

Inspection Report

18 November 2024



Therapie Optilase

Type of service: Independent Hospital-Cosmetic Laser\Intense Pulsed Light
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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

<p>Organisation/Provider: Therapie Medical (UK) Limited</p> <p>Responsible Individual: Mr Philip McGlade</p>	<p>Registered Manager: Miss Helen Dale</p> <p>Date registered: 30 April 2024</p>
<p>Person in charge at the time of inspection: Ms Helen Dale</p>	
<p>Categories of care: Independent Hospital (IH) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT(L)</p>	
<p>Brief description of how the service operates: Therapie Optilase is registered with the Regulation and Quality Improvement Authority (RQIA) as an Independent Hospital (IH) with the following categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers.</p> <p>Therapie Optilase also provides a range of cosmetic/aesthetic treatments. This inspection focused solely on those treatments using a Class 4 laser machine that fall within regulated activity and the categories of care for which the establishment is registered with RQIA.</p> <p>Therapie Medical (UK) Limited is the registered provider for four services registered with RQIA. Mr McGlade is the responsible individual for Therapie Medical (UK) Limited.</p> <p>Equipment available in the service:</p> <p>Laser equipment: Manufacturer: Cynosure Elite Model: IQ Serial Number: RL1C2604A Laser Class: 4 Wavelength: 755-1064nm</p> <p>Manufacturer: Cynosure Elite Model: IQ Serial Number: RL1C2504A Laser Class: 4 Wavelength: 755-1064nm</p> <p>Manufacturer: Cynosure Elite</p>	

Model: IQ
Serial Number: RL1C4803A
Laser Class: 4
Wavelength: 755-1064nm

Type of laser treatments provided:
Hair removal

2.0 Inspection summary

This was an announced inspection, undertaken by a care inspector on 18 November 2024 from 9.50 am to 1.00 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 and IPL safety; management of medical emergencies; infection prevention and control; adherence to best practice guidance in relation to COVID-19; the management of clinical records; 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.

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 undergoing laser treatment on the day of the inspection and it was not deemed appropriate to speak directly with them. However, client feedback was assessed by reviewing the most recent client satisfaction surveys completed by Therapie Optilase.

Posters were issued to Therapie Optilase 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 Therapie Optilase was undertaken on 23 August 2023; 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?

Miss Dale and the compliance manager for Therapie Optilase (management) told us there are sufficient staff in the various roles to fulfil the needs of the establishment and clients.

Management confirmed that laser treatments are only carried out by authorised operators. A register of authorised operators for the laser 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.

Management and records reviewed confirmed all other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received core of knowledge training.

It was determined that appropriate staffing levels were in place to meet the needs of clients and that staff are suitably trained

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

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

A review of two personnel files of authorised operators recruited since the previous inspection and discussion with management confirmed that staff have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

There was evidence of job descriptions and induction checklists for authorised operators.

Discussion with Miss Dale confirmed that she had a clear understanding of the legislation and best practice guidance in relation to recruitment and selection.

It was determined that the recruitment of authorised operators complies with the legislation and best practice guidance.

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

Ms Dale stated 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 an authorised operator 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 Miss Dale, as the safeguarding lead, has 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 a copy 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 available for reference.

It was determined that 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 written protocol in place for dealing with recognised medical emergencies.

It was determined that 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 (IPC) 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.

The laser treatment rooms were clean and clutter free. Discussion with authorised operators evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, authorised operators had up to date training in IPC.

Ms Dale is aware that the Department of Health (DOH) and Public Health Agency (PHA) websites provide advisory information, guidance and alerts with regards to IPC.

It was determined that 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 to minimise the risk of COVID-19 transmission were discussed with authorised operators who outlined the measures that taken by Therapie Optilase to ensure current best practice measures are in place.

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

5.2.7 How does the service ensure the environment is safe?

The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Observations made evidenced that a carbon dioxide (CO₂) 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 which contained the relevant information in relation to laser equipment. There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA) which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires on 2 January 2025.

Up to date, local rules were in place which have been developed by the LPA. The local rules contained the relevant information about the laser equipment being used.

The establishment's LPA completed a risk assessment of the premises during January 2024 and all recommendations made by the LPA have been addressed.

Miss Dale confirmed that laser procedures are carried out following medical treatment protocols. The medical treatment protocols had been produced by a named registered medical practitioner. It was demonstrated that the protocols contained the relevant information about the treatments being provided and are due to expire during September 2025. It was established that systems are in place to review the medical treatment protocols when due.

Miss Dale or another named authorised operator, nominated as the laser protection supervisor (LPS) has overall responsibility for safety during 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 protocols.

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

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 area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

The door to the 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.

The laser is operated using a key. Arrangements are in place for the safe custody of the key when not in use. Protective eyewear is available for the client and operator as outlined in the local rules.

Therapie Optilase has three laser registers.

Authorised operators told us that they complete the relevant section of the register every time the equipment is operated. The registers reviewed included:

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

It was noted that a number of entries in the laser registers had recorded the first name only of the client, did not record the date of treatment and the patch test was not recorded clearly in the registers. Advice was provided on this matter and management gave assurances that the register would be audited going forward to ensure robust recording.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports of the lasers were reviewed.

As a result of the assurances received, it was determined that appropriate arrangements are 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?

Miss Dale confirmed that 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.

The service has a list of fees available for each laser procedure. 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.

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.

Four 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)

It was noted that electronic records had been introduced and advice was provided to ensure the name of the authorised operator and the date of consent is included on the new electronic consent form. It was also advised to move the patch test record to a more prominent position in the client record. Management were receptive to this advice.

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.

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 Miss Dale 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.

Miss Dale 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 to provide an anonymised summary report which is made available to clients and other interested parties. Miss Dale confirmed that an action plan would be developed to inform and improve services provided, if appropriate.

Review of the most recent client satisfaction report dated October 2024 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 business entity operating the service is a corporate body or partnership or an individual owner who is not in day to day management of the practice, unannounced quality monitoring visits by the registered provider must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005.

Miss Dale has overall responsibility for the day to day management of the establishment and is responsible for reporting to the registered provider. Therapie Optilase is operated by Therapie Medical (UK) Limited (as outlined in section 1.0 of this report) and Mr Phillip McGlade is the responsible individual for Therapie Medical (UK) Limited. He 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 on 26 July 2024 and the report was available for inspection. Miss Dale confirmed that the report is sent to the registered provider to enable him to monitor progress with the identified actions. Mr McGlade had signed a returned copy.

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 patients 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 concerning complaints evidenced that complaints had been managed in accordance with best practice guidance. A complaints audit will be undertaken to identify trends, drive quality improvement and to enhance service provision.

Discussion with Miss Dale confirmed that an incident policy and procedure was in place which includes the reporting arrangements to RQIA. Ms Dale 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.

Miss Dale demonstrated a clear understanding of her role and responsibility in accordance with legislation.

Miss Dale 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 Miss Dale.

6.0 Quality Improvement Plan/Areas for Improvement

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Miss Dale, Registered Manager and the compliance manager for Therapie Otilase as part of the inspection process and can be found in the main body of the report.



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