

**Announced Care Inspection  
of  
Therapie Optilase**

**9 February 2016**

## 1. Summary of Inspection

An announced care inspection took place on 9 February 2016 from 10.00 to 15.00. 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.

### 1.1 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.

### 1.2 Actions/Enforcement Resulting from this Inspection

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

### 1.3 Inspection Outcome

	Requirements	Recommendations
<b>Total number of requirements and recommendations made at this inspection</b>	2	1

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

## 2. Service Details

<b>Registered Organisation/Registered Person:</b> Therapie Optilase (Enniskillen) Ltd Mr Mark Shortt	<b>Registered Manager:</b> Ms Kate McNerney (acting) Ms Orla Mulholland (acting )
<b>Person in Charge of the Establishment at the Time of Inspection:</b> Mr Mark Shortt	<b>Date Manager Registered:</b> To be appointed
<b>Categories of Care:</b> PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers	

## 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: Excimer laser  
 Serial Number: M573

Manufacturer: Abbott Medical Systems (AMO)  
 Laser Class: Class 4  
 Model: Intralase IFS Advanced Femtosecond  
 Serial Number: 0814-80003

**Laser Protection Advisor (LPA):** Alex T Zarneh

**Laser Protection Supervisor (LPS):** Lawrence Dowie  
 Lisa McDowell

**Clinical Authorised Users:** Antonio Montania (Consultant Ophthalmologist)

**Non Clinical Authorised Users:** Lawrence Dowie  
 Lisa McDowell  
 Alex Nesbitt

**Types of Treatment provided:** Refractive eye surgery - Lasik and Lasek

### Dermatological Laser Services

#### Laser Equipment

Manufacturer: Alma  
 Laser Class: Class 4  
 Model: Soprano ICE  
 Serial Numbers: S12 ICE 0217, SI2 ICE 0879(2 machines)

**Laser Protection Advisor (LPA):** Alex Zarneh  
**Laser Protection Supervisor (LPS):** Saddiya Akram  
**Medical Support Services:** Dr Ross Martin

#### **Authorised Users**

**Alma Soprano Laser:** Rachel Goldrath  
 Aimee Woods  
 Saddiya Akram  
 Kate McNerney

#### **Types of Treatment Provided**

**Alma Soprano Laser:** Hair removal/reduction

### **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:

<b>Standard 4</b>	<b>Dignity, Respect and Rights</b>
<b>Standard 5</b>	<b>Patient and Client Partnerships</b>
<b>Standard 7</b>	<b>Complaints</b>
<b>Standard 48</b>	<b>Laser and Intense Light Sources</b>

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 Mr Mark Shortt, registered person and Ms Kate McNerney, acting manager and authorised user

The following records were examined during the inspection:

- five patient care records (refractive laser eye surgery )
- five 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

## 5 The Inspection

### 5.1 Review of Requirements and Recommendations from Previous Inspection

The previous inspection of the establishment was an announced care inspection dated 11 November 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 11 November 2014 (approval visit for laser refractive eye surgery )

Previous Inspection Statutory Requirements		Validation of Compliance
<b>Requirement 1</b>  <b>Ref:</b> Article 2(2)  <b>Stated:</b> First time	The registered manager must apply for variation to registration to include private doctor category of care.	<b>Met</b>
	<b>Action taken as confirmed during the inspection:</b> Mr Shortt submitted an application for variation to registration to include private doctor category of care on 10 February 2016	

### 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 five patient care records and five 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.

<b>Number of Requirements:</b>	<b>0</b>	<b>Number of Recommendations:</b>	<b>0</b>
--------------------------------	----------	-----------------------------------	----------

## **5.4 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?**

Therapie Optilase 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 extremely attentive and made the whole process really easy and calm”
- “Happy with the service and treatment”
- “Everyone was friendly and helpful”
- “Felt very much at ease during surgery as the nurse explained what I should be feeling during every stage of surgery”

#### Dermatological laser service

- “Really pleasant staff”
- “Very good service ”
- “Excellent ”
- “Great ”

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.

<b>Number of Requirements:</b>	<b>0</b>	<b>Number of Recommendations:</b>	<b>0</b>
--------------------------------	----------	-----------------------------------	----------

### 5.5 Standard 7 - Complaints

#### Is Care Safe?

No complaints have been recorded by the establishment since the last inspection. However, systems are in place to investigate and respond to complaints within 28 working days (in line with regulations) or if this is not possible, Mr Shortt confirmed that complainants will be kept informed of any delays and the reason for this.

Discussion with Mr Shortt 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 RQIA to the establishment for completion. The returned questionnaire indicated that no complaints have been received for the period 1 January 2014 to 31 March 2015.

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 demonstrated a good understanding of complaints management.

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

**Is Care Compassionate?**

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

The complainant is notified of the outcome and action taken by the establishment to address any concerns raised.

**Areas for Improvement**

No areas for improvement were identified during the inspection.

<b>Number of Requirements:</b>	<b>0</b>	<b>Number of Recommendations:</b>	<b>0</b>
--------------------------------	----------	-----------------------------------	----------

**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.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by a consultant ophthalmologist 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 on 29 January 2016.

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.

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 local rules in place which have been written by their LPA on 29 January 2016.

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 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**

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.

The establishment's LPA completed a risk assessment of the premises in January 2016 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 most areas 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 laser refractive eye suite has three exit doors only two had suitable locks and warning signs in place. A requirement was made to ensure all exit doors from the laser refractive eye suite have suitable locks and a laser warning sign in place when the lasers are in use.

All other 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.

The laser equipment is operated using a key. Arrangements are in place for the safe custody of the laser keys when not in use.

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

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

The local rules refer to protective eyewear level 7 for staff use with the Schwind laser. The protective eyewear was not available for inspection and the inspector was informed the protective eyewear is not worn by staff. A requirement was made to contact the establishment's LPA to clarify the use of the protective eyewear and amend local rules accordingly if necessary.

### **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.

The care records of five 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 laser refractive eye surgery. A completed patient health questionnaire was also available.

Five 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.

The RQIAs LPA conducted a review of the laser service and his findings are appended to this report. A recommendation was made that all areas identified for action in the RQIAs LPA report are fully addressed.

### **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 surgical 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 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.

### **Areas for Improvement**

A requirement was made to contact the establishments LPA to clarify the use of the protective eyewear for staff use with the Schwind laser and amend local rules accordingly if necessary.

A requirement was made to ensure all exit doors from the laser refractive eye suite have suitable locks and a laser warning sign in place at each exit when the lasers are in use.

The RQIAs LPA conducted a review of the laser service and his findings are appended to this report. A recommendation was made that all areas identified for action in the RQIAs LPA report are fully addressed.

<b>Number of Requirements:</b>	<b>2</b>	<b>Number of Recommendations:</b>	<b>1</b>
--------------------------------	----------	-----------------------------------	----------

## **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 registration with RQIA. 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 certificates of registration and insurance were clearly displayed in the reception area of the premises.

#### Areas for Improvement

No areas for improvement were identified during the inspection.

<b>Number of Requirements</b>	<b>0</b>	<b>Number Recommendations:</b>	<b>0</b>
-------------------------------	----------	--------------------------------	----------

## 6 Quality Improvement Plan

The issues identified during this inspection are detailed in the QIP. Details of this QIP were discussed with Mr Mark Shortt 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.

### 6.1 Statutory Requirements

This section outlines the actions which must be taken so that the registered person/s 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](mailto:independent.healthcare@rqia.org.uk) and assessed by the inspector.

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.

Quality Improvement Plan			
<b>Statutory Requirements</b>			
<b>Requirement 1</b>  <b>Ref:</b> Regulation 25(2)d  <b>Stated:</b> First time  <b>To be Completed by:</b> 9 March 2016	The registered person must contact the establishment's LPA to clarify the use of the protective eyewear for the Schwind laser and amend local rules accordingly if necessary.  <b>Response by Registered Person(s) Detailing the Actions Taken:</b> Eyewear (safety goggles) purchased and now in place in both Clinics. (Belfast and Enniskillen)		
<b>Requirement 2</b>  <b>Ref:</b> Regulation 25(2)d  <b>Stated:</b> First time  <b>To be Completed by:</b> 9 March 2016	The registered person must ensure all exit doors from the laser refractive eye suite have suitable locks and a laser warning sign in place at each exit when the lasers are in use.  <b>Response by Registered Person(s) Detailing the Actions Taken:</b> 1 Laser in use sign added. 3 door locks added within access points in Surgery Suite.		
<b>Recommendations</b>			
<b>Recommendation 1</b>  <b>Ref:</b> Standard 48  <b>Stated:</b> First time  <b>To be Completed by:</b> 9 March 2016	It is recommended that all areas identified for action in RQIAs LPA report are fully addressed.  <b>Response by Registered Person(s) Detailing the Actions Taken:</b> Complete.		
<b>Registered Manager Completing QIP</b>	Mark Shortt	<b>Date Completed</b>	07/04/2016
<b>Registered Person Approving QIP</b>	Mark Shortt	<b>Date Approved</b>	07/04/2016
<b>RQIA Inspector Assessing Response</b>	Winnie Maguire	<b>Date Approved</b>	11/04/2016

*\*Please ensure this document is completed in full and returned to [independent.healthcare@rqia.org.uk](mailto:independent.healthcare@rqia.org.uk) from the authorised email address\**

10th February 2016

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

Dear Mrs Maguire

## **Laser Protection Report**

*Therapie & Optilase, Unit 0, Erneside Shopping Centre, Enniskillen BT74 6JQ*

### **Introduction**

This report summarises the main deficiencies in the Laser Protection arrangements which were noted during the inspection visit on 9<sup>th</sup> February 2016. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

### **Comments & Deficiencies**

#### **Therapie**

##### **(1) Local Rules & Incident Grab Sheet**

The Alma lasers used in the clinic are fitted with Alexandrite laser heads providing an output at 755nm, however the documentation also refers to other laser wavelengths which are not used in the clinic. The clinic should discuss this matter with their LPA and amend the documentation as required. In particular the following points were noted:-

- (a) Title of local rules refers to an output at 1064nm
- (b) The local rules state that the protective eyewear should cover the wavelength range 720-1064nm. The eyewear provided does not provide protection at the lower end of the wavelength range. It should be noted that this is simply an error in the local rules as the goggles provide the required level of protection at the laser output wavelength of 755nm.
- (c) The incident grab sheet states that the laser output is at 810nm, again this should be amended as the laser output wavelength is at 755nm.



## **Optilase**

### **(1) Laser door Signs**

The local rules state that Laser Controlled Area door signs should be attached to the entrance doors of the laser treatment room. As insufficient signs were available on the day of inspection additional signs are required.

### **(2) Laser Door Warning Light**

On the inspection day staff were not familiar with the system for illuminating the laser warning lights. It is therefore recommended that a label should be placed beside the switch stating 'Laser Light'.

### **(3) Laser Door Lock**

The door exiting the laser treatment room into the 'surgeons room' should be fitted with a lock which operates from within the treatment room.

### **(4) Protective eyewear**

The local rules state that protective eyewear should be available for use with the 193nm excimer laser if certain members of staff have to approach within the nominal ocular hazard distance (NOHD) of the laser system. As the protective eyewear was not available in the clinic this matter should be clarified with the LPA and actioned if required.

The clinic should inform RQIA when the above deficiencies have been corrected.



---

**Dr Ian Gillan**  
**Laser Protection Adviser to RQIA**

## **Appendix**

### **Therapie, Erneside Shopping Centre, Enniskillen BT74 6JQ**

#### **Laser System**

Manufacturer: Alma Laser distributed by ABC Lasers  
Model: Soprano Ice  
Serial Number: S12ICE 0217  
Laser Wavelength: 755nm Probe  
Class: 4

Manufacturer: Alma Laser distributed by ABC Lasers  
Model: Soprano Ice  
Serial Number: S12ICE 0879  
Laser Wavelength: 755nm Probe  
Class: 4

**Laser Protection Adviser**  
Alex Zarneh

### **Optilase, Erneside Shopping Centre, Enniskillen BT74 6JQ**

#### **Laser Systems**

Manufacturer: Schwind  
Model: Amaris 500E  
Type: Excimer  
Wavelength: 193nm  
Serial Number: M573

Manufacturer: Abbott Medical Systems (AMO)  
Model: IFS Advanced Femtosecond  
Type: Intralase  
Wavelength: 1053nm  
Serial Number: 0814-80003

**Laser Protection Adviser**

Dr Alex Zarneh