Announced Care Inspection Report
29 and 30 May 2019

Optilase Therapie

Type of Service: Independent Hospital (IH) – Refractive Eye Laser Surgery and Dermatological Laser/Intense Pulse Light(IPL) service
Address: 36 Ann Street, Belfast, BT1 4EG
Tel No: 0800 044 3236
Inspector: Winnie Maguire
RQIA's Medical Physics Advisor: Dr Ian Gillan

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

2.0 Profile of service

This is an Independent Hospital (IH) providing refractive laser eye surgery and a dermatological laser and IPL service.

The laser services are provided in two distinct categories:

- Refractive laser eye surgery
- Dermatological laser service

Refractive Laser Eye Surgery

Laser Equipment

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

Laser Protection Advisor (LPA): Alex T Zarneh

Laser Protection Supervisor (LPS): Lawrence Dowie
Lisa McDowell

Clinical authorised operator: Dr Jain Rantitlal (Consultant Ophthalmologist)

Non clinical authorised operators: Lawrence Dowie, Lisa McDowell

Types of Treatment provided: Refractive laser eye surgery - Lasix and Lasex

Dermatological Laser Services

Laser Equipment (Five identical lasers)

Manufacturer:	Cynosure
Laser Class:	Class 4
Model:	Elite EM+
Wavelength:	Alexandrite- 755nm, Nd-Yag -1064nm
Serial Numbers:	ELM1703, ELM1978, ELM1976, ELM1975, ELM1820

Laser protection advisor (LPA): Alex Zarneh

Laser protection supervisor (LPS): Wendy Irvine in her absence another named authorised operator

Medical support services: Dr Paul Reddy (Medical Director of Therapie)

Authorised operators:
Niamh Quinn, Wendy Irvine, Rachel McCaughey, Grainne Cunnane, Kerri Doran, Maeve McArdle, Sinead Walsh, Tiffany Benson, Aime Russell, Eimear Duggan-Fitzpatrick and Robyn McCullagh.

Types of Treatment Provided

Hair removal/reduction

3.0 Service details

Organisation/Registered Provider: Therapie Clinic Ltd **Responsible Individual:** Mr Phillip McGlade	**Registered Manager:** Ms Orla Mulholland
Person in charge at the time of inspection: Ms Orla Mulholland	**Date manager registered:** 04 December 2018
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PT(IL)Intense Light; and PD Private Doctor	

4.0 Inspection summary

An announced inspection took place on 29 May 2019 from 10.30 to 16.35 and 30 May 2019 from 10.10 to 14.30.

On 29 May 2019 the inspector was accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor. The findings and report of Dr Gillan are appended to this report.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: safeguarding; communication; document control and engagement to enhance the patients and clients' experience.

Six areas of improvement were made against the regulations and seven areas of improvement were made against the standards. These areas requiring improvement were in relation to selection and recruitment records, laser safety, infection prevention and control, client records, medical treatment protocols, complaints management, appraisals and ensuring six monthly unannounced monitoring visits are arranged in accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005.

Patients and clients who submitted questionnaire responses indicated that they were very satisfied with the services provided in Optilase Therapie.

Comments provided included:

- "Excellent service."
- "Treatment was amazing from start to finish. Staff were very knowledgeable."

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	6	7

Details of the Quality Improvement Plan (QIP) were discussed with Ms Orla Mulholland, registered manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

Enforcement action did not result from the findings of this inspection.

4.2 Action/enforcement taken following the most recent care inspection dated 29 and 30 May 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 29 and 30 May 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the establishment was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- the returned QIP from the previous care inspection

Questionnaires were provided to patients prior to the inspection by the establishment on behalf of RQIA. Returned completed patient questionnaires were analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire prior to the inspection. No completed staff questionnaires were received by RQIA.

A poster informing patients that an inspection was being conducted was displayed.

During the inspection the inspector met with Ms Orla Mulholland, registered manager, the Optilase manager, a laser technician and a scrub nurse for the refractive laser eye service and one authorised operator for the dermatological laser service. A tour of some areas of the premises was also undertaken.

A sample of records was examined during the inspection in relation to the following areas:

- staffing
- recruitment and section
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- care pathway
- communication
- management and governance arrangements
- practising privileges
- maintenance arrangements

Areas for improvement identified at the last care inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to Ms Orla Mullholland at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 29 and 30 May 2018

The most recent inspection of the establishment was an announced care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 29 and 30 May 2018

Areas for improvement from the last care inspection		
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref**: Standard 48.2 **Stated:** First time	The registered person shall ensure that the register of authorised operators for the refractive laser eye surgery lasers is amended to reflect only the clinical and non-clinical authorised operators.	**Met**
	Action taken as confirmed during the	

	inspection: The register of authorised operators for the refractive laser eye surgery lasers has been amended to reflect only the clinical and non-clinical authorised operators.	
Area for improvement 2 **Ref**: Standard 48.2 **Stated:** First time	The registered person shall ensure that the Harmony XL laser/IPL register of authorised operators is amended to reflect the current authorised operators.	**Met**
	Action taken as confirmed during the inspection: The Harmony XL laser/IPL machine has been removed from the clinic.	
Area for improvement 3 **Ref**: Standard 48.6 **Stated:** First time	The registered person shall ensure that evidence of an accredited LPA appointment is provided.	**Met**
	Action taken as confirmed during the inspection: There is evidence of an accredited LPA appointment in place.	
Area for improvement 4 **Ref**: Standard 48.17 **Stated:** Second time	The registered person shall ensure that the local rules in relation to the laser equipment used in the dermatological laser service outline specific information on the protective eyewear.	**Met**
	Action taken as confirmed during the inspection: All lasers for the dermatological service have been replaced and the local rules in place outline sufficient information in relation to protective eyewear for the client and the operator.	
Area for improvement 5 **Ref**: Standard 48 4 **Stated:** First time	The registered person shall ensure that the medical treatment protocols are amended to reflect only the treatments provided using the Harmony XL laser/IPL machine carried out in the establishment.	**Met**
	Action taken as confirmed during the inspection: As stated previously the Harmony XL laser/IPL machine has been removed from the clinic.	

Area for improvement 6 **Ref**: Standard 48.20 **Stated:** First time	The registered person shall ensure that the establishment's LPA seeks clarification from the manufacturer regarding the output of the Soprano Platinum laser and should consider consulting Northern Ireland Adverse Incident Centre (NIAIC) regarding the conflicting information displayed on the units. The establishment should obtain a copy of the user manual to assist with clarification on this matter.	**Met**
	Action taken as confirmed during the inspection: As stated previously all Soprano Platinum lasers used in the dermatological laser service have been removed from the clinic and replaced. The new Cynosure Elite laser machines comply with current standards.	
Area for improvement 7 **Ref**: Standard 48.10 **Stated:** Second time	The registered person shall ensure that client records for the dermatological laser service are fully and accurately completed.	**Met**
	Action taken as confirmed during the inspection: A review of ten client records found there had been improvement in the completion of client records. An issue on how the client records have been completed in relation to consistency of information is further discussed in section 6.4.	
Area for improvement 8 **Ref**: Standard 19.4 **Stated:** First time	The registered person shall ensure that there are robust document control systems in place.	**Met**
	Action taken as confirmed during the inspection: Audits are carried out to ensure strict document control is in operation. All documents reviewed were found to have good document control in place.	
Area for improvement 9 **Ref**: Standard 18 **Stated:** First time	The registered person shall review the dosage of medical emergency medications to ensure they are in accordance with British National Formulary (BNF).	**Met**
	Action taken as confirmed during the inspection: Additional doses of emergency medication has been purchased and are in accordance with the British National Formulary(BNF) .	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Discussion with management and staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment, patients and clients. This team includes: a consultant ophthalmologist; an optometrist; a laser scrub nurse and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery. The dermatological laser service is staffed separately by 11 authorised operators and a manager.

It was confirmed that refractive laser eye procedures are only carried out by a trained medical practitioner acting as clinical authorised operator, and laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the lasers was maintained.

A register of authorised operators is also maintained for the dermatological laser service.

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

A review of training records evidenced that all authorised operators had core of knowledge training; application training for the equipment in use; basic life support; infection prevention and control; and fire safety.

It was noted that staff who visit the clinic to provide injectable treatments and are not involved in the laser services have not had laser safety awareness training. An area of improvement was identified against the standards to ensure that staff who are not directly involved in the laser service, have laser safety awareness training and a record is maintained and available for inspection.

Evidence was available that confirmed that staff who have professional registration undertake continuing professional development (CPD), in accordance with their professional body's recommendations. An electronic staff register was in place.

Discussion with staff and review of documentation confirmed that there were systems in place for undertaking, recording and monitoring all aspects of staff supervision and ongoing professional development for staff. Ms Mulholland confirmed that staff appraisal systems were in the process of being updated. Staff appraisals have not been undertaken for all staff in the last year. An area of improvement was identified against the standards to ensure that staff appraisals are carried out and recorded at least annually. It was advised to consider that management who conduct staff appraisals undertake training in relation to this role.

A review of a consultant ophthalmologist's details confirmed there was evidence of the following:

- confirmation of identity
- current General Medical Council (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
- arrangements for revalidation

Recruitment and selection

A review of three personnel files of authorised operators recruited since the previous inspection and discussion with management confirmed that new staff have largely been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005. It was noted some recruitment information such as the health declaration and the criminal record declaration were obtained after staff had commenced employment. An area of improvement against the regulations was identified to ensure all information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is obtained prior to the commencement of employment.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Safeguarding

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. Staff were aware of who the nominated safeguarding lead was within the establishment.

Staff had received adult safeguarding training in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults 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 for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

Laser safety

The refractive laser eye surgery service

A laser safety file was in place which contained all of the relevant information in relation to laser equipment.

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 September 2019.

Refractive eye surgical procedures are carried out by a trained medical practitioner in accordance with medical treatment protocols devised by the consultant ophthalmologist.

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

The establishment's LPA completed a risk assessment of the premises in December 2018 and any recommendations made were addressed.

A list of clinical and non-clinical authorised operators was maintained and all authorised operators have signed to state that they have read and understood the local rules.

When the laser equipment is in use for the refractive laser eye surgery service, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to fulfil the role. Discussion with staff confirmed that systems are in place to ensure other authorised operators are aware who the LPS on duty is.

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 surgery is being carried out.

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 laser equipment is operated using keys and passwords. Arrangements were in place for the safe custody of the laser keys when not in use and passwords are only known by authorised operators.

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

Protective eyewear was available for laser technicians if required, as outlined in the local rules.

The establishment has a laser surgical register which is completed every time the equipment is operated and includes:

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

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

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

The dermatological laser service

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Reddy and due for review in August 2019. Systems are in place to review the medical treatment protocols on an annual basis. It was noted that medical treatment protocols contained information relating to treatments not provided by the laser service. An area of improvement was identified against the standards to contact Dr Reddy to review the protocols to ensure only pertinent information relating to treatments provided by the laser service is outlined in the medical treatments protocols.

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

Protective eyewear was clearly outlined in the local rules. Review of the protective eyewear noted a number of issues:

- in laser room 6 the operator protective eyewear had cracked lenses
- there was only one pair of black out protective eyewear which was being shared between five laser rooms
- replacement protective eyewear for previously cracked operator protective eyewear were found not to be in accordance with the level of protection outlined in the local rules
- weekly audits of the laser rooms had not identified these matters

The importance of protective eyewear was fully discussed with Ms Mulholland who confirmed that there had been ongoing problems with the protective eyewear cracking. An area of improvement was identified against the regulations to provide protective eyewear in a state of good repair for each laser machine as outlined in the local rules and to report the defective protective eyewear to the manufacturers and Northern Ireland Adverse Incident Centre (NIAIC).

An area of improvement was identified against the standards to strengthen audit arrangements for the review of laser rooms to include site inspection of the protective eyewear.

During the inspection Ms Mulholland provided evidence of the following:

- additional black out protective eyewear and operator protective eyewear in accordance with the local rules had been ordered
- the cracked protective eyewear and operator protective eyewear not in accordance with local rules been removed from use
- authorised operators had been made aware of the current protective eyewear situation and the necessity to ensure protective eyewear is available and worn by the client and the operator in accordance to the local rules.

The establishment's LPA completed a risk assessment of the premises in December 2018 and recommendations made had been addressed.

Authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser equipment is in use for the dermatological laser service, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to fulfil the role. Discussion with staff confirmed that systems are in place to ensure other authorised operators are aware who the LPS on duty is.

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 door to the treatment rooms are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using keys. It was confirmed the laser keys are kept in a locked area, and a laser key log outlining the signing in and out of the laser keys by authorised operators only is in operation.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has a laser register for each laser which is completed every time the equipment is operated and should include:

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

Review of the laser registers noted the following;

- the name of the client was not written in full, and recorded initials only(this was a change to practice following consideration of the General Data Protection Regulations(GDPR))
- the record of treatment did not contain full details of the laser treatment such as the number of shots.
- an air cooler is coupled with the laser hand piece during treatments. The serial number of each unit must be recorded on the front of the laser registers beside the serial number of the laser machine. This will assist the clinic in any follow up investigations and quality control associated with the performance of the individual coolers.
- authorised operators signatures and initials were on occasions illegible

An area of improvement was identified against the regulations to ensure the laser register is completed accurately, to include the name of the client, the treatment given with precise information such as the number of shots, the air cooler serial number on the front of the laser register, a list of authorised operators signatures/initials with their printed name on the front inner cover of each laser register.

The laser machines had arrangements for their ongoing servicing and maintenance in place.

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser and IPL safety arrangements for the refractive laser eye surgery service and the dermatological laser service; the findings and report of Dr Gillan is appended to this report.

Management of emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided and that most emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained with the exception of a portable suction machine. An area of improvement was identified against the standards in relation to the provision of a portable suction machine. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment.

The policy on managing a medical emergency was in place.

Infection Prevention and Control and Decontamination Procedures

There were clear lines of accountability for infection prevention and control (IPC) in place.

A range of information was available for patients, clients and staff regarding hand washing techniques.

Arrangements were in place to ensure the decontamination of equipment and reusable medical devices are in line with manufacturer's instructions and current best practice. Theatre sterile packs are provided from an accredited organisation. Staff confirmed single use equipment is used where possible.

Staff have been provided with IPC training commensurate with their role.

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

The refractive laser eye suite was found to be clean, tidy, uncluttered and had detailed cleaning schedules completed.

Review of the dermatological laser rooms noted that cleaning schedules had been signed off, however a layer of dust was found under the treatment couches. There were fabric chairs in each of the laser rooms which were not wipeable and therefore not in keeping with best IPC practice. An area of improvement was identified against the standards to remove furniture from laser rooms which cannot be easily cleaned and ensure the laser rooms are clean, tidy and free from dust. The IPC audit for the dermatological laser rooms should be strengthened to include these matters.

A range of IPC audits have been carried out by the laser scrub nurse for the refractive laser eye service including:

- environmental
- hand hygiene
- post treatment infection

The compliance rate was noted to be good and an action plan was in place for areas of non-compliance.

A range of IPC policies and procedures were available

Environment

The premises were maintained to a good standard of maintenance and décor.

Carbon dioxide (CO2) fire extinguishers were available which have been serviced within the last year.

Arrangements are in place for maintaining the environment.

A legionella risk assessment was undertaken as part of the RQIA's registration process in January 2018 and water temperature is monitored and recorded as recommended.

A fire risk assessment had been undertaken and staff confirmed fire training and fire drills had been completed. Staff demonstrated that they were aware of the action to take in the event of a fire.

Areas of good practice

There were examples of good practice found in relation to induction, authorised operator's training and safeguarding.

Areas for improvement

Ensure that staff who are not directly involved in the laser service, have laser safety awareness training and a record is maintained and available for inspection.

Ensure that staff appraisals are carried out and recorded at least annually. Consideration should be given to provide management personnel who conduct staff appraisals with training in relation to this role.

Ensure that all information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is obtained prior to the commencement of employment for all new staff members.

Liaise with Dr Paul Reddy (medical support service) to review the medical treatment protocols to ensure only pertinent information relating to treatments provided by the dermatological laser service is outlined in the medical treatments protocols.

Ensure the provision of protective eyewear in a state of good repair for each laser machine as outlined in the local rules and the reporting of the defective protective eyewear to the manufacturers and Northern Ireland Adverse Incident Centre.

Strengthen audit arrangements for the review of laser rooms to include site inspection of the protective eyewear.

Ensure the laser register is completed accurately, to include the name of the client, the treatment given with precise information such as the number of shots, the air cooler serial number on the front of the laser register, a list of authorised operator's signatures/initials with their printed name on the front inner cover of each laser register.

Ensure the provision a portable suction machine as part of the emergency medical equipment available in the establishment.

Remove furniture from laser rooms which cannot be easily cleaned and ensure the laser rooms are kept clean, tidy and free from dust. The IPC audit should be strengthened to include these matters.

	Regulations	Standards
Areas for improvement	3	6

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Refractive laser eye surgery

Patients have an initial consultation with a qualified optometrist who discusses their treatment options and the cost of the surgery.

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

The establishment 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.

It was confirmed that in accordance to 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 provided with clear post-operative instructions along with contact details for a senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Six patient care records were reviewed. The establishment retains hard copy care records which are supplemented with an electronic record system. The patient care records were well documented, contemporaneous and clearly outlined the patient journey. The care records reviewed contained the following.

- patient details
- medical history
- signed consent form
- initial consultation
- pre-operative notes
- intra-operative notes
- post-operative notes
- review/follow up notes

Dermatological laser service

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment 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, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner, with their consent, for further information if necessary.

Ten client care records were reviewed. Most provided 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 there had been improvement in the completion of client records, however with the introduction of the new lasers there was inconsistency in how the laser treatments were being recorded. Assurances were given that the laser treatment record would be reviewed with staff and further training provided. Ms Mulholland confirmed the client record audit would be redevised to ensure that this element of record completion is robustly audited.

An area of improvement was identified against the regulations to ensure client records for the dermatological laser service include consistent details of the laser treatment provided such as number of shots.

Records management

Observations made evidenced that patient and client records are securely stored.

Systems were in place to audit the completion of clinical records and an action plan is developed to address any identified issues. As stated previously the client record audit is to be strengthened. The outcome of the audit is reviewed through the establishment's clinical governance structures.

Information was available for patients and clients on how to access their health records, under the General Data Protection Regulations (GDPR).

A review of documentation confirmed that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

The establishment is registered with the Information Commissioners Office (ICO).

Communication

As discussed, there was written information for patients and 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 establishment has a policy for advertising and marketing which is in line with legislation.

Staff confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the establishment.

Areas of good practice

There were examples of good practice found in relation to the completion of clinical records for the refractive laser surgery service, the arrangements for records management and ensuring effective communication between patients, clients and staff.

Areas for improvement

Ensure client records for the dermatological laser service include consistent details of the laser treatment provided such as number of shots.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with staff regarding the consultation and treatment or surgery confirmed that patients' and clients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient, client and the optometrist or authorised operator. Laser surgery is provided within a designated laser suite.

Information is provided to the patient and client in verbal and written form at all consultations to allow the patient and client to make choices about their care and treatment and provide informed consent.

Patients meet with the surgeon on a separate day in advance of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Appropriate measures are in place to maintain patient and client confidentiality; and observations made evidenced that care records were stored securely in locked filing cabinets and electronic records are password protected.

Separate patient and client satisfaction surveys are carried out by the establishment on a monthly basis and the results of these are collated to provide a monthly summary report which is made available to patients, clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires for the refractive laser eye surgery service found that patients were satisfied with the quality of treatment, information and care received. Comments included:

- "100% worth it."
- "Brilliant"
- "Great service –slight delay on surgery day."
- "Vision improving every day."
- "Excellent experience from start to finish."

Review of completed client questionnaires for the dermatological laser service found that the service was rated high.

Comments included:

- "The staff are so friendly."
- "Great experience."
- "X is very professional."
- "Excellent service."

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining patient and client confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients and clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment, and staff were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Ms Orla Mulholland, registered manager has overall responsibility for the day to day management of the laser services provided in the establishment. Ms Tiara Fitzpatrick has responsibility for the day to day management of the refractive laser eye surgery service.

Mr Phillip McGlade, responsible individual of Optilase Therapie, had appointed Ms Orla Mulholland (prior to her becoming the registered manager) to monitor the quality of services and undertake a visit to the premises at least every six months in accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. The most recent report of the unannounced monitoring visit dated December 2018 was available for inspection. As Ms Mulholland is now the registered manager for the service and is therefore directly concerned with the conduct of the establishment, it would no longer be appropriate for her to carry out the role as outlined in regulation 26. An area of improvement was identified against the regulations in relation to the responsible individual establishing and implementing arrangements for six monthly monitoring visits in accordance to Regulation 26.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on annual basis. Staff spoken with were aware of the policies and how to access them.

It was demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment, it was identified that further development was required. An area of improvement was identified against the standards to further develop the complaints procedure to include a clear outline of roles and responsibilities in relation to complaints reflecting current organisational structures and to include RQIA's name, address and telephone number as a regulatory only.

Discussion with management demonstrated some awareness of complaints management however roles and responsibilities in relation to complaints were unclear.

Review of the complaints management found that it requires to be strengthened to ensure there is evidence that complaints are being fully recorded, investigated, outcomes established and any learning implemented. It was advised complaints must be managed in accordance with legislation and the establishment's complaints procedure. An area of improvement was identified against the regulations to ensure that complaints are managed in accordance to legislation and the establishment's complaints procedure. Comprehensive complaints records should be available for inspection.

It was confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA. However it was noted that the incident policy did not outline NIAIC as a relevant reporting body. The incident policy was updated during the inspection to include details of the reporting arrangements to NIAIC. A system was 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.

It was confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. A monthly audit is conducted and it was confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. The audit programme included the following:

- laser log completion
- laser goggles safety
- laser machine service records
- clinic policies/procedures
- cleaning schedules
- staff personnel files, training and certificates
- complaints
- patient and client files
- comment card completion

As stated previously some areas of the above audits should be strengthened and robustly implemented and an area of improvement has already been outlined on this matter.
For the refractive laser eye surgery, it was confirmed the consultant ophthalmologist undertakes clinical audit which includes:

- best corrected visual acuity which is audited two monthly for all patients who are three months post- operative.
- post-operative complications
- post –operative surgical site infections.

An action plan is developed as necessary and the results shared with the consultant ophthalmologist's medical appraiser.

The process for granting practising privileges was outlined and it was confirmed medical practitioners will meet with the responsible individual prior to privileges being granted.

A review of medical practitioner's personnel file confirmed that there was a written agreement between the medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years.

A policy and procedure was in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges. It was noted that there was reference to English legislation which is not in force in Northern Ireland (NI). The practicing privileges procedure was amended during the inspection to remove English legislation and to reflect NI legislation.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

It was confirmed that the statement of purpose and the patient's and client's guides are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

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

Areas of good practice

There were examples of good practice found in relation to maintaining good working relationships.

Areas for improvement

The responsible individual must establish and implement arrangements for six monthly monitoring visits in accordance to Regulation 26

The complaint's procedure should be updated to include a clear outline of roles and responsibilities in relation to complaints reflecting current organisational structures and RQIA's name, address and telephone number as a regulatory only.

Ensure that complaints are managed in accordance to legislation and the establishment's complaints procedure. Comprehensive complaints records should be available for inspection.

	Regulations	Standards
Areas for improvement	2	1

6.8 Equality data

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 and clients was discussed with Ms Mulholland .

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

6.9 Patient and staff views

Thirteen patients submitted questionnaire responses to RQIA. All indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led and that they were very satisfied with each of these areas of their care.
Comments included in in submitted questionnaire responses are as follows:

- “Amazing treatments always.”
- “Very knowledgeable staff.”
- “Staff are so friendly and helpful.”
- “Excellent service.”

There were no submitted staff questionnaire responses to RQIA.

7.0 Quality improvement plan (QIP)

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Orla Mulholland, registered manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of a refractive laser eye surgery service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref**: Regulation 19.2 **Stated:** First time **To be completed by:** 30 May 2019	The registered person shall ensure that all information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is obtained prior to the commencement of employment. Ref: 6.4
	Response by registered person detailing the actions taken: All prospective employees will have all checks completed prior to their start date.
Area for improvement 2 **Ref:** Regulation 15.2 **Stated:** First time **To be completed by:** 7 June 2019	The registered person shall ensure the provision of protective eyewear in a state of good repair for each laser machine as outlined in the local rules and the reporting of the defective protective eyewear to the manufacturers and Northern Ireland Adverse Incident Centre. Ref: 6.4
	Response by registered person detailing the actions taken: Replacement eyewear approved by LPA is in situ. Additional audits/team meetings to enforce ongong compliance
Area for improvement 3 **Ref:** Regulation 21(1),(3) Schedule 3 PART II, 3 **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall ensure the laser register is completed accurately, to include the full name of the client, the treatment given with precise information such as the number of shots, the air cooler serial number on the front of the laser register, a list of authorised operators' signatures/initials with their printed name on the front inner cover of each laser register. Ref:6.4

	Response by registered person detailing the actions taken: Sample signatures and air cooler serial number has been added to laser register, team meeting/training and ongoing additional audits to ensure future compliance, new logs with additional required information on order
Area for improvement 4 **Ref:** Regulation 26 **Stated:** First time **To be completed by:** 30 July 2019	The registered person shall ensure that arrangements for six monthly monitoring visits are established and implemented in accordance to Regulation 26. Ref 6.7
	Response by registered person detailing the actions taken: A manager from another clinic is now appointed to carry out bi-annual monitoring visits
Area for improvement 5 **Ref:** Regulation 23 **Stated:** First time **To be completed by:** 30 July 2019	The registered person shall ensure that complaints are managed in accordance to legislation and the establishment's complaints procedure. Comprehensive complaints records should be available for inspection. Ref: 6.7
	Response by registered person detailing the actions taken: A complaints tracker which prompts the required stages of the complaints process will be completed moving forward
Area for improvement 6 **Ref:** Regulation 21(1) **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall ensure client records for the dermatological laser service include consistent details of the laser treatment provided such as number of shots. Ref: 6.5
	Response by registered person detailing the actions taken: additional checks/team briefs/weekly meetings to reinforce consistency
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (2014)	
Area for improvement 1 **Ref**: Standard 48.3 **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall liaise with Dr Paul Reddy (medical support service) to review the medical treatment protocols to ensure only pertinent information relating to treatments provided by the dermatological laser service is outlined in the medical treatments protocols. Ref: 6.4
	Response by registered person detailing the actions taken: Treatments protocols have been reviewed and amended

Area for improvement 2 **Ref**: Standard 48.13 **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall ensure that staff who are not directly involved in the laser service, have laser safety awareness training and a record is maintained and available for inspection. Ref: 6.4
	Response by registered person detailing the actions taken: Staff not directly involved with the lasers have had laser safety training provided by the LPA, delivered by the LPS
Area for improvement 3 **Ref**: Standard 10.6 **Stated:** First time **To be completed by:** 30 July 2019	The registered person shall ensure that staff appraisals are carried out and recorded at least annually. Consideration should be given to provide management personnel who conduct staff appraisals with training in relation to this role. Ref: 6.4
	Response by registered person detailing the actions taken: HR have revised the appraisal process and provided training
Area for improvement 4 **Ref**: Standard 9.3 **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall strengthen audit arrangements for the review of laser rooms to include site inspection of the protective eyewear. Ref:6.4
	Response by registered person detailing the actions taken: complete and ongoing
Area for improvement 5 **Ref**: Standard 18.3 **Stated:** First time **To be completed by:** 30 June 2019	The registered person shall ensure the provision a portable suction machine as part of the emergency medical equipment available in the establishment. Ref: 6.4
	Response by registered person detailing the actions taken: A portable suction machine has been added to the clinics emergency equipment
Area for improvement 6 **Ref**: Standard 20 **Stated:** First time **To be completed by:** 7 June 2019	The registered person shall remove furniture from laser rooms which cannot be easily cleaned and ensure the laser rooms are kept clean, tidy and free from dust. The IPC audit should be strengthened to include these matters. Ref: 6.4
	Response by registered person detailing the actions taken: Non wipeable furniture removed from treatment area, additional checks on IPC audit, to ensure ongoing compliance

Area for improvement 7 **Ref**: Standard 7.1 **Stated:** First time **To be completed by:** 30 July 2019	The registered person shall ensure that the complaint's procedure should be updated to include a clear outline of roles and responsibilities in relation to complaints reflecting current organisational structures and RQIA's name, address and telephone number as a regulatory only. Ref: 6.7
	Response by registered person detailing the actions taken: Complaints procedure updated to reflect lines of accountability and the RQIAs role as regulator only.

Please ensure this document is completed in full and returned via Web Portal

30th May 2019

Mrs W Maguire
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast BT1 3BT

Dear Mrs Maguire

Laser Protection Report

Optilase & Therapie, 35 – 40 Ann Street, Belfast BT1 4EG

Introduction

Further to the inspection visit to the above premises on 29th May 2019, this report summarises the main laser protection aspects where improvement may be required. The findings are based on the requirements of European Laser Standards and the Control of Artificial Optical Radiation at Work Regulations (Northern Ireland) 2010.

Deficiencies & Comments

OPTILASE

Service Report
The engineer's report (28/2/19) for the Scwind laser stated that parts had been ordered to remedy the pressure loss between the valve and reducer. It was uncertain from the report whether this repair was non-urgent and would be carried out at the next service, which is scheduled for July 2019. The service report should provide further information on the action plan.

THERAPIE

Treatment Protocols
The current treatment protocol includes treatments other than the registered hair reduction/removal. The treatment protocol should be reviewed and the treatments not performed in the clinic removed. The date of review or version number should be added to the document in line with document control systems.

Treatment Log
The number of shots fired during each treatment is not currently recorded in the treatment log. An extra column should be added to record this information. Similarly, this information has not been recorded in all the individual patient records.

Air Cooler
An air cooler is coupled to the laser hand piece during treatments. The serial number for each unit must be recorded on the front of the Treatment Log book beside the serial number for the laser. This will assist the clinic in any follow up investigations and quality control associated with the performance of individual coolers.

Protective Eyewear

- During the inspection it was noted that both lenses on one set of protective eyewear was cracked. These damaged goggles should have been removed from the treatment room and a suitable replacement obtained.
- Only one pair of the total blocking shields as detailed in the local rules was available in the clinic
- Due to the cracked goggles and the shortage of total blocking shields alternative protective eyewear (goggles & shields) was being used. The protection level of this alternative protective eyewear was of a lower specification to that specified in the local rules.
- The clinic should make their LPA aware of the above problems with damaged eyewear and seek his advice on whether the Northern Ireland Adverse Incident (NIAIC) should be notified of any potential defect in this product.
- The above lack & damage to eyewear should have been noted during the periodic checks of equipment in the treatment rooms and appropriate corrective action taken.

The clinic should inform RQIA when the above matters have been addressed.

Ian Gillan

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Dr Ian Gillan
Laser Protection Adviser to RQIA

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Appendix

Optilase , 35 – 40 Ann Street, Belfast BT1 4EG

Laser Systems

Manufacturer:	Schwind
Model	Amaris 500E
Type	Excimer
Wavelength	193nm
Serial Number:	M110

Manufacturer:	Abbott Medical Systems (AMO)
Model	IFS Advanced Femtosecond
Type	Intralase
Wavelength	1053nm
Serial Number:	0511-70169

Therapie , 35 – 40 Ann Street, Belfast BT1 4EG

Laser Systems (five identical lasers)

Manufacturer:	Cynosure
Model	Elite EM+
Type	Alexandrite (755nm) & NdYAG (1064nm)
Serial Number:	ELM 1975, ELM 1976, ELM 1978, ELM 1703 & ELM 1820

Laser Protection Adviser

Dr Alex Zarneh

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