

Physique Face and Body Studio RQIA ID: 10729 9 Fairgreen Street Irvinestown BT94 1FD

Tel: 028 68621652

Inspector: Winnie Maguire Inspection ID: IN23857

> Announced Care Inspection of Physique Face and Body Studio

> > 4 February 2016

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 February 2016 from 10.40 to 13.10. On the day of inspection the standards inspected were found to be generally safe, effective and compassionate. A requirement made on the previous inspection relating to a private doctor service in the establishment had not been addressed and Ms Stephanie Harpur owner and manager (RQIA registration pending) provided an explanation which is outlined in the body of the report. The requirement is stated for a second time. The establishment has installed a new IPL machine (known as a MPL machine) and whilst most documentation and safety measures have been updated accordingly 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 care inspection on 11 November 2014.

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
Total number of requirements and recommendations made at this inspection	2	7

The details of the QIP within this report were discussed with the Miss Stephanie Harpur owner and manager (RQIA registration pending) as part of the inspection process. The timescales for completion commence from the date of inspection.

2. Service Details

Registered Organisation/Registered Person: Physique Face and Body Studio Miss Stephanie Harpur	Registered Manager: Miss Stephanie Harpur (registration pending)
Person in Charge of the Establishment at the Time of Inspection: Miss Stephanie Harpur	Date Manager Registered: Registration pending
Categories of Care: PT(IL) Prescribed techniques or prescribed technol sources	logy: establishments using intense light

Intense Pulsed Light (IPL) Equipment

Manufacturer:	Skin First
Model:	Maxi Plus
Serial Number:	MXP05250/A143D020279
	Hand piece 1: HKBD14110846
	Hand piece 2: HKBD14123590

Laser Protection Advisor (LPA) - Dr Philip Loan

Laser Protection Supervisor (LPS)/ILS Safety Officer - Stephanie Harpur

Medical Support Services – Dr Hazem Kahlout

Authorised Users – Stephanie Harpur Esther Prentice Rebecca Elliott

Types of Treatment Provided – Hair Removal

Acne Rosacea Thread veins Pigmentation Skin rejuvenation (using radio frequency and does not require to be registered)

2.1 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.

3. 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 Miss Stephanie Harpur owner /manager and authorised user and Esther Prentice authorised user.

The following records were examined during the inspection:

- Six client care records
- Laser safety file
- IPL risk assessment
- Policies and procedures
- Client feedback questionnaires
- Local rules
- Medical treatment protocols
- Training records
- IPL manufacturers manual
- 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 QIP was not returned.

Areas to follow up:

- a. Application for private doctor service
- b. Complete the registration process for Miss Stephanie Harpur through conducting a fit person's interview.

5.2 Review of Requirements and Recommendations from the Last Care Inspection Dated 11 November 2014

Previous Inspection	Previous Inspection Statutory Requirements			
Requirement 1	The registered provider must apply for variation of registration to include private doctor registration.			
Ref: Regulation 5(1)				
	Action taken as confirmed during the			
Stated: First time	inspection:			
	Miss Harpur confirmed that the private doctor service had not been provided in the establishment since the last inspection as a result of illness. However, Miss Harpur confirmed that the private doctor intends to return in the future if possible. Miss Harpur confirmed that an application to vary the registration would be made. The RQIA registration team forwarded Miss Harpur a variation of registration application pack on 4 February 2016.	Not Met		
	This requirement has not been met and has been stated for the second time.			

5.3 Standard 4 – Dignity, Respect and Rights

Is Care Safe?

Discussion regarding the consultation and treatment process with authorised users 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 authorised users and review of six client care records confirmed that clients are treated and cared for in accordance with legislative requirements for equality and rights.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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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?

Physique Face and Body Studio obtains the views of clients on a formal and informal basis as an integral part of the service they deliver.

The establishment issued feedback questionnaires to clients and ten were returned and completed. Review of the completed questionnaires found that clients were highly satisfied with the quality of treatment, information and care received.

Some comments from clients included:

- "Love this treatment"
- "Very pleased with my service from Physique"
- "Very happy with the results of my treatment"
- "Excellent service and treatment would recommend Physique MPL treatments"

The information received from the client feedback questionnaires is collated into an annual summary report which is made available to clients and other interested parties to read in the waiting area of the establishment.

It was confirmed through discussion that comments received from clients are reviewed by Miss Harpur and an action plan is developed and implemented to address any issues identified. There were no issues identified through the most recent client survey in December 2015.

Is Care Compassionate?

Review of care records and discussion with 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
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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, Miss Harpur confirmed that complainants will be kept informed of any delays and the reason for this.

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 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.

Miss Harpur demonstrated a good understanding of complaints management.

The complaints procedure is contained within the Client Guide; copies of which are available in waiting 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.

Discussion with Miss Harpur demonstrated that the core values of privacy, dignity, respect and patient choice are understood. Miss Harpur confirmed complaints would be handled in a sensitive manner.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements:	0	Number of Recommendations:	0
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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. The service level agreement between the establishment and the LPA was reviewed and this expires on 31 March 2017.

The establishment has installed a new IPL machine and as a result now offers an increased range of treatments. Medical treatment protocols had been revised by Dr Hazem Kahlout in January 2016 as outlined on a signed cover sheet attached to the front of a range of treatment protocols.

On examination of the medical treatment protocols the following was noted:-

The medical treatment protocol for hair removal had clearly identified Dr Kahlout has the author and it contained the relevant information as outlined below.

- 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

However on a number of occasions reference was made to Aculight IPL machine which had been previously in use.

The individual treatment protocols for acne, rosacea, thread veins and pigmentation were set out as treatment sheets and outlined parameters, setting and brief additional information. These sheets had the Skin First logo displayed in the bottom right hand corner and did not have all the relevant information in line with best practice.

A recommendation was made to ensure all medical treatment protocols are in line with the IPL machine currently in use, contain the relevant information and are clearly signed and authorised by a medical practitioner.

Systems are in place to review the medical treatment protocols on an annual basis

The establishment has local rules in place which have been developed by their LPA on 28 January 2016.

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

It was noted that the front cover of the local rules and information on protective eyewear referred to the Aculight IPL machine and not the current Skin First IPL machine. Miss Harpur confirmed the LPA had reviewed the protective eyewear during the site visit on 26 January 2016 and had informed her they were suitable for the Skin First IPL machine.

A recommendation was made to ensure the local rules reflect the Skin First IPL machine and in particular clearly outline the necessary protective eyewear for Skin First IPL machine.

The ILS safety officer has overall responsibility for safety during IPL 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 26 January 2016 and recommendations made are currently being addressed.

Two authorised users have completed training in core of knowledge. A newly appointed authorised user has not yet undertaken core of knowledge training. All three authorised users have completed the safe use and application of the IPL equipment. Review of the safe use and application training certificates noted they outlined hair removal treatment only. Two authorised users confirmed that all treatments undertaken using the IPL machine had been covered by the training. Miss Harpur confirmed she would ask for the certificates to be reissued outlining all treatments covered during safe use and application training.

A requirement was made to ensure the newly appointed authorised user undertakes core of knowledge training.

A recommendation was made to ensure evidence is available for inspection that all authorised users have undertaken safe use and application training for all treatments provided by the IPL machine.

A review of the training records and a discussion with Miss Harpur regarding required mandatory training found the following:

- Basic life support annually a certificate dated November 2014 for all staff was in place. Miss Harpur confirmed all staff had undertaken Basic Life Support training in November 2015. She confirmed she would request the trainer to forward the individual certificates evidencing this training
- Fire safety is undertaken annually
- Infection prevention and control policies and procedures are signed as read and understood by authorised users annually

A recommendation was made to ensure evidence of mandatory training is available for inspection.

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

The environment in which the IPL 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 IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the ILS safety officer.

Laser safety warning signs are displayed when the IPL 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 stated previously it is recommended the local rules are amended to reflect the protective eyewear necessary for the Skin First IPL machine.

The door to the treatment room is locked when the IPL equipment is in use but can be opened from the outside in the event of an emergency.

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

Is Care Effective?

The establishment has a loose leaf proforma supplied by the manufacturer of the IPL machine 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

The present arrangement for recording treatments centrally does not fully comply with the specifications of an IPL register and it was noted only client's initials are being recorded.

A recommendation was made to establish a bound book IPL register or number the loose leaf pages presently used to record IPL treatments and ensure client's full name is recorded.

Six client care records were reviewed. There is treatment record for every client which includes:

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

It was noted blue ink was used frequently to complete the clients care records.

A recommendation was made to use black ink when completing client records.

There are arrangements in place to service and maintain the IPL equipment in line with the manufacturer's guidance.

A number of files were in place which contain a range of information in relation to IPL equipment currently in use and the previous IPL equipment.

A recommendation was made to create a laser safety file containing all relevant and up to date information relating to the IPL equipment currently in use and archive other information in line with the establishment's policy and procedure on record management.

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 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.

Areas for Improvement

A requirement was made to ensure the newly appointed authorised user undertakes core of knowledge training.

A recommendation was made to ensure all medical treatment protocols are in line with the IPL machine currently in use, contain the relevant information and are clearly signed and authorised by a medical practitioner.

A recommendation was made to ensure the local rules reflect the Skin First IPL machine and in particular clearly outline the necessary protective eyewear for Skin First IPL machine.

A recommendation was made to ensure evidence is available for inspection that all authorised users have undertaken safe use and application training for all treatments provided by the IPL machine.

A recommendation was made to ensure evidence of mandatory training is available for inspection.

A recommendation was made to establish a bound book IPL register or number the loose leaf pages presently used to record IPL treatments and ensure the client's full name is recorded.

A recommendation was made to use black ink when completing client care records.

A recommendation was made to create a laser safety file containing all relevant and up to date information relating to the IPL equipment currently in use and archive other information in line with the establishment's policy and procedure on record management.

Number of Requirements:	1	Number of Recommendations:	7	
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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 Miss Harpur regarding the insurance arrangements within the establishment confirmed that current insurance policies were in place. The certificates of RQIA registration and insurance were clearly displayed in the corridor of the premises.

5.7.3 Completion of registration process for Miss Stephanie Harpur as registered provider.

A fit persons interview was conducted with Miss Stephanie Harpur following submission of an application as registered provider/manager. The inspector discussed the regulatory obligations of a registered provider with Miss Stephanie Harpur in respect of the relevant legislation and minimum standards. Miss Harpur evidenced a clear understanding of her role in this regard and registration as registered provider is recommended.

Areas for Improvement

No areas for improvement were identified during the inspection.

Number of Requirements	0	Number Recommendations:	0	1
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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 Miss Harpur as part of the inspection process. The timescales commence from the date of inspection.

In light of a new IPL machine having been installed by the establishment a further inspection will be conducted which will include RQIAs LPA in early March 2016.

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 meet 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 <u>independent.healthcare@rgia.org.uk</u> 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.

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	Quality Improvement Plan
Statutory Requirement	8
Requirement 1	The registered provider must apply for variation of registration to include private doctor registration.
Ref: Regulation 5(1)	Response by Registered Person(s) Detailing the Actions Taken:
Stated: Second time	Forms have been completed and
To be Completed by: 3 March 2016	enclose fee of \$ 100-00.
Requirement 2	The registered provider must ensure the newly appointed authorised
Ref: Regulation 18(2)	user undertakes core of knowledge training.
Stated: First time	Response by Registered Person(s) Detailing the Actions Taken:
	Spoken to Philip too AND TERMITION AND TERMITICANA AND TERMITICANA AND T
To be Completed by: 4 April 2016	
	25 MAR 2018
Recommendations	
Recommendation 1	It is recommended the local rules reflect the Skin First IPU machine and in particular clearly outline the necessary protective eyewear for Skin
Ref: Standard 48	First IPL machine.
Stated: First time	Response by Registered Person(s) Detailing the Actions Taken:
To be Completed by: 3 March 2016	Spoke to philip Loon and he is amending the local rules.
Recommendation 2	It is recommended evidence is available for inspection that all
Ref: Standard 48	authorised users have undertaken safe use and application training for all treatments provided by the IPL machine.
Stated: First time	Response by Registered Person(s) Detailing the Actions Taken:
To be Completed by: 3 March 2016	This has been completed, new and up to acte certificates are in place.
Recommendation 3	It is recommended evidence of mandatory training is available for
Ref: Standard 13	inspection.
Stated: First time	Response by Registered Person(s) Detailing the Actions Taken:
To be Completed by: 3 March 2016	complete - see certificates in IPL room Ifile

Doog man and attended					IN23857		
Recommendation 4	It is recommer	nded to establish a	bound book	IPL registe	r or number the		
Ref: Standard 48	loose leat pag	es presently used ne is recorded.	to record IPL	treatments	and ensure		
Stated: First time	Response by	Registered Pers	on(s) Detailii	ng the Acti	ons Taken:		
To be Completed by: 3 March 2016	in ioon	incompe	ered a	and for	led		
Recommendation 5		ded to use black i					
Ref: Standard 8		Registered Perso					
Stated: First time		taken					
To be Completed by: 3 March 2016			09 31	0.361	2,		
Recommendation 6	It is recommend	led to create a las	er safety file	Containing			
Ref: Standard 48	It is recommended to create a laser safety file containing all relevant and up to date information relating to the IPL equipment currently in use and archive other information in line with the establishment's policy and						
Stated: First time		cord managemen	t.				
To be Completed by: 3 March 2016		Response by Registered Person(s) Detailing the Actions Taken:					
Recommendation 7	It is recommond	od oll medical to					
Ref: Standard 48		ed all medical trea rently in use, con nd authorised by a	ain the releve	ant informat	ne with the ion and are		
Stated: First time		egistered Persor			ns Taken:		
To be Completed by: 3 March 2016		are alrea	dy se				
Registered Manager Co		S.Horp	Dat				
Registered Person App	roving QIP	1 Maria	Dat		11-02-16		
RQIA Inspector Assessi			Apr Dat	oroved e	414/16		
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Please ensure this document is completed in full and returned to <u>independent.healthcare@rgia.org.uk</u> from the authorised email address