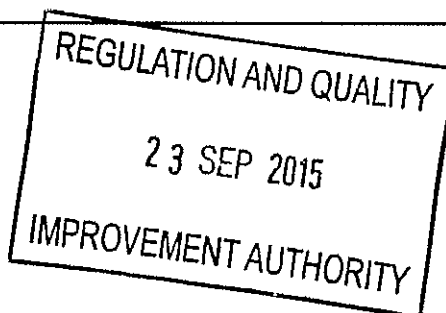


The Regulation and
Quality Improvement
Authority

Therapie Clinic Ltd
RQIA ID: 11286
1 - 3 Fountain Street
Londonderry
BT48 6QX

Inspector: Winnie Maguire
Inspection ID: IN021423

Tel: 028 7126 5379



**Announced Care Inspection
of
Therapie Clinic Ltd**

21 July 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 21 July 2015 from 10.30 to 13.30. Overall on the day of the inspection the establishment was found to be delivering safe, effective and compassionate care. The outcome of the inspection found no areas for concern.

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 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 on 22 July 2014.

.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 | 0 | 0 |

This inspection resulted in no requirements or recommendations being made. Findings of the inspection can be found in the main body of the report.

2. Service Details

| | |
|---|--|
| Registered Organisation/Registered Person: Mark Thomas Shortt | Registered Manager: Lucia McCallion (Registration pending) |
| Person in Charge of the Establishment at the Time of Inspection: Lucia McCallion | Date Manager Registered: Registration pending |
| Categories of Care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources | |

Laser Equipment –two lasers

| | | |
|----------------|------------|------------|
| Manufacturer: | Alma | Alma |
| Model: | Soprano XL | Soprano XL |
| Serial Number: | S12P0120 | S12P0160 |
| Laser Class: | 4 | 4 |
| Wavelength: | 755nm | 755nm |

Laser Protection Advisor (LPA) - Alex Zarneth

Laser Protection Supervisor (LPS) –Lucia McCallion

Medical Support Services –Dr Ross Martin

Authorised Users –Lucia McCallion
 Kate McNerney
 Jayne Gardiner
 Nicole Heaney

Types of Treatment Provided – Hair reduction/removal

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 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 the registered provider; Lucia McCallion clinic manager (registration pending) and authorised user and one other authorised user.

The following records were examined during the inspection:

- Six client care records
- Laser safety file
- Laser risk assessment
- Policies and procedures
- Client feedback questionnaires
- Incident/accident records
- Local rules
- Medical treatment protocols
- Equipment service records
- Complaints 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 22 July 2014. The completed QIP was returned and approved by the care inspector.

No requirements or recommendations were made during this inspection.

5.2 Review of Requirements and Recommendations from the Last Care Inspection Dated 22 July 2014

| Previous Inspection Statutory Requirements | | Validation of Compliance |
|--|---|--------------------------|
| Requirement 1 Ref: Regulation 21 1(a) Stated: First time | The registered person must ensure each episode of laser treatment is fully outlined in the individual client's record. Action taken as confirmed during the inspection: A review of six client records confirmed each episode of laser treatment is fully outlined in individual client records. | Met |
| Previous Inspection Recommendations | | Validation of Compliance |
| Recommendation 1 Ref: Standard C5 Stated: First time | The registered person should ensure staff records their full name when completing complaint records. Action taken as confirmed during the inspection: The establishment has not received any complaints since the last inspection therefore no complaints records had been created. A review of staff meeting minutes and discussion with staff confirmed the matter had been formally dealt with by management. | Met |

| Previous Inspection Recommendations | | Validation of Compliance |
|--|--|--------------------------|
| Recommendation 2 Ref: Standard C5 Stated : First time | The registered person should establish an audit of complaints. | Met |
| | Action taken as confirmed during the inspection: A system for auditing complaints has been established. | |
| Recommendation 3 Ref: Standard P2 Stated : First time | The registered person should ensure staff records their full name when completing client records. | Met |
| | Action taken as confirmed during the inspection: A review of six client records confirmed staff record their full name when completing client records. | |

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and treatment process, with the clinic manager and staff confirmed that clients' modesty and dignity is respected at all times. The consultation and treatment is provided in a private room with the client and authorised user present.

Observations confirmed that client care records were stored securely in a locked filing cabinet.

Is Care Effective?

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

Clients meet with the authorised user undertaking the treatment and are fully involved in decisions regarding their treatment. Clients' wishes are respected and acknowledged by the establishment.

Is Care Compassionate?

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

Staff outlined in detail how they ensured clients are treated with compassion, dignity and respect. This included ensuring the door was locked during treatment, explaining procedures carefully and the use of dignity drapes when necessary.

Areas for Improvement

No areas for improvement were identified during the inspection.

| | | | |
|--------------------------------|----------|-----------------------------------|----------|
| Number of Requirements: | 0 | Number of Recommendations: | 0 |
|--------------------------------|----------|-----------------------------------|----------|

5.4 Standard 5 – Patient and Client Partnership

Is Care Safe?

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

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

Is Care Effective?

Therapie Clinic Ltd obtains the views of clients and/or their representatives on a formal and informal basis as an integral part of the service they deliver.

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

- "Great service"
- "Very good service and staff"
- "Staff are very welcoming and informative"
- "Very relaxing "
- "My therapist was lovely to me"

The information received from the client comment cards is collated into monthly summary report which is made available to clients and other interested parties to read in the information file which is available in the reception area of the establishment.

It was confirmed through discussion that comments received from clients are reviewed by the clinic manager and an action plan is developed and implemented to address any issues identified.

Is Care Compassionate?

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

Areas for Improvement

No areas for improvement were identified during the inspection.

| | | | |
|--------------------------------|----------|-----------------------------------|----------|
| Number of Requirements: | 0 | Number of Recommendations: | 0 |
|--------------------------------|----------|-----------------------------------|----------|

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, the registered provider confirmed that complainants will be kept informed of any delays and the reason for this.

Discussion with the clinic manager confirmed that information from complaints is used to improve the quality of services.

Is Care Effective?

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.

The registered provider and the clinic manager demonstrated a good understanding of complaints management.

A complaints audit has been established as a result of the last inspection and will be undertaken as necessary. The audit information will 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 Client Guide; copies of which are available in the reception area for clients to read.

Is Care Compassionate?

A copy of the complaints procedure is provided to 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.

| | | | |
|--------------------------------|----------|-----------------------------------|----------|
| Number of Requirements: | 0 | Number of Recommendations: | 0 |
|--------------------------------|----------|-----------------------------------|----------|

5.6 Standard 48 - Laser and Intense Light Sources

Is Care Safe?

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.

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

The medical treatment protocol sets 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 25 May 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 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.

The establishment's LPA completed a risk assessment of the premises on 25 May 2015 and no recommendations were made.

The authorised users 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

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 treatment 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.

Protective eyewear is available for the client and operator as outlined in the local rules.

The door to the treatment room is 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 key when not in use.

Is Care Effective?

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

Six client care records 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 of 7 October 2014 were reviewed as part of the inspection process.

A laser safety file is in place which contains all of the relevant information in relation to laser or intense light equipment.

Is Care Compassionate?

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

No areas for improvement were identified during the inspection.

| | | | |
|--------------------------------|----------|-----------------------------------|----------|
| Number of Requirements: | 0 | Number of Recommendations: | 0 |
|--------------------------------|----------|-----------------------------------|----------|

5.7 Additional Areas Examined

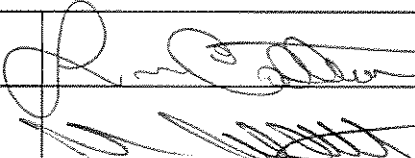


5.7.1 Management of Incidents

No adverse incidents have occurred within the establishment since the 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 the registered provider regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificate of registration was clearly displayed in the reception of the premises.

No requirements or recommendations resulted from this inspection.

| | | | |
|--|--|-----------------------|----------|
| I agree with the content of the report. | | | |
| Registered Manager |  | Date Completed | > |
| Registered Person |  | Date Approved | 7 |
| RQIA Inspector Assessing Response |  | Date Approved | 28/9/15. |

Please provide any additional comments or observations you may wish to make below:

Please complete in full and returned to Independent.Healthcare@rqia.org.uk from the authorised email address

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 service. 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.

2nd September 2015

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

Dear Mrs Maguire

Laser Protection Report

Optilase ,Unit 4 - Cleaver House, Donegall Place, Belfast BT1 5BB

Optilase Inspection

Summary

The Laser safety arrangements are of a high standard.

Introduction

This report summarises the main deficiencies in the Laser Protection arrangements which were noted during the inspection visit earlier today. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Deficiencies & Comments

- (a) The local rules for the excimer (193nm) laser refer to the use of protective eyewear, however the EN207 markings on the available protective eyewear show that protection is not provided at 193nm. In practice only the patient and surgeon are in the room during procedures and the surgeon is protected by the viewing optics.

The clinic should discuss this matter with their LPA and either obtain appropriate eyewear or amend the local rules.

When this deficiency has been corrected the clinic should inform RQIA.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix

Optilase ,Unit 4 - Cleaver House, Donegall Place, Belfast BT1 5BB

Laser Systems

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

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

Laser Protection Adviser

Dr Alex Zarneh