

Inspector: Winifred Maguire Inspection ID: IN021609

RQIA ID: 11916 Unit 4, Cleaver House Donegall Place 2 3 SEP 2015 **BT1 5BB** IMPROVEMENT AUTHORITY

Tel: 028 9043 8397

Belfast

Optilase Therapie

Announced Care Inspection of **Optilase Therapie**

4 August 2015

The Regulation and Quality Improvement Authority 9th Floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT Tel: 028 9051 7500 Fax: 028 9051 7501 Web: www.rqia.org.uk

1. Summary of Inspection

An announced care inspection took place on 4 August 2015 from 10.00 to 17.00. Overall on the day of inspection the standards inspected were found to be generally safe, effective and compassionate. Areas for improvement were identified and are set out in the Quality Improvement Plan (QIP) within this report.

This inspection was underpinned by 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's (DHSPPS) Minimum Care Standards for Healthcare Establishments (July 2014).

.1 Actions/Enforcement Taken Following the Last Care Inspection

Other than those actions detailed in the previous QIP there were no further actions required to be taken following the last inspection.

.2 Actions/Enforcement Resulting from this Inspection

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

.3 Inspection Outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	1	1

The details of the QIP within this report were discussed with the Mark Shortt registered person /manager as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/Registered Person: Mark Shortt	Registered Manager: Mark Shortt			
Person in Charge of the Establishment at the Time of Inspection: Mark Shortt	Date Manager Registered: 22 December 2011			
Categories of Care: 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 and PD Private Doctor				

Laser equipment

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 users:

Wayne Crewe-Brown (Consultant Ophthalmologist)

Wolfgang Riha (Consultant Ophthalmologist)

Non clinical authorised Users:

Lawrence Dowie Lisa McDowell Samantha Mallon

Types of Treatment provided:

Refractive eye surgery - Lasix and Lasex

Dermatological Laser Services

Laser Equipment

Manufacturer:

Alma

Laser Class:

Class 4

Model:

Harmony XL

Serial Number:

HXL01057

Manufacturer:

Alma

Laser Class:

Class 4 + infrared

Model:

Soprano

Serial Numbers:

S12P0071, S12P0072, S12P1079 (3 machines)

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 and in her absence another named

authorised user

Medical support services:

Dr Ross Martin

Authorised users

Alma Soprano laser:

Michelle Connor Lauren Eastwood Josephine Robb Collette Murray Sinead Walsh Emma Douglas Nicola McKee Angela Diamond Claire Weir

Harmony XL laser:

Michelle Connor Claire Weir Collette Murray Josephine Robb

Types of Treatment Provided

Alma soprano laser:

Hair removal/reduction

Harmony XL laser:

Skin resurfacing Skin rejuvenation

3. Inspection Focus

The inspection sought to assess progress with the issues raised during and since the previous inspection and to determine if the following standards have been met:

- Standard 4 Dignity, Respect and Rights
- Standard 5 Patient and Client Partnerships
- Standard 7 Complaints
- Standard 48 Laser and Intense Light Sources

Other areas inspected: Incidents, insurance arrangements and RQIA registration.

4. Methods/Process

Specific methods/processes used in this inspection include the following:

Prior to the inspection the following records were analysed: pre-inspection information and complaints return.

During the inspection the inspector met with Mark Shortt registered person/manager, two authorised users for the dermatological laser service and one non-clinical authorised user for the refractive laser eye surgery service.

The following records were examined during the inspection:

- Six patient care records (refractive laser eye surgery)
- Six client care records (dermatological laser service)
- · Laser safety files
- · Laser risk assessments
- Policies and procedures
- · Patient/client feedback questionnaires
- Incident/accident records
- Local rules
- Medical treatment protocols
- Equipment service records
- · Complaints records

5. The Inspection

1.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 29-30 September 2014. The completed QIP was returned and approved by the care inspector.

5.2 Review of Requirements and Recommendations from the Last Care Inspection Dated 29-30 September 2014

Previous Inspection	Statutory Requirements	Validation of Compliance
Requirement 1 Ref: Regulation 23 (4) Stated: First time	The registered person must ensure there is evidence of a final response to complainants. Action taken as confirmed during the inspection: Complaints records reviewed found that complaints were not robustly managed and did not comply with the establishment's complaints procedure and legislation. The requirement has not been met and is further expanded to include all aspects of complaints management. It is stated for a second time.	Not Met
Requirement 2 Ref: Regulation 28 (1) (d) Stated: First time	The registered person must ensure incidents are reported in line with legislation. Action taken as confirmed during the inspection: Incidents have been reported in line with legislation.	Met
Requirement 3 Ref: Regulation 39 Stated: First time	The registered person must ensure local rules are signed by authorised users only. Action taken as confirmed during the inspection: The local rules are signed by authorised users only.	Met
Requirement 4 Ref: Regulation 4 Stated: First time	The registered person must apply for a variation of registration to include IPL services as a category of care. Action taken as confirmed during the inspection: Review of the establishment's registration certificate confirmed PT (IL) "Prescribed techniques or prescribed technology: establishments using intense light" is outlined as a category of care.	Met

Requirement 5 Ref: Regulation 39 Stated: First time	The registered person must ensure a LPS is present when the lasers are in use and staff are aware of who has the responsibility as LPS. Action taken as confirmed during the inspection: Discussion with staff confirmed a LPS is present when lasers are in use and staff are aware of who has the responsibility as LPS.	Met
Requirement 6 Ref: Schedule 3 Part 11 (3)	The registered person must ensure laser registers for the dermatological laser/IPL service are accurate and in line with best practice.	Met
Stated: First time	Action taken as confirmed during the inspection: Review of laser registers for dermatological laser/IPL service found they were accurate and completed in line with best practice	
Requirement 7 Ref: Regulation	The registered person must ensure client records are accurately and comprehensively completed.	
Stated: First time	Action taken as confirmed during the inspection: Client records were found to be accurately and comprehensively completed.	Met
Requirement 8 Ref: Regulation 25 (2)	The registered person must ensure the laser is not switched on with the key in situ when the authorised user is not in attendance.	Met
Stated: First time	Action taken as confirmed during the inspection: Staff spoken to and observation confirmed the laser is not switched on with the key in situ when the authorised user is not in attendance.	INGL

Requirement 9 Ref: Regulation 39 Stated: First time	The registered person must contact the LPA to clarify the correct protective eye wear for the refractive eye surgery lasers. Ref: Standard 48 Action taken as confirmed during the inspection: The protective eye wear for refractive eye surgery lasers is in place as outlined in local rules.	Met
Requirement 10 Ref: Regulation 15(7) Stated: First time	The registered person must ensure protective eye wear is clean and in good condition. Action taken as confirmed during the inspection: Review of protective eye wear found it to be clean and in good condition.	Met
Requirement 11 Ref: Regulation 28 (1) The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 Stated: First/Second/Third time	The registered person must ensure the certificate of registration is displayed in a prominent position in the establishment at all times. Action taken as confirmed during the inspection: The certificate of registration is displayed in the reception area of the establishment.	Met
Previous Inspection		Validation of Compliance
Recommendation 1 Ref: Standard 48 Stated: First time	The registered person should strengthen the client record audit tool. Action taken as confirmed during the inspection: A robust client audit tool is in place.	Met

Recommendation 2 Ref: Standard 48	The registered person should provide a "laser in use" light as outlined in the main body of the report.	
Stated: First time	Action taken as confirmed during the inspection: A "laser in use" light is in place on all entrance and exit doors to the laser refractive eye surgery suite.	Met

5.3 Standard 4 - Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the laser refractive eye consultation and surgery, with the registered person and staff confirmed that patients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient and an optometrist. The surgery is provided within a designated laser suite. The consultation and treatment for the dermatological laser service is provided in a private room with the client and authorised user present.

Observations confirmed that patient and client care records were stored securely in locked filing cabinets.

Is Care Effective?

It was confirmed through the above discussion and observation that patients and clients are treated in accordance with the DHSSPS standards for Improving the Patient & Client Experience.

Patients undergoing laser refractive eye surgery meet with the surgeon on the planned day of surgery and are fully involved in decisions regarding their treatment. Dermatological laser service clients meet with the authorised user undertaking the treatment and are fully involved in decisions regarding their treatment. Patient's and client's wishes are respected and acknowledged by the establishment.

Is Care Compassionate?

Discussion with staff and review of six patient care records and six client care records confirmed that patients and clients are treated and cared for in accordance with legislative requirements for equality and rights.

Staff were observed treating patients and clients with compassion, dignity and respect.

Areas for improvement

No areas for improvement were identified during the inspection.

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Standard 5 - Patient and Client Partnership

Is Care Safe?

Patients and clients are asked for their comments in relation to the quality of treatment provided, information and care received.

The information from patients and clients comments are collected in an anonymised format, summarised and used by the establishment to make improvements to services.

Is Care Effective?

Optilase Therapie obtains the views of patients and clients on a formal and informal basis as an integral part of the service they deliver.

The establishment issue feedback questionnaires to patients and clients on an ongoing basis. Review of the completed questionnaires found that patients and clients were satisfied with the quality of treatment, information and care received. Some comments from patients and clients included:

Laser refractive eye surgery service:

- "The surgeon was fantastic and made me feel empowered and informed about my treatment"
- "Really put me at ease throughout"
- "Very reassuring staff"
- "Excellent experience"
- "Too long waiting time"

Dermatological laser service:

- "It has been great"
- "Always such a friendly atmosphere"
- "Really pleasant staff"
- · "Professional and friendly"
- "Therapist was very informative"
- "The therapist had great knowledge on the subject"

The information received from the patient and client feedback questionnaires is collated into separate monthly reports which are made available to patients, clients and other interested parties to read in the information files located in the waiting rooms of the establishment.

It was confirmed through discussion that comments received from patients and clients are reviewed by management and discussed at staff meetings. An action plan is developed and implemented to address any issues identified.

Is Care Compassionate?

Review of care records and discussion with staff confirmed that treatment and care are planned and developed with meaningful patient and client involvement; facilitated and provided in a flexible manner to meet the assessed needs of each individual patient and client.

Areas for Improvement

No areas for improvement were identified during the inspection.

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Number of Requir	rements:	0	Number of Recommendations:	0

5.5 Standard 7 - Complaints

Is Care Safe?

Mr Shortt confirmed no complaints have been received in relation to the dermatological laser service since the last inspection.

A review of four complaint records relating to the laser refractive eye surgery was carried out.

The following was noted:

- Complaints were not managed within the establishment's complaints procedure timescales or in line with legislative timescales
- Investigation records were insufficient. There were no records of meetings referred to in correspondence, no written statements from key staff referred to in the complaints responding to concerns and no record of a review of patient care records which Mr Shortt confirmed had been reviewed.
- · The details of one verbal complaint had not been recorded.

Discussion with Mr Shortt and staff confirmed that information from complaints is used to improve the quality of services.

Is Care Effective?

It is not in the remit of RQIA to investigate complaints made by or on the behalf of individuals, as this is the responsibility of the providers. However, if there is considered to be a breach of regulation as stated in The Independent Health Care Regulations (Northern Ireland) 2005, RQIA has a responsibility to review the issues through inspection.

A complaints questionnaire was forwarded by the Regulation and Quality Improvement Authority (RQIA) to the practice for completion. Discussion with Mr Shortt and review of the documentation indicated that complaints have not been managed in accordance with best practice.

The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies and the legislation.

Mr Shortt, registered person/manager, demonstrated some understanding of complaints management.

Review of the complaints register and complaints records evidenced that not all complaints were well documented, fully investigated and had outcomes recorded in line with the complaints procedure and legislation. Complaints records were observed to be stored securely in line with data protection legislation.

A meaningful complaints audit is not undertaken. Mr Shortt was advised the audit information should be used to identify trends and enhance services provided as part of the establishment's quality assurance arrangements.

The complaints procedure is contained within the Patient and Client Guide; copies of which are available in waiting areas for patients and clients to read.

Is Care Compassionate?

A copy of the complaints procedure is provided to patients, clients and to any person acting on their behalf.

The complainant is not always notified in a timely fashion of the outcome and action taken by the establishment to address any concerns raised.

Areas for Improvement

The establishment must manage complaints in line with legislation and the establishment's complaints procedure.

It is recommended a robust audit of complaints is established and fully implemented.

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Number of Requirements:	1	Number of Recommendations:	1

5.6 Standard 48 - Laser and Intense Light Sources.

Is Care Safe?

Refractive laser eye surgery service

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

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 on July 2016.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by Wayne Crew-Brown in August 2015. Systems are in place to review the medical treatment protocols on an annual basis.

The medical treatment protocols set out:

- Indications
- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- · Recognition of treatment related problems
- · Procedure if anything goes wrong with the treatment
- Permitted variation on machine variables
- Procedure in the event of equipment failure

The establishment has local rules in place which have been developed by their LPA in June 2015.

The local rules cover:

- The potential hazards associated with lasers
- Controlled and safe access
- Authorised operator's responsibilities
- · Methods of safe working
- Safety checks
- · Personal protective equipment
- · Prevention of use by unauthorised persons
- Adverse incidents procedures

The laser protection supervisor has overall responsibility for safety during refractive eye surgery as recorded within the local rules.

A list of clinical and non-clinical authorised users is maintained and authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

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.

Dermatological laser service

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.

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 on July 2016.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Ross Martin; written on 4 May 2015. Systems are in place to review the medical treatment protocols on an annual basis.

The medical treatment protocols set out:

- Indications
- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- Recognition of treatment related problems
- Procedure if anything goes wrong with the treatment
- · Permitted variation on machine variables
- Procedure in the event of equipment failure

The establishment has four sets of local rules in place which had been developed by their LPA in June 2015.

The local rules cover:

- · The potential hazards associated with lasers
- Controlled and safe access
- · Authorised operator's responsibilities
- Methods of safe working
- Safety checks
- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incidents procedures

The laser protection supervisor has overall responsibility for safety during laser treatments as recorded within the local rules.

A list of authorised users is maintained and the authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

Clients are provided with written aftercare instructions following treatment.

Refractive laser eye surgery service and Dermatological laser service

The establishment's LPA completed a risk assessment of the premises in June 2015 and no recommendations were made.

The authorised users for both services have completed training in core of knowledge and the safe use and application of the laser equipment.

Review of the training records confirmed that all authorised users had also undertaken the following required mandatory training in line with RQIA guidance:

- Basic life support annually
- Fire safety annually
- Infection prevention and control annually

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

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.

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

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use, as described within the local rules. There are also illuminated laser warning signs in use in line with local rules.

Protective eyewear is available as outlined in the local rules for laser technicians/surgical assistants and the authorised users of the dermatological lasers.

The door to the laser suite and 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 a key. Arrangements are in place for the safe custody of the laser keys when not in use.

Is Care Effective?

The establishment has a laser surgical register and individual laser registers for each machine which are 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

Review of the laser surgical register during the inspection found it to be comprehensively completed. Advice was given to ensure greater consistency in recording authorised users names in the dermatological laser registers.

The care records of six patients undergoing laser refractive eye surgery were reviewed and found to be comprehensively completed. There was a clear patient pathway recorded within the care records from the initial consultation, to pre-operative, intra-operative and post-operative care. Systems are in place to review the patient following surgery for as long as necessary.

There was evidence of signed consent forms within the care records reviewed which clearly outlined the associated risks and complications of refractive eye surgery. A completed patient health questionnaire was also available.

Six client care records from the dermatological laser service were reviewed. There is an accurate and up to date treatment record for every client which includes:

- Client details
- Medical history
- Signed consent form
- Skin assessment (where appropriate)
- Patch test (where appropriate); and
- Record of treatment delivered including number of shots and fluence settings (where appropriate)

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

Two laser safety files are in place which contains all of the relevant information in relation to lasers.

Is Care Compassionate?

Refractive laser eye surgery

As previously stated patients meet with their surgeon to discuss their individual surgery and any concerns they may have.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

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.

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/IPL 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.

Number of Requirements:	0	Number of Recommendations:	0

5.7 Additional Areas Examined

5.7.1 Management of Incidents

The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.

No adverse incidents have occurred within the establishment since last inspection. However systems are in place to manage, document, fully investigate incidents and disseminate the outcomes.

5.7.2 RQIA Registration and Insurance Arrangements

Discussion with Mr Shortt regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificate of RQIA registration was clearly displayed in the reception of the premises.

Areas for Improvement

No areas for improvement were identified during the inspection.

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6 Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Mark Shortt registered person/manager as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained 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 your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

5.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered person meets legislative requirements based on The HPSS (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.

6.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments. They promote current good practice and if adopted by the registered person may enhance service, quality and delivery.

6.3 Actions Taken by the Registered Manager/Registered Person

The QIP should be completed by the registered person/registered manager and detail the actions taken to meet the legislative requirements stated. The registered person will review and approve the QIP to confirm that these actions have been completed. Once fully completed, the QIP will be returned to independent.healthcare@rqia.org.uk and assessed by the inspector.

Quality Improvement Plan					
Statutory Requirement	s recorded to the				
Requirement 1	The registered pomanaged in line	erson/manager must ensu with the establishment's c	•	•	
Ref: Regulation 23 Stated: Second time	legislation.	a sistemed Down and (a) Date	ilim a Aba A a4i a	T-1	
Stated: Second time	1	egistered Person(s) Deta	-		
To be Completed by: 4 September 2015	von carp	with bouter a	documentate	n in Place	
4 Oeptember 2013	All work	ges biegel, d	ramed.		
Recommendations					
Recommendation 1	The registered per audit of complain	erson/manager should est its.	tablish and imple	ement an	
Ref: Standard 7	·				
Stated: First time	_	egistered Person(s) Deta	_	į	
To be Completed by: 4 November 2015	, 000 cu	Man Islala	3 (20	, apro	
Registered Manager Completing QIP Date Completed					
Registered Person App	proving QIP	tell u	Date Approved	10/21/10	
RQIA Inspector Assessing Response Date Approved D8 09/09/15					

It should be noted that this Inspection report should not be regarded as a comprehensive review of all strengths and weaknesses that exist in the establishment. The findings set out are only those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not absolve the registered person/manager from their responsibility for maintaining compliance with minimum standards and regulations. It is expected that the requirements and recommendations set out in this report will provide the registered person/manager with the necessary information to assist them in fulfilling their responsibilities and enhance practice within the establishment.

^{*}Please ensure the QIP is completed in full and returned to independent.Healthcare@rqia.org.uk from the authorised email address*