Act 1974.
	
	Risks according to underlying diagnosis
	• Diagnosis needed prior to treatment (excluding hair removal) to prevent inappropriate treatment of pigmented lesions and port wine stains
	• Pigmented lesions, excluding sole photo-damage, need to have diagnosis confirmed by a clinician before laser can be performed. Delay in diagnosis can be significantly dangerous.
	• All practitioners under must have passed a CPSA recognised course on the identification of photochromia and high risk pigmented lesions.
	• Suggestion to identify red flags for pigmented lesions including:
	  ○ Single lesion
	  ○ Asymmetrical
	  ○ Unilateral
	  ○ Different colours,
	  ○ Any history of skin cancer,
	  ○ Lesions since childhood/birth
	  ○ Non-facial pigmented lesions.
	• Practitioners must be able to identify lesions deemed suspicious via referral to 'ABCDE' (Asymmetry, borders, colour, diameter, evolving) of dermatology or similar assessment tools.
	• Basic dermatological assessment of pigmented lesions to be mandatory component of training programmes.
	Lesions deemed to be suspicious must be referred to appropriate medical supervisor.
	• General photo damage that does not include discrete

	lesions must be photographed, but may not require referral depending upon background and qualifications of practitioner. • Clinical photography documentation is vital important both pre and post treatment. Photographs pre-treatment is mandatory for all cases, including photo-damage. • Non-clinicians need to work in a Multidisciplinary Team (MDT) environment and confirm/prove competencies. Practitioners should have insight of their limitations. • Appropriate accredited training providers with clinical expertise. Online module with support from the BAD in order to be considered to deliver appropriate training and a basic level of competence required. The focus of these modules is to safeguard patients. • Appropriate accredited training providers with clinical expertise, e.g. BAD, to convene training courses on pigmented and vascular lesion identification appropriate for LIPLED interventions. • Diagnosis must be established prior to treatment and must for part of the consent form. **Risks according to anatomical location** • Any treatment to **periorbital lesions** require Level 7 qualification and under supervision as per HEE. HEE does not define the level of supervision required. The supervisor is fully accountable for risks and complications. o Supervision is determined by professional background of practitioner (see matrix) o Supervisors must be able to diagnose, treat, discuss alternative treatments and deal with the complications • Any Level 6 fractional **ablative treatment** near the**, neck and genitals** must have direct access to a GMC registered practitioner **Risks according to injury** • Any treatments which cause injury into the epidermis with risk of oozing, crusting, bleeding and require wound care and topical treatment should have a **PSRB registered supervisor** as this requires the ability to prescribe and manage adverse events. This includes: any type of **ablative treatment** including CO2 plasma energy treatments (*to be updated according to emerging treatments) and any sub-ablative treatments, **fractionated laser** and **energy based peels**. • Proposal to define 'deep' / fully ablative in order to categorise level of risk of procedure and related training/supervision levels required. E.g. Procedures intended to ablate sufficient tissue to breach the epidermis/dermal barrier, that are expected to require wound care and topical treatment, e.g. CO_2 skin resurfacing,

	require practitioners qualified to Level 6, as appropriate persons able to identify and manage adverse events (see *Supervision Matrix*) • Procedures that do not ablate deep tissue, e.g. fractional Er:YAG, Er:Glass, plasma technologies, intended for skin 'rejuvenation' may be undertaken by practitioners qualified at Level 5 subject to appropriate training and supervision (see *Supervision Matrix*) • Procedures within the periorbital region, and non-fractional ablative default to Level 7 qualified practitioners (see *Supervision Matrix*) **Risks according to pigmentation** • To treat dyschromia must have BAD approved pigmentation identification course **<u>References</u>** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – as per Standard 1
Risks to practitioner **and assisting staff**	As defined by the recommendations of the BMLA essential standards [1]. **<u>Risks according to laser protection</u>** • Roles and responsibilities of people operating on the premises are clearly defined • There is a named Laser Protection Supervisor (LPS)/Laser Supervising Officer (LSO) • The LPS/LSO has been specifically trained for the devices in use • The LPS /LSO has *Core of Knowledge* • The Laser Protection Adviser (LPA) hold a current certification from a recognised awarding body **Risks according to authorised users** • Have the minimum training of a recognised/accredited Core of Knowledge taken within the last 5 years • Have received manufacturer or device specific training. • Have read Local Rules • Can produce evidence of certificates/training **Risks according to Health and Safety** • Laser/light risk assessments must have been complete and appropriate for use • Risk assessments must inform Local Rules and facility file • An eye and skin adverse incident policy and procedure must

	be in place. All stakeholders must be aware of its contents • Incidents must be reported to the LPA and LPS where appropriate • All legally reportable accidents, incidents or ill-health is reported to RIDDOR [2]. **Risks according to indemnity** • Adequate practitioner indemnity is required – professional indemnity mandatory - as per overarching principles • All practitioners providing laser, light and energy based treatments need appropriate insurance for each practitioner, device and modality being undertaken • Supervisors must be insured to supervise **Risks according to supervision requirements** • Refer to the *Supervision Matrix* **<u>References</u>** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – as per Standard 1 2. RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013. http://www.hse.gov.uk/riddor/
Consent	• Use of GMC standard [1] and Department of Health [2] guidance for consent • Mandatory signed written consent for every patient Prior to every treatment/visit consent must be re-confirmed • Informed consent for the patient including adverse events and alternatives New consent required every 12 months • Carbon copy or equivalent copy of consent must be offered to the patient every time • Every practice should be in accordance with Code of Practice and Data Protection Act for photography including separate photography consent form, procedure consent form and storage [1]. • If a patient declines to have photograph taken then practitioner has right to decline treatment and this is at the practitioner's discretion. This must be documented in the notes. **<u>References</u>** 1. Consent. Patient and doctors making decisions together.

	Good medical practice. GMC. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp 2. Reference guide to consent for examination or treatment. Department of Health. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition 3. Data Protection. https://www.gov.uk/data-protection/the-data-protection-act
Cooling off	• **be as per the overarching principles.** • Pre-treatment photographs mandatory for all cases. • Photographs of pigmented lesions, excluding photo-damage should have photographs reviewed/signed off by a competent clinician prior to treatment. Pigmented lesions need established diagnosis prior to even patch testing. • Patch test on the day of consultation for hair reduction / tattoo removal, subject to informed consent for treatment and photography, with a cooling off period of minimum 7 days before returning to commence treatment, subject to patch test having produced no adverse skin reactions/events.

Box 2. Premises requirements	
Premises **Procedure room**	**Premises** As per overarching principles **Procedure room** As per overarching principles and additionally: • BMLA essential standards (*Standard 3*) must be met [1] **Laser, light controlled areas – clearly defined** • There must be a suitable entrance warning sign or light entry system which complies with Safety and Signs and Signals Regulations 1996 [2] and BS EN 60825-1 [3] • There must be a suitable door locks or interlock system installed • Laser proof blinds/barriers in place at windows, which block optical radiation, if indicated by local rules • Sink and hand washing facility • Reflective surfaces risk assessed • Documented key control policy

	• Sink and hand washing facilities immediately available • Reflective surfaces identified and risk assessed • All ignition hazards identified and risk assessed • Adequate extraction fans • Evidence of a service agreement • Appropriate eye protection in place based on the controlled area risk assessment • A documented lone worker policy **Faculty Treatment Administration** • There must be accurate records of device, serial numbers, and intended treatments for each device **There must be separate treatment protocols for each device approved by Expert Register Healthcare Professional (registered by their appropriate professional body) including the following** • Names and technical specification of equipment • Contraindications • Treatment technique – general • Treatment technique – specific • Client consent prior to treatment • Cleanliness and infection control • Pre-treatment tests • Post-treatment care • Recognition of treatment-related problems • Emergency procedures • Permitted variation on machine variables • Procedure in the event of equipment failure A PLUME extractor subject to risk assessment by qualified Laser Protection Adviser (LPA) and nature of environmental and building control regulations, e.g. air quality requirements. See (Chartered Institute of Building Services Engineers (CIBSE) Guide for Environmental Design. **References** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – as per Standard 1 2. Safety and Signs and Signals Regulations 1996 3. BS EN 60825-1 4. Chartered Institute of Building Services Engineers (CIBSE) Guide for Environmental Design. http://www.cibse.org/knowledge/knowledge-items/detail?id=a0q20000008I79JAAS
	LIPLED Devices need to be assessed against

Equipment	• IEC62471 (CIES 009):200 [1] **All LIPLED devices must be assessed against the following:** • Aperture label, • Class/max power • Wavelength label, • Hazard warning and precautions label • Mains on indicator • System on indicator • Standby mode indicator • Emergency off switch • Capture key operation • Optical safety filters/shutters **Personal protective equipment (PPE) must be assessed against the following:** • BS EN 207:2017 [2] BS EN 208:2009 [3] • BS 1SO 12609-1:2013 [4] • BS 1SO 12609-2:2013 [5] **PPE must be checked audited and checked for the following:** • Quantity • Make • Use by date • Filter colour • Condition/cleanliness • Storage • CE Mark • Eyewear covers full wavelength range - **Topical Anaesthesia** • All medications must be managed as per overarching principles • Medication should be stored as per manufacturer's instructions • Topical anaesthetic creams are medicines therefore prescribers should refer to Summary of Product Characteristics (SPC) [6] with regards to dosing as this will vary according to different anaesthetic creams and for different areas of the body • Patient must not be advised to purchase multiple products over the counter and administer above the recommended dose. • All practitioners must be trained to recognise local anaesthetic toxicity **Resuscitation** • Resuscitation requirements are as per overarching principles. • If prescription medicines (including topical) are being

	administered with potential harmful toxic effects, the practitioner must be trained to recognise, treat and escalate appropriately **References** 1. IEC62471 (CIES 009):200 2. BS EN 207:2017 https://shop.bsigroup.com/ProductDetail/?pid=000000000030336444 3. BS EN 208:2009 https://shop.bsigroup.com/ProductDetail/?pid=000000000030169127 4. BS 1SO 12609-1:2013 https://shop.bsigroup.com/ProductDetail/?pid=000000000030187419 5. BS 1SO 12609-2:2013 https://shop.bsigroup.com/ProductDetail/?pid=000000000030187422 6. Summary of Product – Topical Anaesthesia. https://www.medicines.org.uk/emc/medicine/24217)
Clinical waste and sharps requirements	As per overarching principles and additionally • Sharps managed as per regulation [1] • All bodily fluids/human tissue into clinical waste bins and appropriate disposal. Appropriate disposal according to regulations [2]. • A sharps bin must be available in the procedure room (including for disposal of razors/razor blades/sharps) **References** 1. Health and Safety (Sharp Instrument in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm 2. Classify different types of waste. https://www.gov.uk/how-to-classify-different-types-of-waste/overview
Device management and storage	As per BMLA essential standards (*Standard 3*) **References** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – as per Standard 3

Box 3. Education and Training requirements	

HEE levels	HEE does not define if there should be direct supervision. However, supervisor is accountable for all risks and complications. *(See Supervision Matrix)*
	
	Recommendation:
	
	• Any treatments which cause injury into the epidermis with risk of oozing, crusting, bleeding and require wound care and topical treatment should be **Level 6 or 7 requiring PSRB registered supervisor** as requires ability to prescribe and manage adverse events. This includes: any type of **ablative treatment** including CO2 plasma energy treatments (*to be updated according to emerging treatments) and any sub-ablative treatments, **fractionated laser** and **energy based peels**.
	• Any treatment of **vascular lesions** with any of the following will require Level 7 qualifications and GMC registered appropriate supervision:
	  ○ Eyelid involvement
	  ○ When purpura is the desired endpoint
	  ○ Any doubt about diagnosis
	  ○ Lesion is present since birth
	• All **pigmented lesions,** excluding sole photo-damage**,** need pre-treatment photographs require diagnosis confirmed prior to any treatment. Level 4 and 5 practitioners are permitted to treat dyschromia but must have BAD approved pigmentation identification course. If there is any doubt in the diagnosis, this should be discussed with a clinician.
	• Must ensure patients get safe, adequate and appropriate treatment. Practitioner must be aware of alternatives and recommend most appropriate treatment.
	• If the practitioner does not know the diagnosis, then a suitably trained clinician must review the lesion/presenting condition.

Degree requirements and qualifications	**Non-clinicians must have minimum qualification of level 4. This requires:** • Laser Core of knowledge • Manufactory/industry certificate • Level 4 qualification as per HEE framework • Non-clinicians must have a minimum qualification of level 4 (however for the first 2 years of provisional registration, level 3 entrants will be accepted, subject to confirmed intention of progression to Level 4)

	Our aim is to not prevent people from entering laser/IPL practice but to adhere and demonstrate competence through the HEE levels. Training should include core safety and industry certificate.
Accredited course	As per overarching principles and additionally: • As above • Content of the course should be in line with the CPSA standards and HEE framework • Should include teaching in the assessment of Body Dysmorphic Disorder and mental health assessment. • Reflective practice should be included in teaching
Resuscitation	As per overarching principles
Logbook and number cases	• For each treatment modality need to demonstrate a mix of different caseload with range of skin types and anatomical sites • To gain qualification for **Level 4 and 5**: to perform 10 treatments supervised (by defined supervisor) on a range of skin types and body parts. As part of training. o To maintain annual practice minimum 10 cases per year. If not met or discontinuation of performing treatment for more than12months will need refresher training of 5 cases with a supervisor. • To gain qualification for **Level 6**: 5 supervised in training facility, then a pre-registration period with further direct supervision by appropriate PSRB supervisor on 5 cases, with a minimum of 2 of those cases to be supervised by PSRB supervisor who will be accountable for practice in clinic. o To maintain annual practice minimum 10 cases per year. If not met or discontinuation of performing treatment for more than12months will need refresher training of 5 cases with a supervisor. • For medical doctors who do not have laser/IPL as part of their regular training framework will need supervision from a PSRB registered suitable supervisor with laser competency • If changing to a new clinic with new supervisor: new supervisor must observe minimum of 1 case • Case based discussions as part of consultations with understanding of clinical end-point of both laser and IPL • All require patient testimonials

Continual professional development (CPD)	As per overarching principles As per BMLA standards [1] • Validated and accredited CPD • Annual minimum CPD points: 10 hours • A minimum attendance of one conference or equivalent providing verified CPD. • Evidence for ongoing education, documented annual appraisal for all levels and audit work. • Teaching, management and leadership as per standards of code of practice • All practitioners who wish to organise or teach on courses should meet The JCCP Education and Training Standards which are cited on the JCCP website entitled 'The JCCP Education and Training Providers Register Standards' **References** • British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.'

Box 4. Supervision – *See Supervision Matrix*	
Assessment of patient	If any doubt of diagnosis – this requires review by GMC registered appropriate clinical supervisor to aid in diagnosis and management • Photographs of all cases should be taken prior to treatment • Photographs of pigmented lesions should have photographs reviewed/signed off by competent clinician prior to treatment. The clinician must be trained in the diagnosis and referral process for suspected skin malignancy.
Selection of treatment	Must be face to face assessment of patient with a suitably qualified practitioner
Using device - supervision	Laser/IPL Protection supervisor should be on site Laser/IPL Protection adviser can be external As per *Supervision Matrix* and additionally:

	Following require PSRB registered supervisor input:
	• Any treatments which cause injury into the epidermis with risk of oozing, crusting, bleeding and require wound care and topical treatment should be **Level 7 requiring PSRB registered supervisor** as requires ability to prescribe and manage adverse events. This includes: any type of **ablative treatment** including CO2 plasma energy treatments (*to be updated according to emerging treatments) and any sub-ablative treatments, **fractionated laser** and **energy based peels**.
	• All **pigmented lesions** need pre-treatment photographs and diagnosis confirmed prior to any treatment. Photos reviewed by clinician deemed qualified in diagnosing pigmented lesions.
	• Any treatment for **vascular lesions** with following will require a GMC registered supervisor (Level 7): to aid in diagnosis and management of:
	  ○ Eyelid involvement
	  ○ Purpura is the desired endpoint
	  ○ Any doubt about diagnosis
	  ○ Lesion is present since birth
	• Treatment with long pulsed Nd:YAG laser for certain vascular lesions on the face, e.g. telangiectasia, laser on the face may require supervision by a suitably experienced PSRB practitioner due to its depth of penetration.
	• To treat dyschromia must have BAD approved pigmentation identification course

Box 5. Administration	
Safe and effective practice	According to the British Medical Laser Association 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.' – as per *Standard 1 & 2* As per above for: • **PPE** • **Eye protection** • **PPE** • **Anaesthesia and medicines** • **Laser records** • **Resuscitation** • **Evidence of training and HEE Level** • **Supervision** **<u>References</u>**

	1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.'

Box 6. Record of procedure	
Documentation	As per overarching principles and BMLA Essential Standards. Additionally: • Mandatory documentation of consultation • Mandatory written consent for every patient. • Prior to every treatment/visit consent must be re-confirmed. • New consent required every 12 months. • Carbon copy or equivalent copy of consent to patient should be offered to patient every time
Photographs	As per overarching principles and additionally: • Images/videos should be stored as per national guidance [1] • Pre and post photographs must be taken pre intervention, and at stages of treatment • Consent attained at first treatment and then verified at each stage **References** 1. Information for Health Organisations. https://ico.org.uk/for-organisations/health/
Storage	As per overarching principles

Box 7. Patient follow–up

Appropriate follow up	• Fractional/Non-fractional Ablative Treatment mandatory offer of follow up within 2 weeks of treatment • For non-ablative recommended follow up is offered but on discretion of practitioner
Patient given contact telephone number	As per overarching principles and additionally: • All patients must be given emergency contact details for in and out of hours.
Supply written information	• A post-procedure leaflet with explicit information of risks, complications and relevant to treatment to clarify when in an emergency to go to A&E
Informed of complications to look for	• Written aftercare instructions must contain descriptions of complications to look out for and what to do if they develop
Patient given opportunity to feed back – complain or compliment	As per overarching principles

Box 8. Logbook and Case Numbers	

Logbook	• A practitioner logbook is essential to practice
	• Practitioners should keep individual record of activity.
	• Must be contemporaneous
	• Either digital of paper
	• Additional information to be contained:
	  ○ Date
	  ○ Time
	  ○ Non-identifiable patient ID number
	  ○ Practitioner name
	  ○ Practitioner ID
	  ○ Indication
	  ○ Diagnosis
	  ○ Device used
	  ○ Treatment course
	  ○ Anatomical location
	  ○ Complications/adverse events

Number of	• All **level 4 & 5** including hair removal to be signed off with a mix of **10 treatments** with understanding of clinical end-point

supervised cases prior to practice	of both laser and IPL with range of skin types, anatomical sites: 10 cases to gain qualification in training course. ○ To maintain annual practice minimum **10 treatments per year.** If not met or discontinuation of performing particular treatment for more than12months will need refresher training with a supervisor of 5 cases. • Tattoo removal and benign vascular lesions, with range of skin types, anatomical sites: **10 cases** to gain qualification in training course. ○ To maintain annual practice minimum **10 treatments per year**. If not met or discontinuation of performing treatment for more than12months will need refresher training with a supervisor of 5 cases. • **Level 6** (including use of fractionated laser) for signing off will require **5 supervised cases during training**, and pre-registration period with **further direct supervision with PSRB appropriate supervisor on 5 cases**, with a minimum of **2 of those cases to be supervised by PSRB appropriate supervisor who will be accountable for practice in clinic**. They will require contemporaneous logbook as evidence for annual appraisal. • For medical doctors if lasers/IPL not part of framework of training will need supervision by PSRB appropriate registered supervisor with laser competence.
Number of annual cases to maintain practice	• **All level 4 and 5 including hair removal, tattoo removal and benign vascular lesions:** To maintain annual practice minimum **10 treatments per year**. If not met or discontinuation of treatment for 12 months and less will need refresher training with a supervisor of 5 cases. • **Level 6 (**including use of fractionated laser) for signing off will require **5 supervised cases** during training, and pre-registration period with **further direct supervision with PSRB appropriate supervisor on 5 cases**, with a minimum of 2 of those cases to be supervised by PSRB appropriate supervisor who will be accountable for practice in clinic. They will require contemporaneous logbook as evidence for annual appraisal.

Box 9. CPD and appraisal	
Related annual conference, teaching or	As per BMLA standards and overarching principles [1]. Additionally: • Validated and accredited CPD

leadership role	• A minimum attendance of one conference i.e. Verified CPD conference and minimum of 10 hours of CPD • Evidence for ongoing education, documented annual appraisal for all levels and regular audit of clinical practice • As per standards of code of practice regarding teaching, management and leadership **References** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.'
Logbook	See Box 9
Annual audit	As per BMLA Essential Standards [1] and: • 1 audit / quality improvement project per year • Review of practice to provide at annual appraisal • Must review outcomes, adverse events and complications **References** 1. British Medical Laser Association (BMLA) 'Essential Standards Regarding Class 3B and Class 4 Lasers and Intense Light Sources in Non-surgical Applications.'
Patient reported outcome measures (PROMs)	• Every patient must be given the opportunity to feedback their outcomes at the end of every patient episode and formal quantitative and qualitative PROMS are recommended • Patient involvement/feedback to be shown as evidence
Review of complaints and compliments	As per overarching principles and additionally: • Must have a local quarterly review of outcomes • Must have an annual appraisal where outcomes are discussed
Work based assessments	As part of training evidence up to level of qualification
Annual appraisal including this	As per overarching principles • There must be an annual appraisal of performance activity

scope of work	and audit
For PSRB professionals: **Five year revalidation including this scope of work**	• Within 5 year cycle will have to repeat training course and revalidation of core of knowledge. • 5 year appraisal to review above are met • Industry training is valid • Non-PSRB practitioners must also emulate this pattern