

Announced Variation to Registration Care Inspection Report 9 January 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: 08000121565

Inspector: Winifred Maguire

RQIA'S Medical Physics Adviser: Dr Ian Gillan

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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 provider 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 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
 Laser Class: Class 4
 Model: Amaris 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, Nicole Brown,
 Christine Duffy, Joenil Ong, Donna Thompson

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

Dermatological Laser Services**Laser Equipment**

Manufacturer: Alma
 Laser Class: Class 4
 Model: Harmony XL
 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

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): Fionnuala McKenna and in her absence another named authorised operator

Medical support services: Dr Ross Martin

Authorised operators

Soprano Platinum laser: Michelle Connor, Emma Douglas, Nicola Nugent, Fionnuala McKenna, Niamh Quinn, Emma Ferris, Sorcha Mc Kenna, Wendy Irwin, Danielle Douglas, Caomihne Lee McVey

Harmony XL laser: Michelle Connor, Emma Douglas, Nicola Nugent, Fionnuala McKenna

Types of Treatment Provided

Soprano Platinum laser: Hair removal/reduction

Harmony XL laser: Skin resurfacing
Skin rejuvenation

3.0 Service details

Organisation/Registered Provider: Therapie Clinic Ltd Responsible Individual: Mr Phillip McGlade	Registered Manager: Ms Emma MacFarlane
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	Date Registered: 8 December 2017
Person in charge at the time of inspection: Mr Phillip McGlade	

4.0 Inspection summary

An announced variation to registration inspection of Outilase Therapie took place on 9 January 2018 from 10.00 to 14.00.

Dr Ian Gillan, RQIA's Medical Physics Advisor accompanied the inspectors to review the laser safety arrangements; the findings and report of Dr Gillan is appended to this report. Mr Gavin Doherty, estates inspector, undertook a pre-registration premises inspection on the same day. The report and findings of the premises inspection will be issued under separate cover.

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, Social Services and Public Safety (DHSSPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection sought to assess an application submitted to RQIA for a variation of registration in relation to change of premises for Outilase Therapie to Ann Street, Belfast.

The variation to registration to Outilase Therapie was granted from a care perspective following this inspection and the subsequent provision of information which was sought to evidence that matters highlighted as a result of the inspection had been fully addressed. This is outlined in the main body of the report.

The building is set out over three floors with services provided as follows:
 Ground floor- dermatological laser service (known as Therapie)
 First floor – refractive laser eye surgery service (known as Outilase)

Second floor – administrative offices, storage and a communal staff area.

An announced inspection will be scheduled for April 2018 when all aspects of the service will be reviewed to ensure Optilase Therapie continues to provide a safe and effective service following the change of premises.

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	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mr Phillip McGlade, registered person and Ms Emma McFarlane, registered manager, as part of the inspection process and can be found in the main body of the report.

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

Other than those actions detailed in the QIP, no further actions were required to be taken following the most recent inspection on 29 &30 August 2017.

5.0 How we inspect

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

- variation of registration application
- the updated statement of purpose

During the inspection the inspector met with Mr Phillip McGlade , registered person, Ms Emma McFarland, registered manager, Ms Fionnuala Mc Kenna, Therapie service manager, Ms Donna Thompson, Optilase service manager, and two non-clinical authorised operators for the refractive laser eye service. A tour of the premises associated with the laser service was also undertaken.

The following records were examined during the inspection:

- operational policies and procedures
- statement of purpose
- patient guide and client guide
- training records and schedules
- laser safety file
- laser equipment installation documentation
- infection prevention and control report
- cleaning schedules

- induction/orientation programmes

The findings of the inspection were provided to Mr Phillip McGlade, registered person; Ms Emma McFarland, registered manager; Ms Fionnuala Mc Kenna, Therapie service manager; and Ms Donna Thompson, Optilase service manager; at the conclusion of the inspection.

6.0 The inspection

This inspection focused solely on the variation to registration application made by Mr McGlade, registered person to RQIA. The areas for improvement from the last care inspection on 29 & 30 August 2017 were not reviewed as part of the inspection and are carried forward to the next care inspection.

6.3 Inspection findings

Statement of purpose

A statement of purpose was prepared in a recognised format which covered the key areas and themes outlined in Regulation 7, Schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005. A minor amendment was made during the inspection.

Patient guide and client guide

A patient guide for the refractive laser eye service and a client guide for the dermatological laser service were prepared in a recognised format which covered the key areas and themes specified in Regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005.

Patient and client partnerships

The establishment will continue to obtain the views of patients and clients on the quality of treatment, information and care received using patient and client questionnaires.

The information obtained from patients and clients will be collated into an anonymised format, summarised and used by the establishment to make improvements to the services. A copy of the summary reports will be made available to patients and clients; and other interested parties.

Complaints

The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies (April 2009) and the Independent Health Care Regulations (Northern Ireland) 2005. Staff spoken with demonstrated an understanding of complaints management.

Systems are in place to effectively document and manage complaints.

Recruitment of staff

The establishment has a policy and procedure in place for the recruitment and selection of authorised operators and senior management confirmed that staff will continue be recruited in

line with Regulation 19 (2) Schedule 2 of the Independent Healthcare Regulations (Northern Ireland) 2005.

Job descriptions are issued to authorised operators on appointment.

Staff training and development and training for staff using lasers or intense light sources

It was confirmed staff continue to undertake up to date training commensurate with their role, including mandatory training. Training records were available, however not reviewed on this inspection.

Discussion took place on the preparation of staff for the delivery of laser services in the new premises.

Ms McFarlane confirmed staff were to be given a period of short orientation to the premises prior to the commencement of services. It was advised that a formal written induction / orientation programme for all staff be devised and completed prior to the commencement of services.

Following the inspection, completed signed orientation programmes for staff were submitted to RQIA on 9 January 2018.

Infection prevention control

The establishment has policies and procedures in place for infection prevention and control(IPC).

An external IPC advisor's report was reviewed and it was noted the report had a range of recommendations outlined. Ms McFarlane confirmed that she had only received the report the evening before and was working to action the recommendations. It was advised that given the range and number of recommendations made in the IPC report, that arrangements should be made for the IPC external advisor to re- visit the premises and carry out a further review.

The IPC external advisor re-visited the premises on 11 January 2018 and conducted a review of the recommendations outlined in the previous IPC report.

A report of the IPC review on 11 January 2018 was submitted to RQIA on 12 January 2018. It confirmed that the IPC external advisor was "very happy" that the changes he had recommended had been implemented.

The inspector undertook a tour of the premises, which was noted to be still undergoing final snagging work. It was confirmed the premises had been cleaned however on review there remained considerable dust and grime from the ongoing work.

It was emphasised that on completion of the snagging work, a final certified deep clean must be undertaken and evidence of this should be forwarded to RQIA. On 9 January 2018 a certificate of a deep clean for the entire premises by a contract cleaner, was submitted to RQIA. Ms McFarlane confirmed that she had overseen the deep clean to ensure all areas were properly cleaned and had organised for a cleaning crew to provide their services daily over the next number of days until the dust has settled in the building.

It was noted the walls in the laser rooms on the ground floor were grooved making cleaning difficult. This had been also mentioned in the IPC report. It was advised to develop detailed cleaning schedules for these rooms specifically outlining the arrangements for cleaning the walls. The IPC report dated 11 January 2018 confirmed specific arrangements had been put in place on this matter which were reflected in the cleaning schedules.

It was noted the seating in the waiting areas had velvet covering which would make cleaning difficult. Again this was highlighted in the initial IPC report. The IPC report on 11 January 2018, commented that Ms McFarlane had arranged periodic steam cleaning.

The establishment had hand washing facilities available within the treatment rooms adjacent to the laser rooms on the ground floor. Hand sanitising gel was available in the laser rooms. The refractive laser eye treatment room had a surgical scrub up area in place.

There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available.

Patient and client information and laser procedures

The establishment has policies and procedures for advertising and marketing which are factual and not misleading. Advertisements do not offer discounts linked to a deadline for booking appointments. Promotional events do not include financial incentives for potential clients to book a consultation at the event.

It was confirmed that patients and clients will continue to be provided with written information on the specific laser procedures that explains the risks, complications and expected outcomes of the treatment. Patients and clients will also continue to receive aftercare instructions related to the type of laser treatment provided.

The patient and client consultation process will remain as before.

The establishment is registered with the Information Commissioner's Office (ICO).

Procedures for the use of lasers

Laser procedures will continue to be carried out by trained operators in accordance with medical treatment protocols produced by Dr Ross Martin on 3 August 2017 for the dermatological laser service and medical treatment protocols devised by Mr W Crew-Browne, Consultant Ophthalmologist for the refractive laser eye surgery service.

Systems are in place to review the medical treatment protocols annually.

The medical treatment protocols set out:

- contraindications
- technique
- pre-treatment tests
- pre-treatment care
- post-treatment care
- recognition of treatment-related problems
- procedure if anything goes wrong with treatment

- permitted variation on machine variables
- procedure in the event of equipment failure

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis.

A risk assessment of the premises was undertaken by the LPA in December 2017 with a review date for July 2018 and all issues identified have been addressed by the laser protection supervisor s (LPS).

The establishment has local rules in place which have been developed by their LPA in December 2017.

Systems are in place to review the local rules annually.

The local rules cover:

- the potential hazards associated with lasers and intense light sources
- controlled and safe access
- authorised operators' responsibilities
- methods of safe working
- safety checks
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

The following was noted in relation to the local rules for each piece of laser equipment:

Refractive laser eye surgery service:

Schwind, Amaris 500E Class 4 laser and Abbott Medical Systems(AMO) Intralase IFS Advanced Femtosecond, Class 3b laser ,were not signed by all authorised operators. Following the inspection, copies of the signed local rules for these lasers were submitted to RQIA.

Dermatological laser service:

The three ABC Soprano Platinum lasers had the required manufacturer's label on the rear of the lasers which stated that the output wavelength is 800 – 820nm, whereas the local rules stated output wavelengths of 755nm & 810 – 1064nm. The protective eyewear outlined in the local rules for these laser machines did not reflect sufficient protective detail. It was advised that these discrepancies should be brought to the attention of Optilase Therapie's LPA. Following the inspection, it was confirmed that the LPA had been contacted on the matter and electronic copies of the local rules for each of these lasers were submitted to RQIA which had been amended to reflect the wavelength as stated on the rear of the laser machines and to provide further detail on the protective level for the protective laser eyewear.

On the day of inspection a copy of the manufacturer's operating instructions for these machines were not available on site. Following inspection the operating and servicing manuals for the soprano platinum laser machines were submitted to RQIA. A review of these laser machines in conjunction with the operating and service manuals will be undertaken by RQIA's LPA during an inspection to be scheduled for April 2018.

The local rules for the ABC Harmony XL Class 4 laser did not clearly state the level of protection of the required protective eyewear to be worn by the operator and client. Following inspection, the local rules were amended to provide further detail in relation to the protective eyewear.

A register has been established for each laser machine and it was noted the following information is recorded:

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

The format and completion of patient and client records will continue as before.

Safe operation of intense light sources

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

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

Laser safety warning lights will be displayed when the lasers are in use and switched off when not in use as described within the local rules.

Protective eyewear was available and labelled for use during inspection for the patients, clients and operators as outlined in the local rules.

On the day of inspection the door locks to the laser rooms on the ground floor were being upgraded to ensure that they can be locked from within the laser rooms and can be opened from the outside in the event of an emergency, as outlined in the local rules. The laser equipment is key or keypad operated. There are arrangements for safe custody of laser keys and restricted access to laser keypad codes in place.

There were separate laser safety files in place for the refractive laser eye surgery service and the dermatological laser service.

It was confirmed that arrangements have been established for laser equipment to be serviced and maintained in line with the manufacturers' guidance. An installation certificate for each laser machine was in place dated January 2018.

Carbon dioxide (CO₂) extinguishers suitable for electrical fires were available in the establishment.

Employers and public liability insurance was in place dated 23 December 2017.

All matters highlighted in Dr Ian Gillan's appended report were either confirmed as actioned or will be further examined during the inspection in April 2018.

Management of emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. 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.

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.

Areas of good practice

There was evidence of good practice in relation to laser safety arrangements, authorised operator's training and patient and client partnership arrangements.

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

There were no areas for improvement identified during this inspection, and a QIP is not required or included, as part of this inspection report.

9th January 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 & Therapie, 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

Optilase

Authorised users and staff closely involved with the laser treatment should sign the declaration confirming that they will abide with the Local Rules.

Therapie

Rooms:- On the day of inspection the door locks were being upgraded to ensure that the doors could be locked from within the room but opened from the outside in the event of an emergency.

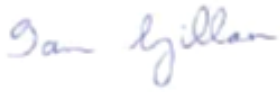
ABC Soprano Platinum:-

- (1) The required manufacturer's label on the rear of the lasers states that the output wavelength is 800 – 820nm, whereas the Local Rules state output wavelengths of 755 nm & 810 – 1064nm. This discrepancy should be brought to the attention of the clinics LPA. Depending on the outcome of these considerations, the local rules may require amendment or if the laser is incorrectly marked the LPA may recommend a notification to MHRA.
- (2) It would be normal practice for the LPA to detail the protection level of the required laser goggles within the local rules.
- (3) On the day of inspection a copy of the manufacturer's operating instructions were not available on site.

ABC Harmony:-

- (1) The local rules should clearly state the level of protection of the required protective eyewear to be worn by the operator and client. This should be considered for both the laser and IPL components.

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

A handwritten signature in blue ink that reads "Ian Gillan". The signature is written in a cursive style.

Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

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

Laser & IPL 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

Manufacturer: ABC Lasers
 Model Soprano Platinum
 Type Diode
 Wavelength 800-820nm
 Serial Number: 0380

Manufacturer: ABC Lasers
 Model Soprano Platinum
 Type Diode
 Wavelength 800-820nm
 Serial Number: 0381

Manufacturer: ABC Lasers
 Model Soprano Platinum
 Type Diode
 Wavelength 800-820nm
 Serial Number: 0382

Manufacturer: ABC
 Model Harmony XL
 Wavelength Laser @ 2940nm plus thee IPL applicators
 Serial Number: XXL 1057

Laser Protection Adviser

Dr Alex Zarneh



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