

Inspection Report

2 and 6 December 2021



On Second Thought Laser Tattoo Removal

Type of service: Independent Hospital – Cosmetic Laser Service Address: 1 - 9 Carnmoney Road, Unit 3 Lesley House, Glengormley, Co. Antrim, BT36 6HL Tel No: 079 4304 1853

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/, The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

Organisation/Registered Provider:	Registered Manager:
Mr David Raphael	Mr David Raphael
	Date registered: 4 February 2020

Person in charge at the time of inspection:

Mr David Raphael

Categories of care:

Independent Hospital (IH)

Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT(L)

Prescribed techniques or prescribed technology: establishments using intense light sources PT(IL) – following this inspection

Brief description of how the service operates:

On Second Thought Laser Tattoo Removal is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with a prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT (L) category.

A variation to registration application was submitted to RQIA to add a prescribed techniques or prescribed technology: establishments using intense light sources PT (IL) category.

Laser equipment:

Manufacturer:	Lynton Lasers
Model:	Luminette Q
Serial Number:	LETQ-096-19
Laser Class:	4
Wavelength:	532nm and 1064nm

IPL equipment:

Manufacturer:	Lynton
Model:	Excelight Flashlamp system
Serial Number:	EXC-199-21
Wavelength:	532nm and 1064nm

Laser protection advisor (LPA): Dr Andrew J Barry

Laser protection supervisor (LPS): Mr David Raphael

Authorised operator: Mr David Raphael Types of laser treatments provided: Tattoo removal Fungal nail treatment Skin pigmented lesion removal

Medical support services: Dr Ross Martin

Types of IPL treatment provided: Hair reduction Skin rejuvenation Vascular lesion treatment Pigmented lesion treatments Acne treatments

2.0 Inspection summary

This was a variation to registration inspection, undertaken remotely by a care inspector on 2 and 6 December 2021 using a desk based inspection approach. Dr Ishmail Badr, RQIA's Medical Physics Expert, supported the inspection remotely and reviewed details of the new IPL machine and associated safety arrangements. Dr Badr's findings are appended to this report.

The annual announced inspection of On Second Thought Laser Tattoo Removal had been undertaken on 22 July 2021, with no areas for improvement identified. Following the inspection a variation of registration application was submitted to RQIA on 6 October 2021 by Mr David Raphael, Registered Person, to add a prescribed techniques or prescribed technology: establishments using intense light sources PT (IL) category. It was agreed that this variation of registration inspection could be conducted remotely using a desk based approach.

The inspection sought to review the readiness of the establishment for the provision of care and treatment associated with the new intense pulse light (IPL) machine. This inspection focused solely on those treatments using the intense pulse light (IPL) machine that fall within regulated activity.

Review of the variation application established that there were no changes made to the premises to facilitate the new IPL machine as it will be located in the existing treatment room. Therefore an RQIA estates assessment was not required in respect of this application.

The IPL documents were reviewed by Dr Badr, RQIA's Medical Physics Expert, on 6 December 2021 and no recommendations were made.

The variation to registration application to add a prescribed techniques or prescribed technology: establishments using intense light sources PT (IL) category was approved from a care perspective following this inspection.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the practice is operating in accordance with the relevant legislation and minimum standards.

Before the inspection Mr Raphael was asked to submit specific information to RQIA. This information was reviewed by the care inspector and Dr Badr. This included the following records:

- the variation of registration application
- the updated statement of purpose and client guide
- information in relation to the new IPL machine that included; the local rules and LPA risk assessment; medical treatment protocols; photographic images of the new IPL machine and the protective eyewear in place
- records of training for the authorised operator
- the arrangement for clients undergoing IPL treatment
- written and verbal communication received since the previous care inspection
- the previous care inspection report

Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

4.0 What people told us about the service

As this inspection was conducted remotely it was not possible to speak with clients.

During the annual announced inspection undertaken on 22 July 2021 clients had provided feedback indicating a high level of satisfaction with the standard of care and service provided by the establishment.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

The last inspection to On Second Thought Laser Tattoo Removal was undertaken on 22 July 2021 and no areas for improvement were identified.

5.2 Inspection outcome

5.2.1 Is the Statement of Purpose in keeping with Regulation 7, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005?

A Statement of Purpose was prepared in a recognised format which covered the key areas and themes outlined in Regulation 7, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. The Statement of Purpose had been updated to reflect any changes detailed in the variation to registration application. Mr Raphael is aware that the Statement of Purpose is considered to be a live document and should be reviewed and updated as and when necessary.

5.2.2 Is the Patient Guide in keeping with Regulation 8, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005?

A Patient Guide was available in a recognised format which covered the key areas and themes specified in Regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005. The Patient Guide had been updated to reflect any changes detailed in the variation to registration application. Mr Raphael is aware that the Patient Guide is considered to be a live document and should be reviewed and updated as and when necessary.

5.2.3 How does the service ensure that IPL procedures are safe?

<u>Staffing</u>

Mr Raphael is the only person who works in On Second Thought Laser Tattoo Removal. Mr Raphael told us that IPL treatments will only be carried out by him as the sole authorised operator.

Mr Raphael stated that he does not intend to recruit any additional authorised operators at the present time. It was confirmed with Mr Raphael that should authorised operators be recruited in the future all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

During the inspection on 22 July 2021 it was evidenced that Mr Raphael had up to date training in core of knowledge training, application training for the laser machine, basic life support, infection prevention and control, fire safety awareness and safeguarding adults at risk of harm in keeping with the RQIA training guidance. Prior to this inspection Mr Raphael provided copies of training certificates that verified dates of when this training had been completed and also verified that he had completed application training for the IPL machine and the treatments to be offered.

Appropriate staffing levels were in place to meet the needs of clients.

IPL safety

As previously stated this inspection focused solely on the additional arrangement that had been put in place for the IPL machine as the laser safety arrangements had been reviewed during the previous inspection on 22 July 2021.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires on 30 September 2022.

Up to date local rules, written on 1 October 2021 by establishment's LPA, were in place and it was confirmed these are valid for 12 months form the date of issue.

The establishment's LPA completed a virtual risk assessment of the premises on 1 October 2021 and it was confirmed that all recommendations made by the establishment's LPA have been addressed.

As discussed, Mr Raphael is the only person who works in the establishment and will be the only authorised operator undertaking IPL treatments. Medical treatment protocols in respect of treatments to be offered using the IPL machine were in place. These had been produced by a named registered medical practitioner on 15 August 2021 and are due to be reviewed on 14 August 2022. The medical treatment protocols contained the relevant information about the IPL treatments being provided.

Mr Raphael as the laser protection supervisor (LPS) and sole authorised operator has overall responsibility for safety during IPL treatments. Mr Raphael had signed to state that he had read and understood the local rules and medical treatment protocols.

When the IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

The environment in which the IPL equipment will be used was reviewed during the previous inspection and was found to be safe and controlled to protect other persons while treatment is in progress. Mr Raphael had confirmed that no changes have been made to the premises and that the IPL machine is located in the existing treatment room.

At the previous inspection it was determined that the controlled area (treatment room) is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Mr Raphael had demonstrated that the laser safety warning signs would only be displayed when the laser/ IPL equipment is in use and removed when not in use. The door to the treatment room is locked when the laser/IPL equipment is in use but can be opened from the outside in the event of an emergency.

Mr Raphael confirmed that the laser and IPL machine would not be in use in the controlled area at the same time.

The IPL machine is operated using a keypad code. It was verified that arrangements are in place for the safe custody of the keypad code when not in use.

Photographic images of the protective eyewear in place were provided prior to the inspection and shared with Dr Badr, who verified that, the protective eyewear available for the client and operator are in accordance with the local rules.

It was confirmed that a dedicated IPL register is in place and includes:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure
- any accident or adverse incident

Mr Raphael confirmed that the IPL register will be completed every time the IPL equipment is operated.

A copy of the installation report by the service engineer, dated 17 November 2021, was provided by email. Mr Raphael confirmed that servicing arrangements are in place for the IPL equipment.

It was determined that appropriate arrangements were in place to operate the IPL equipment.

Client pathway

Mr Raphael confirmed by email that clients receiving IPL treatments will be provided with an initial consultation to discuss their treatment and any concerns they may have. Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client. Written information will be provided to the client pre and post treatment outlining the treatment provided, any risks, complications and expected outcomes.

Mr Raphael also confirmed the service has a list of fees available and this has been updated to include all IPL procedures offered.

It was established that IPL client care records would be maintained in the same format as the existing laser client records and will include:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

The previous inspection evidenced good practice in relation to the management of clinical records, maintaining client confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Mr Raphael provided assurance that robust measures remain in place to maintain client confidentiality and to ensure that client information is stored securely at all times.

6.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
Total number of Areas for Improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mr David Raphael, Registered Person, following this inspection and can be found in the main body of the report.

Laser Protection Adviser's Report

Clinic Details

On Second Thought Laser Tattoo Removal 1-9 Carnmoney Road Unit 3, Lesley House Glengormley BT36 6HL

Introduction

A review of the risk assessment, local rules, IPL installation sheet, Expert Medical Practitioner protocol, machine labels and protective eyewear were performed by the undersigned LPA on behalf of RQIA. The practice has a current licence to perform laser procedures and has applied for the licensing to be extended to include use of the Lynton Excelight Intense Pulsed Light system for a range of superficial cosmetic procedures.

The room in which the IPL will be used has been inspected previously by RQIA for its suitability for class 4 laser use and was deemed fit for purpose (which would also be suitable for IPL use).

The client is understood to have undertaken applications training from the IPL supplier.

This report summarises the outcome of the review, including any improvements which may be required (where applicable). The review and consequent recommendations (where applicable) are based on the requirements of the Minimum Care Standards for Independent Healthcare Establishments published by the Health, Social Services and Public Safety (DHSSPSNI) July 2014.

IPL Equipment

Make	Model	Class	Serial Number	Wavelength
Lynton	EXCELIGHT®	NA	Not known	550-1100 nm &
				625-1100 nm

I can confirm that the local rules, risk assessment, IPL installation sheet from Lynton, IPL labels and the Expert Medical Practitioner protocol were satisfactory. The eyewear (for the operator and client, including the blackout client shields) is appropriate to the device and its use is correctly described in the local rules. The EMP protocol covers all relevant applications for the Excelight device. All of the documentation is fit for purpose and is provided in accordance with the requirements of the Minimum Care Standards.

Comments & Recommendations, None.

Annas Barly

Dr Ishmail Badr Laser Protection Adviser





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