

Inspection Report

24 March 2025



Optilase Belfast

Type of Service: Independent Hospital (IH) – Refractive Eye Lasers

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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 \(July 2014\)](#)

1.0 Service information

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|---|---|---------------|-----------|--------------|---------|--------|--------------|----------------|------|---------------|------------------------------|--------------|----------|--------|------------------------------------|----------------|--------------|
| <p>Organisation/Provider: Optilase (UK) Limited</p> <p>Responsible Individual: Mr Phillip McGlade</p> | <p>Registered Manager: Ms Aoife Kelly</p> <p>Date registered: 29 March 2024</p> | | | | | | | | | | | | | | | | |
| <p>Person in charge at the time of inspection: Surgery manager</p> | | | | | | | | | | | | | | | | | |
| <p>Categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor AH (DS) Acute hospitals (day surgery only)</p> | | | | | | | | | | | | | | | | | |
| <p>Brief description of how the service operates: Optilase Belfast is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing laser eye surgery using Class 3B or Class 4 lasers PT (L); private doctor (PD) and acute hospitals (day surgery only) AH (DS) categories of care.</p> <p>Optilase (UK) Limited is the registered provider and Mr Phillip McGlade is the responsible individual.</p> <p>Equipment available in the service:</p> <p><u>Refractive Laser Eye Surgery Equipment</u></p> <table> <tr> <td>Manufacturer:</td> <td>Schwind A</td> </tr> <tr> <td>Laser Class:</td> <td>Class 4</td> </tr> <tr> <td>Model:</td> <td>Armaris 500E</td> </tr> <tr> <td>Serial Number:</td> <td>M110</td> </tr> <tr> <td>Manufacturer:</td> <td>Abbott Medical Systems (AMO)</td> </tr> <tr> <td>Laser Class:</td> <td>Class 3B</td> </tr> <tr> <td>Model:</td> <td>Intralase IFS Advanced Femtosecond</td> </tr> <tr> <td>Serial Number:</td> <td>F50511-70169</td> </tr> </table> <p>Types of treatment provided: Refractive laser eye surgery - Lasix and Lasex</p> | | Manufacturer: | Schwind A | Laser Class: | Class 4 | Model: | Armaris 500E | Serial Number: | M110 | Manufacturer: | Abbott Medical Systems (AMO) | Laser Class: | Class 3B | Model: | Intralase IFS Advanced Femtosecond | Serial Number: | F50511-70169 |
| Manufacturer: | Schwind A | | | | | | | | | | | | | | | | |
| Laser Class: | Class 4 | | | | | | | | | | | | | | | | |
| Model: | Armaris 500E | | | | | | | | | | | | | | | | |
| Serial Number: | M110 | | | | | | | | | | | | | | | | |
| Manufacturer: | Abbott Medical Systems (AMO) | | | | | | | | | | | | | | | | |
| Laser Class: | Class 3B | | | | | | | | | | | | | | | | |
| Model: | Intralase IFS Advanced Femtosecond | | | | | | | | | | | | | | | | |
| Serial Number: | F50511-70169 | | | | | | | | | | | | | | | | |

2.0 Inspection summary

This was an announced inspection undertaken by two care inspectors on 24 March 2025 from 10.00 am to 3.00 pm. RQIA's Laser Protection Advisor (LPA) accompanied the inspectors and reviewed the laser equipment and the laser safety arrangements. Their findings and recommendations are appended to this report.

The purpose of the inspection was to assess progress with areas for improvement identified during and since the last inspection and 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 patients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the management of clinical records; clinical and organisational governance; and effective communication between patients and staff.

Additional areas of good practice identified included maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

No immediate concerns were identified regarding the delivery of front line patient 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 surgery manager.

The information obtained is then considered before a determination is made on whether the clinic 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 Belfast.

Posters were issued to Optilase Belfast by RQIA prior to the inspection inviting clients and staff to complete an electronic questionnaire.

Thirteen clients submitted responses. Client responses indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All clients indicated that they were either satisfied or very satisfied with each of these areas of their care.

A number of client responses included positive comments pertaining to the friendliness and knowledge of staff and the excellent service provided. One client response indicated disappointment when attempting to contact the clinic through the call centre.

Three staff submitted questionnaire responses. Staff responses indicated that they felt client care was safe, effective, that clients were treated with compassion and that the service was well led. All staff indicated that they were either satisfied or very satisfied with each of these areas of client care. Two staff responses included positive comments pertaining to patient safety, team work and patient centred care.

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 Belfast was undertaken on 21 March 2024; 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 patients and staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of two consultant ophthalmologists, two optometrists, registered nurses and laser technicians/surgical assistants. It was confirmed that all staff have specialist qualifications and skills in refractive laser eye surgery patient care.

The clinic staff take part in ongoing training to update their knowledge and skills, relevant to their role. Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team. A review of documentation evidenced that a new staff member recently recruited had completed an induction programme.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A review of the records confirmed that all staff had undertaken training in keeping with [RQIA training guidance](#).

Discussion with Ms Kelly and the surgery manager and review of documentation identified that arrangements were in place to check the registration status for all clinical staff on appointment and on an ongoing basis. The arrangements for monitoring the professional indemnity of all staff were also in place, as was a system for the monitoring of any practicing privileges (discussed further in section 5.2.9).

Discussion with staff confirmed there are good working relationships. Staff spoke positively regarding the clinic, felt valued as members of the team and confirmed they were supported by management.

It was determined that appropriate staffing levels were in place to meet the needs of patients and the staff were suitably trained to carry out their duties.

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 staff were reviewed.

A recruitment and selection policy and procedure, which adhered to legislation and best practice guidance was in place.

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

A review of the new staff members' personnel file evidenced that all recruitment documentation, as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, had been sought and retained for inspection.

It was determined that recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance should staff be recruited in the future.

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

It was confirmed that 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.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Ms Kelly and the surgery manager confirmed that staff were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

There are two safeguarding leads in the clinic and they are named in the policy. A review of training verified that both safeguarding leads had completed safeguarding training at the level required in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards. The safeguarding lead for the day is identified to all staff members during the daily morning safety brief.

It was confirmed that a copy of the regional guidance document entitled [Adult Safeguarding Prevention and Protection in Partnership \(July 2015\)](#) was available for reference.

Appropriate arrangements were in place to manage a safeguarding issue should it arise.

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

The arrangements in respect of the management of medical emergencies were reviewed.

A review of the management of medical emergencies policy identified that it accurately reflected the arrangements that were found to be in place for managing a medical emergency. Protocols were also available to guide the team on how to manage recognised medical emergencies.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

Review of the emergency medicines and equipment found that systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available.

Staff spoken with were able to describe the actions they would take, in the event of a medical emergency, and were familiar with the location of medical emergency medicines and equipment.

Discussion with staff confirmed that the management of medical emergencies is included in the induction programme. A review of training records evidenced that one consultant ophthalmologist had completed advanced life support training; the other consultant ophthalmologist and all other staff had completed basic life support training.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency should one arise.

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

The arrangements for IPC procedures throughout the clinic were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

A robust programme of IPC auditing was in place and it was confirmed that a validation report was in place in respect of the treatment room ventilation. All audit outcomes are shared with staff during monthly surgery team meetings and it was confirmed that any matters identified had been addressed.

A tour of the premises was undertaken and the clinic was found to be clean, tidy and uncluttered. Cleaning records were completed and up to date.

Staff described the arrangements to decontaminate the environment and equipment between patients in keeping with best practice.

A review of training records confirmed that staff had received IPC training commensurate with their roles and responsibilities. Staff demonstrated good knowledge and understanding of IPC procedures.

The surgery manager informed us that single use medical devices are used during cataract surgery and then disposed of.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance.

The laser suite and treatment room provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

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

5.2.6 How does the service ensure that laser procedures are safe?

The arrangements in respect of the safe use of the laser equipment were reviewed.

A review of the laser safety files found that they contained all of the relevant information in relation to all the 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 clinic and the LPA had been reviewed and was up to date.

The clinic's LPA completed a risk assessment of the premises during November 2024 and no recommendations were made.

It was confirmed that refractive laser eye procedures are only carried out by the consultant ophthalmologists acting as the clinical authorised operators and are assisted by laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the lasers is maintained and kept up to date.

The surgery manager confirmed that the consultant ophthalmologists undertake laser eye surgical procedures in accordance with medical treatment protocols produced by a named consultant ophthalmologist and systems were in place to review the medical treatment protocols on an annual basis.

Up to date local rules were in place which have been developed by the LPA and these contained the relevant information pertaining to the laser equipment being used. Arrangements were in place to review the local rules on an annual basis. The local rules included the following:

- the potential hazards associated with lasers
- controlled and safe access
- authorised operators' responsibilities
- methods of safe working
- safety checks

- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

The surgery manager confirmed that the LPS is aware that when the laser equipment is in use, the safety of all persons in the controlled area is her responsibility. Arrangements were in place for another authorised operator to deputise for the LPS, in her absence, who is suitably skilled to fulfil the role.

As previously discussed a review of training records confirmed that all clinical authorised operators had up to date training in core of knowledge; basic life support; infection prevention and control; fire safety awareness; and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

The surgery manager confirmed that the laser surgical register is maintained every time the lasers are operated to include:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure given
- any accidents or adverse incidents

A review of the laser surgical register found it to be comprehensively completed.

The laser suite where the laser equipment is used was found to be safe and controlled to protect other persons while treatments are in progress. Discussion with staff confirmed that the doors to the laser suite are locked, when the laser equipment is in use, but can be opened from the outside in the event of an emergency.

The lasers are operated using keys and passwords that unauthorised staff do not have access to. There were arrangements in place in relation to the safe custody of the keys and passwords of all laser equipment for the refractive eye lasers.

It was confirmed that protective eyewear was available for non-clinical authorised operators if required. A review of the eyewear evidenced that it was provided as outlined by the LPA in the local rules.

The laser safety warning signs are illuminated outside of the laser suite and the identified treatment room when the laser equipment is in use and turned off when not in use, as described within the local rules.

Arrangements have been established for equipment to be serviced and maintained in line with the manufacturers' guidance. The most recent service reports were reviewed.

Carbon dioxide (CO₂) fire extinguishers, suitable for electrical fires were available in the clinic and arrangements were in place to ensure the fire extinguishers are serviced, in keeping with manufacturer's instruction.

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

5.2.7 How does the clinic ensure patients have a planned programme of care and have sufficient information to consent to treatment?

Staff confirmed that all patients have an initial consultation with an optometrist who discusses their treatment options and the cost of the surgery.

During the initial consultation, patients are asked to complete a health questionnaire. Systems were in place to contact the patient's general practitioner (GP), with their consent, for further information if necessary.

The clinic has a list of fees available for each type of surgical procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

In accordance with General Medical Council (GMC) and the Royal College of Ophthalmologists guidance, patients meet with their surgeon on a separate day in advance of surgery, to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery to complete the consent process for surgery.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment. Patients are also provided with clear post-operative instructions along with contact details if they experience any concerns. Systems were in place to refer patients directly to the consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Two patient care records reviewed were found to be well documented, contemporaneous and clearly outlined the patient journey.

The management of records within the clinic were found to be in line with legislation and best practice.

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

5.2.8 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within Optilase Belfast

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 had overall responsibility for the day to day management of the establishment and is responsible for reporting to the registered provider.

Optilase Belfast 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.

Clinical and medical governance

As previously discussed, the team consists of two consultant ophthalmologists, optometrists, registered nurses and laser technicians/surgical assistants who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

Both consultant ophthalmologists are considered to be private doctors as they no longer hold an elective post in the HSC sector in Northern Ireland (NI) nor are they on the GP performer list in NI. Review of the consultant ophthalmologists' record confirmed evidence of the following:

- confirmation of identity
- current GMC registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer (RO)
- arrangements for revalidation

As previously discussed, both consultant ophthalmologists had completed training in accordance with RQIA's training guidance for private doctors and are aware of their responsibilities under the GMC Good medical practice (2024) guidance.

All medical practitioners working within the clinic must have a designated RO. An RO is an experienced senior doctor who works with the GMC to make sure doctors are reviewing their work. In accordance with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. As part of the revalidation process RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. The consultant ophthalmologists working within the clinic have a designated external ROs and have revalidated accordingly.

Standard 30 of the Minimum Care Standards for Independent Healthcare Establishments (2014) specifies that registered independent hospitals should have an appointed medical advisory committee (MAC) and outlines the roles and responsibilities of the MAC.

A review of records and discussion with staff verified that the MAC has been established. Terms of reference for the MAC were in place and these have been developed in accordance with Standard 30.

The MAC meet quarterly with responsibility for consultant ophthalmologist performance and laser eye surgery specific matters. It was evidenced that the MAC meetings have standing agenda items and are used as a forum to discuss: clinical governance issues, the appointment and renewal of practising privileges agreements, the review of performance indicators, corrective action in relation to adverse clinical incidents and any other untoward event or near miss. A review of the MAC meeting minutes confirmed that these meetings were being undertaken on a quarterly basis in line with the criteria set out in Standard 30.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the clinic.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practising privileges agreements was in place.

A review of practising privileges records confirmed that all required documents were in place. It was confirmed that the practising privileges agreement is updated every two years.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of robust medical governance arrangements within the organisation.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals.

The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed to address any shortfalls identified during the audit process.

A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

A statement of purpose and patient's guide were in place and Ms Kelly confirmed that these documents will be kept under review and updated as necessary.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place.

Notifiable Events/Incidents

A robust system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

Ms Kelly confirmed that any learning from incidents would be discussed with staff. There was a process in place for analysing incidents and events to detect potential or actual trends so that a prompt and effective response can be considered at the earliest opportunity. An audit would be maintained, reviewed and the findings presented to the directors during their quarterly meetings.

Complaints Management

A copy of the complaints procedure was available in the clinic and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling.

The surgery manager confirmed that a copy of the complaints procedure is made available for patients and/or their representatives on request and staff demonstrated a good awareness of complaints management.

It was confirmed that one complaint had been received since the previous inspection. A review of records and discussion with the surgery manager demonstrated that the complaint was being appropriately managed in line with the clinic’s complaints policy and procedures. It was confirmed that any information gathered from complaints would be used to improve the quality of services provided.

Overall, the governance structures within the hospital provided the required level of assurance to Mr McGlade.

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

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with staff.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

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 Ms Kelly and the surgery manager, as part of the inspection process and can be found in the main body of the report.



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