

# Inspection Report

10 May 2023



## Optilase Therapie

Type of service: Independent Hospital – Cosmetic laser/intense pulse light (IPL) and refractive eye laser service

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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 [Minimum Care Standards for Independent Healthcare Establishments \(July 2014\)](#)

## 1.0 Service information

<b>Organisation/Registered Provider:</b> Optilase (UK) Limited  <b>Responsible Individual:</b> Mr Phillip McGlade	<b>Registered Manager:</b> Mr Kyle Apsley – acting manager
<b>Person in charge at the time of inspection:</b> The clinic manager, Optilase Therapie	
<b>Categories of care:</b> 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) Private Doctor (PD)	
<b>Brief description of how the service operates:</b> Optilase Therapie is registered with the Regulation and Quality Improvement Authority (RQIA) as an Independent Hospital (IH) with the above categories of care. The cosmetic laser service treatments are offered from the ground floor of the building and a refractive laser eye surgery service from the first floor.  Optilase (UK) Limited is the registered provider for Optilase Therapie and Mr Phillip McGlade is the responsible individual. Mr McGlade is also the responsible individual for three other services registered with RQIA.  During a previous RQIA inspection it was highlighted that the cosmetic laser service and the refractive eye service were being managed and operated as two separate distinct services. It was agreed that RQIA would review this arrangement and arranged to meet with Mr McGlade.  On 15 August 2022 RQIA met with Mr McGlade and the managers of the refractive laser eye service and the cosmetic laser service. RQIA proposed that the registration of Optilase Therapie was reviewed to facilitate the refractive laser eye service and the cosmetic laser service to be registered as two separate services. Mr McGlade and the managers accepted this proposal and stated that the cosmetic laser service would remain as Optilase Therapie and that a new registration application would be submitted in respect of the refractive laser eye service to be known as Optilase Belfast.  An application to register Optilase Belfast (the refractive laser eye service) as a separate entity was received by RQIA on 16 December 2022. When RQIA planned to undertake this inspection the Optilase Belfast registration application was incomplete, therefore a decision was made that the inspection of Optilase Therapie	

would consist of two separate inspections; one for the refractive eye service and one for the cosmetic laser service. This inspection focused solely on the cosmetic laser service.

It is noted that intense pulse light (IPL) equipment is not provided and has not been in place for a significant period of time, meaning the PT(IL) category is no longer relevant. This matter will be followed up by RQIA under separate cover.

#### **Equipment available in the service:**

##### **Cosmetic Laser Service Equipment**

Six identical lasers are in place; five were installed on 30 March 2022 and one was installed on 10 June 2022

Manufacturer:	Cynosure
Laser Class:	Class 4
Model:	Elite IQ
Wavelength:	Alexandrite- 755nm, Nd-Yag -1064nm
Serial Numbers:	RL220902; RL220903; RL220906; RL220914; RL220916; RL220920

#### **Laser protection advisor (LPA):**

Mr Alex Zarneh

#### **Laser protection supervisor (LPS):**

Ms Morgan Curran

#### **Medical support services:**

Dr Paul Reddy (Medical Director of Therapie)

#### **Authorised operators:**

Ms Morgan Curran and 15 other named authorised operators

#### **Type of treatment provided:**

Hair removal/reduction

## **2.0 Inspection summary**

This was an announced inspection, undertaken by a care inspector on 10 May 2023 from 10.30 am to 3.00 pm.

The purpose of the inspection was to assess progress with areas for improvement identified during the last care inspection and to assess compliance with the legislation and minimum standards.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; laser safety; the management of the clients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the clinic's adherence to best practice guidance in relation to COVID-19; the management of clinical records; clinical and organisational governance; and effective communication between clients and staff.

Additional areas of good practice identified included 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.

No immediate concerns were identified regarding the delivery of front line client care.

### **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.

This inspection was facilitated by the clinic manager, Optilase Therapie and Mr Kyle Apsley, acting registered manager and compliance manager for Optilase (UK) Limited.

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

Clients were not present on the day of the inspection and client feedback was assessed by reviewing the most recent client satisfaction surveys completed by Optilase Therapie.

Posters were issued to Optilase Therapie by RQIA prior to the inspection inviting clients and staff to complete an electronic questionnaire. No completed client or staff questionnaires were submitted to RQIA prior to the inspection.

### **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 Optilase Therapie was undertaken on 21 March 2022; no areas for improvement were identified.

## **5.2 Inspection outcome**

### **5.2.1 How does this service ensure that staffing levels are safe to meet the needs of clients?**

The clinic manager told us there are sufficient staff in the various roles to fulfil the needs of the establishment and clients.

The clinic manager confirmed that laser treatments are only carried out by authorised operators. A register of authorised operators for the laser equipment is maintained and kept up to date.

A review of completed induction programmes evidenced that induction training is provided to new staff on commencement of employment.

A review of training records evidenced that authorised operators have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety awareness and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

### **5.2.2 How does the service ensure that recruitment and selection procedures are safe?**

The arrangements in respect of the recruitment and selection of authorised operators were reviewed.

Robust recruitment and selection policies and procedures, which adhered to legislation and best practice guidance for the recruitment of authorised operators were in place. These arrangements ensure that all required recruitment documentation has been sought and retained for inspection.

The staff register reviewed was found to be up to date and included the names and details of all authorised operators in keeping with legislation. It was noted that eight new authorised operators had been appointed since the previous RQIA inspection.

Discussion with the clinic manager and Mr Apsley and a review of a sample of three new authorised operators' personnel files confirmed that the new authorised operators have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

The service had appropriate arrangements in place to ensure recruitment procedures are safe.

### **5.2.3 How does the service ensure that it is equipped to manage a safeguarding issue should it arise?**

The clinic manager informed us that laser treatments are not provided to persons under the age of 18 years.

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

Discussion with the clinic manager confirmed that she was aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Review of records demonstrated that the clinic manager and Mr Apsley, as safeguarding leads, had completed formal level two training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

It was confirmed that copies of the regional policy entitled Co-operating to Safeguard Children and Young People in Northern Ireland (August 2017) and the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) were both available for reference.

The service had appropriate arrangements in place to manage a safeguarding issue should it arise.

### **5.2.4 How does the service ensure that medical emergency procedures are safe?**

All authorised operators had up to date training in basic life support and were aware of what action to take in the event of a medical emergency. There was a resuscitation policy in place and a review of this evidenced that it was comprehensive, reflected legislation and best practice guidance.

The service had appropriate arrangements in place to manage a medical emergency.

### **5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?**

The IPC arrangements were reviewed throughout the establishment to evidence that the risk of infection transmission to clients, visitors and staff was minimised.

There was an overarching IPC policy and associated procedures in place. A review of these documents demonstrated that they were comprehensive and reflected legislation and best practice guidance in all areas.

A tour of the premises was undertaken and areas reviewed were found to be clean and tidy. The clinic has six dedicated laser treatment rooms which were each reviewed and found to be clean and clutter free.

Cleaning schedules were in place and records were completed and up to date. Authorised operators described the procedure to decontaminate the environment and equipment between clients and this was in keeping with best practice.

Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, authorised operators have up to date training in IPC.

The service had appropriate arrangements in place in relation to IPC and decontamination.

#### **5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?**

The management of operations in response to the COVID-19 pandemic were discussed with the clinic manager and Mr Apsley who outlined the measures taken by Optilase Therapie to ensure current best practice measures are in place.

The management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

#### **5.2.7 How does the service ensure the environment is safe?**

As previously discussed the clinic has six dedicated laser treatment rooms and additional storage rooms. The premises were maintained to a good standard of maintenance and décor.

Observations made evidenced that a carbon dioxide (CO<sub>2</sub>) fire extinguisher is available which has been serviced within the last year.

It was determined that appropriate arrangements were in place to maintain the environment.

#### **5.2.8 How does the service ensure that laser procedures are safe?**

A laser safety file was in place in each of the six treatment rooms, each file contained relevant information in relation to laser equipment in place.

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 in December 2023.

The establishment's LPA completed a risk assessment of the premises during December 2022 and all recommendations made by the LPA have been addressed.

A review of up to date, local rules, developed by the LPA, confirmed that relevant information about the laser equipment being used, was in place. It was noted that a copy of the local rules was contained in each of the laser safety files.

Mr Apsley and the clinic manager informed us that laser hair removal procedures are carried out following a medical treatment protocol. The medical treatment protocol had been produced by a



named registered medical practitioner. It was demonstrated the protocol contained the relevant information about the treatment being provided and is due to expire during August 2023. It was established that systems are in place to review the medical treatment protocol when due.

The identified LPS has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Authorised operators had signed to state that they had read and understood the local rules and medical treatment protocol.

When the laser equipment is in use, the safety of all persons in the controlled areas is the responsibility of the LPS. Arrangements are in place for two other authorised operators, who are suitably skilled to fulfil the role and deputise for the LPS in their absence. Discussion with staff confirmed that systems are in place to ensure all authorised operators are aware of who is the LPS on duty at any given time.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The controlled areas are clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

The door to each treatment room is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency. Authorised operators were aware that the laser safety warning signs should only be displayed when the laser equipment is in use and removed when not in use.

Each laser machine is operated using a key. Robust arrangements were in place for the safe custody of the laser equipment keys when not in use.

Protective eyewear is available for the client and operator as outlined in the local rules. A system was in place to check the condition of the protective eyewear on a weekly basis, and a record is retained in this regard.

A review of records verified that an individual laser register was in place in respect of each of the six laser machines. Authorised operators told us that they complete the respective register every time the equipment is operated. A review of the laser registers demonstrated that the following details are included:

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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance.



As previously stated six identical lasers are in place; five were installed on 30 March 2022, each of which was serviced on 20 April 2023. The other laser machine was installed on 10 June 2022 and was serviced on 23 March 2023.

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

#### **5.2.9 How does the service ensure that clients have a planned programme of care and have sufficient information to consent to treatment?**

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. There is written information for clients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The service has a list of fees available for hair removal laser procedures. Fees for treatments are agreed during the initial consultation and may vary depending on treatment area and the individual requirements of the client.

During the initial consultation each client's personal information is recorded including their general practitioner (GP) details in keeping with legislative requirements and clients are asked to complete a health questionnaire.

Three client care records were reviewed. There was an accurate and up to date treatment record for every client which included:

- 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)

Observations made evidenced that client records are securely stored. A policy and procedure was available which included the creation, storage, recording, retention and disposal of records and data protection.

The service has a policy for advertising and marketing which is in line with legislation.

It was determined that appropriate arrangements were in place to ensure that clients have a planned programme of care and have sufficient information to consent to treatment.

#### **5.2.10 How does the service ensure that clients are treated with dignity, respect and are involved in the decision making process?**

Discussion with an authorised operator regarding the consultation and treatment process confirmed that clients are treated with dignity and respect.

The consultation and treatment are provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely in a lockable storage case.

The clinic manager told us that clients are provided with the opportunity to complete a satisfaction survey when their treatment is complete. The results of these are collated on a monthly basis to provide an anonymised summary report which is made available to clients and other interested parties. The clinic manager confirmed that an action plan would be developed to inform and improve services provided, if appropriate.

Review of the most recent client satisfaction reports dated February 2023 and March 2023 found that clients were highly satisfied with the quality of treatment, information and care received.

It was determined that appropriate arrangements were in place to ensure that clients are treated with dignity, respect and are involved in decisions regarding their choice of treatment.

#### **5.2.11 How does the registered provider assure themselves of the quality of the services provided?**

Where the entity operating the service is a corporate body or partnership or an individual owner who is not in day to day management of the service, Regulation 26 unannounced quality monitoring visits must be undertaken and documented every six months. The clinic manager has responsibility for the day to day management of the establishment and is supported by Mr Apsley who is responsible for reporting to Mr McGlade.

Optilase Therapie is operated by Optilase (UK) Limited and Mr McGlade as the responsible individual, nominates a member of the senior management team to monitor the quality of services and undertake a visit to the premises at least every six months in accordance with legislation. The most recent unannounced monitoring visit had been undertaken as required and the report was available for inspection. It was confirmed that all reports are sent to Mr McGlade to enable him to monitor progress with the identified actions if required.

Mr Apsley has been the acting registered manager for Optilase Therapie since July 2021 and this arrangement was discussed. Mr Apsley confirmed that Optilase (UK) Limited will submit a registered manager application to RQIA in respect of the current clinic manager to become the new registered manager. Mr Apsley was advised that this application should be submitted to RQIA at the earliest opportunity.

Policies and procedures were available outlining the arrangements associated with the laser treatments. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis or more frequently if required.

The arrangements for the management of complaints and incidents were reviewed to ensure that they were being managed in keeping with legislation and best practice guidance.

The complaints policy and procedure provided clear instructions for clients and staff to follow. Clients were made aware of how to make a complaint by way of the client's guide. Arrangements were in place to record any complaint received in a complaints register and retain all relevant records including details of any investigation undertaken, all communication with complainants, the outcome of the complaint and the complainant's level of satisfaction. A review of records confirmed that no complaints had been received since the previous inspection.

A review of records confirmed that an incident policy and procedure was in place which includes the reporting arrangements to RQIA. It was confirmed that incidents would be effectively documented and investigated in line with legislation. All relevant incidents are reported to RQIA and other relevant organisations in accordance with legislation and RQIA [Statutory Notification of Incidents and Deaths](#). Arrangements are in place to audit adverse incidents to identify trends and improve service provided.

Mr Apsley demonstrated a clear understanding of his role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within the specified timeframes. The clinic manager and Mr Apsley confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was displayed in a prominent place.

Observation of insurance documentation confirmed that current insurance policies were in place.

It was determined that suitable arrangements are in place to enable the responsible individual to assure themselves of the quality of the services provided.

#### 5.2.12 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients was discussed with staff. It was demonstrated that the equality data collected was managed in line with best practice.

### 7.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
<b>Total number of Areas for Improvement</b>	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with the clinic manager and Mr Apsley, as part of the inspection process and can be found in the main body of the report.



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