Announced Care Inspection Report
29 & 30 May 2018

Optilase Therapie

Type of Service: Independent Hospital (IH) – Refractive Laser Eye Surgery and Dermatological Laser/Intense Pulsed Light (IPL) Service
Address: 36 Ann Street, Belfast, BT1 4EG
Tel No: 0800 044 3236
Inspector: Winifred 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: Wayne Crew-Browne (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

Manufacturer: Alma
Laser Class: Class 4/IPL
Model: Harmony XL
Wavelength: ER:YAG- 2940nm
IPL Yellow Handpiece – 570-950nm
IPL Green Handpiece---540-950nm
Serial Number: HXL01057

Manufacturer: ABC
Laser Class: Class 4
Model: Soprano Platinum
Wavelength: 755nm, 810nm, 1064nm
Serial Number: PLAT0380

Manufacturer: ABC
Laser Class: Class 4
Model: Soprano Platinum
Wavelength: 755nm, 810nm, 1064nm
Serial Number: PLAT0381

Manufacturer:	ABC
Laser Class:	Class 4
Model:	Soprano Platinum
Wavelength:	755nm, 810nm, 1064nm
Serial Numbers:	PLAT0382

Manufacturer:	ABC
Laser Class:	Class 4
Model:	Soprano Platinum
Wavelength:	755nm, 810nm, 1064nm
Serial Numbers:	PLAT0905

Manufacturer:	ABC
Laser Class:	Class 4
Model:	Soprano Platinum
Wavelength:	755nm, 810nm, 1064nm
Serial Numbers:	PLAT0733

Associated equipment

Equipment:	Plume evacuator
Manufacturer:	Quatro
Model:	Fresh Air 400
Serial number:	18461

Equipment:	Skin Cooler
Manufacturer:	ABC
Model:	Lasercryo air
Serial number:	110310483

Laser protection advisor (LPA): Alex Zarneh

Laser protection supervisor (LPS): Michelle Connor in her absence another named authorised operator

Medical support services: Dr Ross Martin

Authorised operators

Soprano Platinum laser: Michelle Connor, Niamh Quinn, Emma Ferris, Wendy Irvine, Rachel McCaughey, Grainne Cunnane, Sarah Crawford, Kerri Doran, Maeve McArdle Sinead Walsh, Tiffany Benson.

Harmony XL laser: Michelle Connor, Niamh Quinn, Wendy Irvine.

Types of Treatment Provided

Soprano Platinum laser: Hair removal/reduction

Harmony XL laser: Skin resurfacing
Skin rejuvenation/vascular

3.0 Service details

Organisation/Registered Provider: Therapie Clinic Ltd **Responsible Individual:** Mr Phillip McGlade	**Registered Manager:** Ms Emma McFarlane
Person in charge at the time of inspection: Orla Mulholland (dermatological service) Tiaran Fitzpatrick (refractive laser eye service)	**Date manager registered:** 8 December 2017
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers; PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources and PD private doctor	

4.0 Inspection summary

An announced inspection took place on 29 May 2018 from 10.00 to 16.00 and 30 May 2018 from 11.00 to 15.05.

Dr Ian Gillan, RQIA's Medical Physics Advisor accompanied the inspector to review the laser and IPL safety arrangements; the findings and report of Dr Gillan is 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: patient safety in respect of staff training and development; recruitment; safeguarding and the environment. Other examples included: the management of the patient communication; records management and engagement to enhance the patients' experience.

Nine areas requiring improvement were identified against the standards in relation to providing evidence of an accredited LPA appointment; amending the register of authorised operators for the refractive laser eye surgery lasers to reflect only the clinical and non-clinical authorised operators; amending the register of authorised operators for the Harmony XL laser machine to reflect current authorised operators;reviewing medical treatment protocols for the Harmony XL laser machine to include only those treatments provided using the laser/IPL handpieces in the establishment ;providing specific information in the local rules on the protective eyewear associated with the wavelengths for the Soprano Platinum and the Harmony XL laser machines, this is stated for a second time; ensuring that the LPA seeks clarification in relation to the inconsistencies on the labelling of the Soprano Platinum lasers; ensuring there are robust version document control systems in place; review dosage of medical emergency medications to ensure they are in accordance with British National Formulary (BNF); and ensuring client records for the dermatological laser service are fully and accurately completed identifying clearly which laser machine has been used, this is stated for a second time.

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

- “Excellent service and support.”
- “Optilase were fantastic from start to finish.Cannot fault the service at all.”

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

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	9

Details of the Quality Improvement Plan (QIP) were discussed with Ms Orla Mulholland, Therapie service manager and Ms Tiaran Fitzpatrick, Optilase service 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 9 January 2018

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 9 January 2018.

5.0 How we inspect

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

- notifiable events since the previous care inspection
- duty calls
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the returned QIP from the previous care inspection
- the previous care inspection reports (9 January 2018 and 29 and 30 August 2017)

Questionnaires were provided to patients and clients prior to the inspection by the establishment on behalf of RQIA. Returned completed patients and clients questionnaires were also analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire, however RQIA did not receive any completed questionniares.

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

During the inspection, the inspector met with Ms Orla Mulholland,Therapie service manager; Ms Tiaran Fitzpatrick, Optilase service manager; a laser technician for the refractive eye surgery; a laser scrub nurse; and an authorised operator for the dermatological laser service.

The following records were examined during the inspection:

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

Areas for improvement identified during the care inspection on 29 and 30 August 2017 were reviewed and assessment of compliance recorded as ‘met’, ‘partially met’, or ‘not met’.

The findings of the inspection were provided to Ms Orla Mulholland and Ms Tiaran Fitzpatrick at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the inspection dated 29 - 30August 2017 which were carried forward from the most recent inspection 9 January 2018

The inspection of the establishment on 29 – 30 August 2017 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 care inspection dated 29-30 August 2017

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for improvement 1 **Ref**: Regulation 15 (2) **Stated:** First time	The registered person shall ensure that the Harmony XL laser machine is maintained and serviced in accordance to manufacturer's instructions and a record retained for inspection.	**Met**
	Action taken as confirmed during the inspection: The Harmony XL laser machine is scheduled for a service week commencing 4 June 2018	
Area for improvement 2 **Ref:** Regulation 25 (2)d **Stated:** First time	The registered person shall ensure that the broken pane of glass placed underneath the wash hand basin in laser room '4' is removed.	**Met**
	Action taken as confirmed during the inspection: Optilase Therapie has moved premises therefore this area of improvement is no longer relevant . All areas of the new premises were noted to be in good state of repair.	
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)		
Area for improvement 1 **Ref**: Standard 48.13 **Stated:** First time	The registered person shall ensure that all staff employed at the establishment, but not directly involved in the use of the laser equipment, receives laser safety awareness training and a record is maintained of the training.	**Met**
	Action taken as confirmed during the inspection: All staff employed at the establishment, but not directly involved in the use of the laser equipment, has received laser safety awareness training and a record is maintained of the training.	

Area for improvement 2 **Ref:** Standard 12.5 **Stated:** First time	The registered person shall ensure that an electronic staff register is re-established	**Met**
	Action taken as confirmed during the inspection: A copy of an electronic staff register was available for inspection . It was updated during the inspection to reflect current staff employed.	
Area for improvement 3 **Ref**: Standard 20.2 **Stated:** First time	The registered person shall ensure that infection prevention control (IPC) policies and procedures are in place which adequately reflects the IPC arrangements for the refractive laser eye surgery service.	**Met**
	Action taken as confirmed during the inspection: IPC policies and procedures were in place which adequately reflects the IPC arrangements for the refractive laser eye surgery service.	
Area for improvement 4 **Ref:** Standard 48.17 **Stated:** First time	The registered person shall ensure that the local rules in relation to the laser equipment used in the dermatological laser service should outline specific information on the protective eyewear.	**Not met**
	Action taken as confirmed during the inspection: The local rules in relation to the laser equipment used in the dermatological laser service was found not to fully outline specific information on the protective eyewear. This area of improvement is stated for a second time	

Area for improvement 5 **Ref**: Standard 22.11 **Stated:** First time	The registered person shall ensure that the dermatological laser rooms are cleaned in line with cleaning schedules including underneath the client treatment couches.	**Met**
	Action taken as confirmed during the inspection: The laser rooms were found to be clean and tidy. Cleaning sign off sheets were completed.	
Area for improvement 6 **Ref:** Standard 22.3 **Stated:** First time	The registered person shall ensure that a current fixed electrical wiring certificate is available for inspection.	**Met**
	Action taken as confirmed during the inspection: The service has moved premises in January 2018 and a premsies inspection was carried out by a RQIA estates inspector, a current fixed electrical wiring certificate was reviewed as part of this inspection .	
Area for improvement 7 **Ref**: Standard 48.10 **Stated:** First time	The registered person shall ensure that client records for the dermatological laser service are fully and accurately completed.	**Not met**
	Action taken as confirmed during the inspection: A review of client records found that the laser/IPL used to provide the treatment was not fully recorded in the client records. This area of improvement is stated for a second time	
Area for improvement 8 **Ref:** Standard 11.1 **Stated:** First time	The registered person shall ensure that the policy and procedure for the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges is amended to remove reference to the English legislation.	**Met**
	Action taken as confirmed during the inspection: The policy and procedure for the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges has been amended to remove reference to the English legislation.	

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 includes a team of: a consultant ophthalmologist; an optometrist; laser scrub nurses; 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 and it was noted a number of other staff who were not authorised operators had signed the register. An area of improvement was identified against the standards to amend the register of authorised operators for the refractive laser eye surgery lasers to reflect only the clinical and non-clinical authorised operators. A register of authorised operators is also maintained for the dermatological laser service. It was noted that the register for the Harmony XL laser did not fully reflect the current authorised operators. An area of improvement was identified against the standards to amend the Harmony XL register of authorised operators to reflect the current authorised operators.

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 for the refractive laser eye surgery service had up to date training in core of knowledge training; application training for the equipment in use; basic life support; infection prevention and control; and fire safety. Authorised operators for the dermatological laser service had up to date training in application training for the equipment in use; basic life support; infection prevention and control; and fire safety. However recently appointed authorised operators had not undertaken core of knowledge training. Following the inspection evidence was provided that all authorised operators had undertaken core of knowledge training.

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

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 are systems in place for undertaking, recording and monitoring all aspects of staff supervision, ongoing professional development for staff and staff appraisal.

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

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. Minor amendments were made to the policy during the inspection.

Laser/IPL 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.

It was noted that the appointed LPA for the service ,certificate had expired in March 2018. It was confirmed that the LPA had been made aware of this and was in the process of recertifying with the appropriate authority. An area of improvement was identified to provide evidence of an accredited LPA appointment. The service level agreement between the establishment and the LPA was reviewed and this expires in July 2018.

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 June 2017 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 Ross Martin and due for review in 2019. Systems are in place to review the medical treatment protocols on an annual basis. It was noted that the medical treatment protocols for the Harmony XL laser/IPL machine included treatments not provided by the establishment. An area of improvement was identified against the standards to amend the medcial treatment protocols to reflect only the treatments provided using the Harmony XL laser/IPL machine carried out in the establishment.

Up to date local rules were in place which have been developed by the LPA. The local rules contained most of the relevant information pertaining to the laser equipment being used. The protective eyewear information relating to each laser machine was found to be generic. It was difficult to clearly ascertain the specific type of protective eyewear recommended for each machine, particularly as the Soprano Platinum laser machines had a range of wavelengths and the Harmony XL machine had two handpieces, each providing treatment at a different wavelengths. As stated, the local rules provided generic information and therefore it was not possible to match the protective eyewear provided to the information outlined in the local rules. An area of improvement against the standards was identified for a second time in relation to ensuring the local rules outline specific information on protective eyewear.

All protective eyewear was clearly labelled for use.

It was noted that there were inconsistencies in the labelling of the Soprano Platinum laser systems . Dr Gillan's report appended to this report outlines further detail on this matter. An area of improvement was identified against the standards to ensure that the establishment's LPA seeks clarification from the manufacturer regarding the output of the 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.

The date stated on the front of the local rules for several of the laser systems differs from that on the footer of some pages within the the document . This creates uncertainty around the version of the document which was read before staff signed the statement at the end of the local rules. An area of improvement was made against the standards to ensure that there are robust document control systems in place.

The establishment's LPA completed a risk assessment of the premises in December 2017 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. Staff were reminded of the importance of this on inspection.

The establishment has a laser register for each laser 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

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

It was confirmed the Harmony XL laser/IPL machine had servicing arranged for the week commencing 4 June 2018

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 emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. An area of improvement was identified against the standards to review dosage of medical emergency medications to ensure they are in accordance with British National Formulary (BNF). 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. Minor amendments were made to the policy during inspection and it was found to provide clear instructions on what to do in the event of a medical emergency.

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. Staff confirmed single use equipment is used where possible. Theatre sterile packs are provided from an accredited organisation.

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.

A range of IPC audits have been carried out 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 had been serviced within the last year.

As stated previously Optilase Therapie had moved premises in January 2018 and a variation to registration inspection was conducted prior to approval for use. As part of the inspection conducted in January 2018 ,a premises inspection had been undertaken by an RQIA estates inspector.

Patient, client and staff views

Eighteen patients and clients submitted questionnaire responses. All indicated that they felt safe and protected from harm and were very satisfied.

RQIA did not received any completed staff questionnaire responses.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to: staff recruitment; induction; training; supervision and appraisal; adult safeguarding; risk management and the environment.

Areas for improvement
Amend the register of authorised operators for the refractive laser eye surgery lasers to reflect only the clinical and non-clinical authorised operators.

Amend the Harmony XL laser/IPL register of authorised operators to reflect the current authortised operators.

Provide evidence of an accredited LPA appointment.

The local rules in relation to the laser equipment used in the dermatological laser service should outline specific information on the protective eyewear.

Amend the medcial treatment protocols to reflect only the treatments provided using the Harmony XL laser/IPL machine carried out in the establishment.

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.

Ensure that there are robust document control systems in place.

Review the dosage of medical emergency medications to ensure they are in accordance with British National Formulary (BNF).

	Regulations	Standards
Total number of areas for improvement	0	8

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 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.

Five 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 that client records did not reflect the laserIPL machine used to provide the treatment. Given that there are six laser machines in place it would be important to ensure the client record can be used to identify which laser /IPL machine was used to provide treatment. An area of improvement was identified against the standards for a second time to ensure client records for the dermatological laser service are fully and accurately completed identifying clearly which laser machine has been used.

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. 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.

Patient, and client and views

All patients and clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them and were very satisfied with this aspect of care.

RQIA did not receive any completed staff questionnaire responses.

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 are fully and accurately completed, identifying clearly which laser machine has been used.

	Regulations	Standards
Total number of areas for improvement	0	1

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 an 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.

Review of completed client questionnaires for the dermatological laser service, found that there were no written comments and the service was rated high .

Equality data

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

Patient and client views

All patients and clients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care and were very satisfied with this aspect of care.

RQIA did not receive any completed staff questionnaire responses.

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
Total number of 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 able to describe their roles and responsibilities and 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 Mulholland has overall responsibility for the day to day management of the dermatological laser service, and Ms Fitzpatrick has overall responsibility for the day to day management of the refractive laser eye

surgery service. Ms Emma McFarlane regional manager for Optilase Therapie, who is based in the establishment is the registered manager.

Mr Phillip McGlade, responsible individual of Optilase , carries out regular visits to the establishment. A log of his visits was available for inspection.

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. Discussion with staff demonstrated an awareness of complaints management.

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

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 medical practitioner's personnel file reviewed 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.

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.

Patient, client and staff views

All patients and clients who submitted questionnaire responses indicated that they felt that the service is well managed and were very satisfied with this aspect of the service.

As previously indicated, RQIA did not receive any completed staff questionnaire responses.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to the management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement
No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Mulholland, Therapie service manager and Ms Fitzpatrick Optilase service 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 the laser/IPL 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; 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 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.

RQIA will phase out the issue of draft reports via paperlite in the near future. Registered providers should ensure that their services are opted in for the receipt of reports via Web Portal. If you require further information, please visit www.rqia.org.uk/webportal or contact the web portal team in RQIA on 028 9051 7500.

Quality Improvement Plan	
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref**: Standard 48.2 **Stated:** First time **To be completed by:** 30 June 2018	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. Ref: 6.4
	Response by registered person detailing the actions taken: This has now been completed
Area for improvement 2 **Ref**: Standard 48.2 **Stated:** First time **To be completed by:** 30 June 2018	The registered person shall ensure that the Harmony XL laser/IPL register of authorised operators is amended to reflect the current authorised operators. Ref: 6.4
	Response by registered person detailing the actions taken: This has now been completed
Area for improvement 3 **Ref**: Standard 48.6 **Stated:** First time **To be completed by:** 14 June 2018	The registered person shall ensure that evidence of an accredited LPA appointment is provided. Ref: 6.4
	Response by registered person detailing the actions taken: Alex Zarneh is awaiting his new up to date LPA certification and has liased with Dr Gillan on this matter. It has been agreed that Alex can continue in his role as LPA.

Area for improvement 4 **Ref**: Standard 48.17 **Stated:** Second time **To be completed by:** 30 June 2018	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. Ref: 6.4
	Response by registered person detailing the actions taken: This is being updated and corrected by Alex
Area for improvement 5 **Ref**: Standard 48 4 **Stated:** First time **To be completed by:** 30 June 2018	The registered person shall ensure that the medcial treatment protocols are amended to reflect only the treatments provided using the Harmony XL laser/IPL machine carried out in the establishment. Ref: 6.4
	Response by registered person detailing the actions taken: This is now complete
Area for improvement 6 **Ref**: Standard 48.20 **Stated:** First time **To be completed by:** 30 June 2018	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. Ref: 6.4
	Response by registered person detailing the actions taken: Alex has been in contact with Dr Gillan on this matter and has arranged a site visit, this will all be brought up to date
Area for improvement 7 **Ref**: Standard 48.10 **Stated:** Second time **To be completed by:** 30 May 2018	The registered person shall ensure that client records for the dermatological laser service are fully and accurately completed. Ref: 6.5
	Response by registered person detailing the actions taken: All staff are being re-trained and daily checks will be completed on all client records to ensure compliance, all new satff have now completed core of knowledge training.
Area for improvement 8 **Ref**: Standard 19.4 **Stated:** First time **To be completed by:** 30 June 2018	The registered person shall ensure that there are robust document control systems in place. Ref: 6.4
	Response by registered person detailing the actions taken: This issue has been addressed with the manager and team and will be ongoing, Emma will carry out weekly audits in this area.

Area for improvement 9 **Ref**: Standard 18 **Stated:** First time **To be completed by:** 14 June 2018	The registered person shall review the dosage of medical emergency medications to ensure they are in accordance with British National Formulary (BNF). Ref: 6.4
	Response by registered person detailing the actions taken: This has been reviewed and a staff meeeting has taken place to ensure all are fully aware of what to do in an emergeny situation

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

*

29th May 2018

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

Dear Mrs Maguire

Laser Protection Report

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

Introduction

Further to the inspection visit to the above premises earlier today, 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

(1) Dr Zarneh's certificate to act as an LPA expired in March 2018. This must be updated before Dr Zarneh reviews the local rules and risk assessment at the next review date of July 2018. The certificate should also be in place prior to his next LPA visit.

(2) The contacts named on the front of the Local Rules should be updated as one of the named contacts is no longer employed by Optilase.

(3) The training certificates in the laser safety file should be reviewed and where new training has taken place the correct certificate inserted. A programme for future training should also be considered.

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

Dr Ian Gillan
Laser Protection Adviser to RQIA

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 (Advance Medical Optics)
Model	IFS Advanced Femtosecond
Type	Intralase
Wavelength	1053nm
Serial Number:	0511-70169

Laser Protection Adviser

Dr Alex Zarneh

1st June 2018

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

Dear Mrs Maguire

Laser Protection Report

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

Introduction

Further to the inspection visit to the above premises on 30th May 2018, 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

LPA

(1) Dr Zarneh's certificate to act as an LPA expired in March 2018. This must be updated before Dr Zarneh reviews the local rules and risk assessment at the next review date of July 2018. The certificate should also be in place prior to his next LPA visit.

ABC Soprano Platinum systems

(1) Output Wavelength

There are several conflicting references to the output wavelength of these systems:-

(a) Local Rules state 755 – 1064nm
(b) EN 60825-1 label on the rear of the laser states 740-820nm, 1045 – 1080nm
(c) American Standards label on the rear of the laser states 800-820nm
(d) American Standards on connecting socket of laser hand piece states 750-1080nm

The clinic's LPA should seek clarification with the manufacturer regarding the output of the laser and should consider consulting the MHRA/NIAIC regarding this conflicting information displayed on the unit. It should be noted that the treatment head combines three separate lasers and therefore the system can output several wavelengths at the same time.

(2) Output power and Energy

The American Standards label on the connecting socket of the laser hand piece states that the maximum power output is 500W, however in my opinion the power output is more likely to be around 500mW. On the day of inspection only a short user guide was available however further information on the laser specification should be available in the user manual.

The clinic should obtain a copy of the user manual and the clinic's LPA should discuss the systems output specification with the manufacturer and confirm the output power.

(3) Eyewear Protection

The local rules state that the user/operator should wear eyewear of protection Level 3 and the client should wear eyewear of protection Level 5. As the system is a laser the applicable standard is EN207 and the protection level should refer to the L protection level at the output wavelengths. The LPA must therefore amend this section of the local rules.

During his next LPA visit Dr Zarneh should confirm whether the protective eyewear currently being used provides the level of protection which he has calculated.

(4) Servicing of Laser

The service reports for several of the systems referred to particles trapped in the filters and that the filters had not been changed for about a year. During the inspection the clinic contacted the service agent and the recommended servicing interval of 6 months will be followed in future. It is important that staff follow up on any notes or action points within service reports.

(5) Treatment Protocols

It is recommended that the Treatment Protocols should be amended to only cover treatments provided by the clinic.

(6) Document Control

An improved document control system should be introduced in the clinic. The date stated on the front page of the local rules for several of the laser systems differs from that on the footer of some of the pages within the document. This creates uncertainly around the version of the document, which was read before staff signed the statement at the end of the local rules.

ABC Harmony

(1) Eyewear Protection

The local rules state that the user/operator should wear eyewear which is CE marked but does not state the level of protection required. The applicable standard is EN207 and the protection level should refer to the L protection level at the output wavelengths. The LPA must therefore amend this section of the local rules.

During his next LPA visit, Dr Zarneh should confirm whether the protective eyewear currently being used provides the level of protection which he has calculated.

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

Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

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

Laser Systems

Manufacturer:	ABC Lasers
Model	Soprano Platinum
Type	Diode
Class	Class 4
Serial Number:	0380
Serial Number:	0381
Serial Number:	0382
Serial Number:	0733
Serial Number:	0905

Manufacturer:	ABC
Model	Harmony XL
Wavelength	Laser @ 2940nm Yellow IPL applicator 570-590nm Green IPL applicator 540-590nm
Serial Number:	XXL 1057

Laser Protection Adviser

Dr Alex Zarneh

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