Inspection Report

19 May 2021

Younique Aesthetics Ltd

Type of Service: Independent Hospital (IH) – Intense Pulse Light (IPL) Service
Address: 5 Monaghan Court, Mongahan Street, Newry, BT35 6BH
Tel No: 028 3025 6254

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ The Independent Health Care Regulations (Northern Ireland) 2005 and Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Registered Provider: Younique Aesthetics Ltd **Responsible Individual:** Mrs Aine Larkin	**Registered Manager:** Mrs Aine Larkin **Date registered:** 13 February 2018
Person in charge at the time of inspection: Mrs Aine Larkin	
Categories of care: Independent Hospital (IH) PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources	

Brief description of how the service operates:
Younique Aesthetics Ltd provides a range of cosmetic/aesthetic treatments. This inspection focused solely on those treatments using an intense pulse light (IPL) machine that fall within regulated activity and the categories of care for which the establishment is registered with RQIA.

Equipment available in the service:

IPL equipment:

Manufacturer: Jeisys
Model: Cellec
Serial Number: CCIC16004

Manufacturer: Venus Versa
Model: Tribella
Serial Number: VE004211

Laser protection advisor (LPA):
Ms Anna Bass (Lasermet)

Laser protection supervisor (LPS):
Mrs Aine Larkin

Medical support services:
Dr Paul Myers

Authorised operators:
Mrs Aine Larkin, Ms Aileen Wilson and Ms Sandra Brady

Types of IPL treatments provided:
- hair reduction
- skin rejuvenation
- facial thread veins
- acne

2.0 Inspection summary

This was an unannounced inspection, undertaken by two care inspectors on 19 May 2021 from 11.00 am to 1.30pm. Prior to this inspection RQIA received information indicating that this establishment may be linked to an unregistered laser/IPL service operating in Belfast.

The focus of the inspection was to review the arrangements for the provision of IPL treatments in this service and to assess the progress of areas identified for improvement as a result of the previous inspection of Younique Aesthetic Ltd undertaken on 10 March 2020. We also sought to establish the link/relationship between this service and the unregistered laser/IPL service operating in Belfast. The completed Quality Improvement Plan (QIP) was due to be returned to RQIA on or before 24 April 2020 and had still not been received by RQIA by the time of this inspection, more than one year later. Following correspondence with Mrs Larkin the previous QIP was received by RQIA on 2 June 2021, however, the completed information lacked sufficient detail to enable RQIA to determine that each area for improvement had been met.

During this inspection, some aspects of good practice were identified in respect of information and communication provided to clients in respect of IPL treatments, however, we also identified a number of areas that required immediate improvement in relation to the safe provision of IPL treatments. These were discussed with Mrs Aine Larkin at the conclusion of the inspection. Mrs Larkin was also provided with written correspondence, following the inspection, outlining the areas that required immediate attention and we requested submission of an action plan detailing how these matters would be addressed. RQIA received the action plan confirming that the immediate patient safety issues had been addressed on 25 May 2021. Further information is outlined in section 5.2.1 of this report.

In relation to our concerns about risks to patient safety and lack of responsiveness to QIP's RQIA invited Mrs Larkin to attend a serious concerns meeting on 7 June 2021. At the serious concerns meeting Mrs Larkin was informed of the expectations of RQIA in relation to her role and responsibilities as a responsible individual, completion and return of the QIP in a timely manner and the role of the laser protection advisor (LPS). Mrs Larkin was advised on the importance of using the opportunity when completing the QIP to provide assurance to both RQIA and the public on the actions taken to address any areas for improvement. We acknowledged that the service was closed for periods of time as a result of the global pandemic.

On 14 June 2021, Mrs Larkin submitted further documentary evidence verifying the actions taken to address the areas for improvement identified in the QIP from 10 March 2020.

At the serious concerns meeting on 7 June 2021 detailed discussions took place regarding the link/relationship between this service and the unregistered laser/IPL service operating in Belfast. Based on the additional information provided we accepted that Mrs Larkin is not accountable for the unregistered service.

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the establishment is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

4.0 What people told us about the service

Feedback from clients was not obtained as this was an unannounced inspection and no clients were attending for IPL treatments at the time.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

Areas for improvement from the last inspection on 10 March 2020		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for Improvement 1 **Ref**: Regulation 15(2) **Stated:** First time	The registered person shall ensure that in relation to the Venus Versa IPL the following should be addressed prior to it being made operational: • all relevant information pertaining to the IPL is located and retained in the laser safety file. • any recommendations made by the laser protection advisor (LPA) are addressed • a copy of the commissioning report is submitted to RQIA.	**Met**

	Action taken as confirmed during the inspection: Following a review of the information provided to RQIA on 25 May 2021, 2 June 2021 and 14 June 2021, this area for improvement has been assessed as met. Further detail is provided in section 5.2.1.	
Area for Improvement 2 **Ref**: Regulation 21 (1) **Stated:** First time	The registered person shall ensure that the following is included in client care records: • 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)	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met, further detail is provided in section 5.2.1.	
Action required to ensure compliance with the Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref**: Standard 48.12 **Stated:** First time	The registered person shall ensure that all authorised operators have up to date training in basic life support and fire safety awareness.	**Met**
	Action taken as confirmed during the inspection: Following a review of the information provided to RQIA on 25 May 2021, 2 June 2021 and 14 June 2021, this area for improvement has been assessed as met. Further detail is provided in section 5.2.1.	
Area for Improvement 2 **Ref**: Standard 5.1 **Stated:** First time	The registered person shall ensure that client satisfaction surveys are carried out by the establishment. The result of surveys should be collated to provide a summary report on an annual basis, which is made available to clients and other interested parties. An action plan should be developed to inform and improve services provided, if appropriate.	**Met**

	Action taken as confirmed during the inspection: Following a review of the information provided to RQIA on 2 and 14 June 2021, this area for improvement has been assessed as met.	

5.2 Inspection outcome

5.2.1 How does the service ensure that IPL procedures are safe?

The IPL equipment available in the service was reviewed to ensure that it was compliant with European Standard EN 60825-1. It was confirmed that there had been no changes to the equipment since the previous inspection. The IPL equipment in place was as listed in section 1.0 of this report. On 25 May 2021, RQIA received correspondence from Mrs Larkin which stated that the Jeisys Cellec IPL machine is no longer in use. It was advised that Mrs Larkin as the LPS should inform the LPA of this change in IPL equipment.

As discussed in section 5.1, an area for improvement was made during the previous inspection to address identified issues pertaining to the Venus Versa IPL machine. A laser safety file was in place which contained confirmation of the appointment and duties of a certified LPA that is reviewed on an annual basis. The current service level agreement between the establishment and the LPA was last reviewed on 3 August 2020 and expires on 2 August 2021.

Two sets of local rules were retained in the laser safety file; one for the Jeisys Cellec machine, dated 23 August 2020; and one for the Venus Versa machine, dated 23 January 2020. The local rules contained relevant information about the IPL equipment being used.

The establishment's LPA completed a virtual risk assessment on 15 February 2021 and provided an Annual Site Audit Report that included an action plan. The action plan listed six areas to be addressed and stated these areas were to be completed before the IPL machines are used. The action plan had been signed by Mrs Larkin on 5 March 2021 indicating that all recommendations contained within the action plan had been satisfactorily completed. A review of the listed LPA recommendations demonstrated that only four of these areas had been addressed. One recommendation stating that suitable servicing arrangements are in place for the Venus Versa IPL, with documentation retained on file, could not be evidenced. This was discussed with the clinic manager who provided a copy of the Venus Versa installation report dated 27 November 2019. The installation/commissioning report had been included in a previous area for improvement to be submitted to RQIA; however this document had not been received by RQIA at the time of the inspection. There was no information available to confirm that servicing arrangements had been established. Mrs Larkin stated that servicing arrangements could not be arranged for the Venus Versa due to COVID-19 travel restrictions affecting the service engineer.

As previously discussed, on 25 May 2021 Mrs Larkin provided a written response to RQIA and stated that servicing arrangements could not be arranged for the Venus Versa due to COVID-19 travel restrictions. RQIA advised Mrs Larkin to inform the LPA of the current situation in respect of servicing of the IPL machines and seek their advice in this regard. Mrs Larkin was reminded that it is the LPS's responsibility to follow the advice given by the LPA.

On 14 June 2021, RQIA received written correspondence from Mrs Larkin which stated that the IPL equipment is scheduled to be serviced on 15 June 2021. An area for improvement was identified against the regulations that a copy of the most recent IPL service report should be provided to RQIA on submission of the QIP.

A second recommendation included in the Annual Site Audit Report action plan related to the provision of client total blocking eyewear, as specified in the local rules. Two sets of client total blocking eyewear were in place, one set of white coloured total blocking eyewear and one set of black coloured total blocking eyewear. The markings on the black coloured total blocking eye wear was unreadable; therefore it was not possible to determine if this eyewear provided the required level of protection as stated in the local rules. Protective eye wear was discussed with the clinic manager who stated they were not familiar with this. On 25 May 2021, Mrs Larkin provided RQIA with images via electronic mail, which verified the white coloured total blocking eyewear was in keeping with the local rules. In order to avoid confusion the black coloured total blocking eyewear should be removed from the treatment room. An area for improvement was identified against the standards to ensure the black coloured total block client eyewear is removed from the IPL treatment room.

Following submission of the additional information provided to RQIA on 14 June 2021 the area for improvement made during the previous inspection to address issues identified pertaining to the Venus Versa IPL machine has been assessed as met.

In accordance with best practice guidance authorised operators must sign and date the authorised operator register. The purpose of signing the register is to confirm that they have read and understood the local rules and medical treatment protocols. The local rules documents for the Jeisys Cellec and the Venus Versa each contained a list of authorised operators that had been signed by the authorised operators on 22 February 2020.

Medical treatment protocols produced during August 2020 were in place. A system was in place to review the medical treatment protocols, when due in August 2021. The medical treatment protocols contained the relevant information about the IPL treatments being provided.

The LPS has overall responsibility for ensuring safety during IPL treatments. Mrs Larkin in her role as the LPS had signed the laser safety file to state that she has read and understood the local rules and medical treatment protocols.

When the IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. 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. The door to the IPL 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 Jeisys Cellec IPL machine is activated when the machine is plugged in. The specific IPL safety arrangements, in line with this IPL machine not being key or keypad operated is outlined in the respective set of local rules. The Venus Versa IPL machine is operated using a keypad code, the local rules state the keypad code should not be stored with the IPL machine when the machine is not in use. On the day of the inspection the keypad code was noted to be provided on a piece of paper found on the top of the machine display panel. The operation methods of the IPL equipment was discussed with Mrs Larkin who stated she was unsure of the operating methods as she had not recently been involved in providing IPL treatments.

An area for improvement was identified to implement a robust system to ensure the Venus Versa keypad code is stored securely and not left unattended in the treatment room at any time.

Younique Aesthetic Ltd had one IPL register in place and the register had been completed to include the following information:

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

It was noted that the Annual Site Audit Report action plan stated that a second laser register should be obtained in order that each IPL machine has its own register. On 25 May 2021, RQIA received correspondence from Mrs Larkin which stated that the Jeisys Cellec IPL machine was no longer in use, therefore, the existing register will be sufficient to use for the Venus Versa IPL machine.

As discussed in section 5.1, an area for improvement was identified during the previous inspection in relation to client care records. A review of a selection of client records confirmed that client records were held in paper form and included the following detail:

- 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)

This area for improvement was assessed as having been met.

It was observed that client records were retained in a lever arch file located in the IPL treatment room. The IPL treatment room is used to provide other beauty treatments therefore this presented a risk of client information being accessed by other persons. The management of client records was discussed with Mrs Larkin. An area for improvement was identified against the regulations to ensure client records are stored securely at all times.

In addition, it was noted that two client IPL treatment records, dated May 2021, were not documented in IPL register. An area for improvement was identified against the standards to ensure that the IPL register is completed each time the IPL equipment is operated.

An authorised operator of IPL equipment is required to complete specific training to ensure they can safely provide IPL treatments. Training records reviewed confirmed that two authorised operators had up to date training in core of knowledge, safe application for the equipment in use, infection prevention and control and safeguarding adults at risk of harm in keeping with the RQIA training guidance. However, basic life support and fire safety awareness training was overdue for two identified authorised operators.

Review of the additional information provided to RQIA on 2 June 2021 included training certificates which evidenced that the two identified authorised operators had completed fire safety and safeguarding training on 8 June 2021 and basic life support training on 9 June 2021.

Review of Mrs Larkin's training records, as the LPS and an authorised operator, identified that training was overdue in respect of core of knowledge, safe application for the equipment in use, infection prevention and control, basic life support, fire safety awareness and safeguarding adults at risk of harm. Mrs Larkin had signed the IPL authorised operators list for both the Jeisys Cellec and Venus Versa and therefore should have completed safe application training in respect of both IPL machines. On 25 May 2021, RQIA received correspondence from Mrs Larkin which stated that Mrs Larkin no longer operates the Venus Versa machine. RQIA has since been informed by Mrs Larkin that she intends to appoint a new LPS and stand down from the roles of authorised operator and LPS. An area for improvement has been identified against the standards to ensure an LPS is in place who is suitably experienced, knowledgeable and skilled to undertake this role.

An area for improvement has been identified against the regulations to implement robust oversight arrangements to ensure the authorised operators' training is up to date and in keeping with the RQIA training guidance; with records retained and available for inspection.

All other staff employed at the establishment, but not directly involved in the use of the IPL equipment have received laser safety awareness training. It was confirmed that this training is refreshed on an annual basis.

The clinic manager told us that an initial consultation is undertaken with all clients and clients are asked to complete a health questionnaire. Client records reviewed evidenced that systems are in place to contact the client's general practitioner (GP), with their consent, for further information if necessary. The clinic manager also shared with us the pre-treatment and post treatment advice leaflets provided to clients. The establishment has a list of fees that are made available to clients for each type of IPL procedure.

A carbon dioxide (CO2) fire extinguisher suitable for electrical fires was available in the establishment. It was confirmed that this fire extinguisher had been serviced in keeping with manufacturer's instruction.

A hand washing basin was available in the IPL treatment room along with adequate supplies of liquid soap and disposable paper towels. It was observed that the hot water dispensed from the basin was at a very high temperature and therefore posed a risk of scalding. This was brought to the attention of Mrs Larkin who confirmed, on 25 May 2021, that a warning sign had been placed to advise staff and clients regarding the hot temperature of the water.

There was no waste receptacle observed in the IPL treatment room and Mrs Larkin was advised that a pedal or sensor operated lidded waste receptacle should be provided. On 25 May 2021, RQIA received correspondence from Mrs Larkin which confirmed that a foot operated lidded waste receptacle was now in place.

It was observed that the treatment couch covering had some small tears, as these torn areas cannot be effectively cleaned and decontaminated, this was raised with Mrs Larkin. On 25 May 2021, RQIA received correspondence from Mrs Larkin which confirmed that the IPL treatment room couch had been replaced.

A large clock with shiny silver frame was observed on the IPL treatment room wall, as there should be no reflective surfaces in the IPL treatment area, Mrs Larkin was advised that the clock should be covered when IPL treatments are in progress or alternatively removed from this area. On 25 May 2021, RQIA received correspondence from Mrs Larkin stating that the clock had been permanently removed from the IPL treatment room.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular, businesses need to consider the risks to their clients and staff.

Observations made during the inspection indicated that appropriate arrangements are in place in relation to maintaining social distancing; implementation of enhanced IPC procedures; and the client pathway to include COVID-19 screening prior to attending appointments.

6.0 Conclusion

Based on the inspection findings and discussions held we are satisfied that this service is providing IPL treatments in a caring and compassionate manner. Two areas for improvement were identified against the regulations to ensure a copy of the recent Venus Versa service report is submitted to RQIA and to implement robust oversight arrangements to ensure staff training is completed and up to date. Five areas for improvement were identified against the standards relating to the provision of protective eyewear; safe custody of the IPL keypad code; storage of client information; maintenance of the IPL register and the need to ensure an LPS is in place who is suitably experienced, knowledgeable and skilled to undertake this role.

7.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified were action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and Minimum Care Standards for Independent Healthcare Establishments (July 2014)

	Regulations	Standards
Total number of Areas for Improvement	2	5

Areas for improvement and details of the QIP were discussed with Mrs Aine Larkin, Responsible Individual, as part of the inspection process. The timescales for completion commence from the date of inspection.

Quality Improvement Plan

Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref**: Regulation 15 (2) **Stated:** Second time **To be completed by:** 30 June 2021	The registered person shall ensure a copy of the most recent service report for the Venus Versa IPL equipment is provided to RQIA upon submission of the QIP. Ref: 5.2.1
	Response by registered person detailing the actions taken: Service was carried out on Tuesday 15th June The report has been placed into the laser file and will also be sent alongside the QIP.
Area for improvement 2 **Ref:** Regulation 18 (2) **Stated:** First time **To be completed by:** 30 June 2021	The registered person shall implement robust oversight arrangements to ensure the authorised operators' training is kept up to date and in keeping with the RQIA training guidance; with records retained and available for inspection. Ref: 5.2.1
	Response by registered person detailing the actions taken: Our LPS has created a spreadsheet with the required training, ie Core Knowledge, Fire Safety, Basic Life Support and Adult Safeguarding. Each operators' date of completion, and date of expiry is listed. The LPS reviews this spreadsheet on a monthly basis and if any certificates are expiring that coming month, the necessary training is arranged. A copy of the required training is also attached to the front of each operator's personnel file, and again our LPS reviews this on a monthly basis to check that it has been updated correctly. When any new certificates are issued the old ones are removed from the personnel file.
Action required to ensure compliance with the Minimum Care Standards for Independent Healthcare Establishments (July 2014)	
Area for improvement 1 **Ref:** Standard 48.17 **Stated:** First time **To be completed by:** 30 June 2021	The registered person shall ensure that the black coloured total blocking client eyewear is removed from the IPL treatment room. Ref: 5.2.1
	Response by registered person detailing the actions taken: The black coloured eyewear has been removed from the IPL treatment room and the new regultation standard patient eyewear have been placed into the room and clearly marked. This is evidenced in the photo previously submitted to RQIA.

Area for improvement 2 **Ref:** Standard 48.19 **Stated:** First time **To be completed by:** 19 May 2021	The registered person shall implement a robust system to ensure the Venus Versa IPL equipment keypad code is stored securely and not left unattended in the treatment room at any time. Ref: 5.2.1
	Response by registered person detailing the actions taken: In future, all monthly expiration codes will be emailed directly to the operator and not printed out to avoid the slim chance that a patient may enter the locked IPL room.

Area for improvement 3 **Ref:** Standard 8.4 **Stated:** First time **To be completed by:** 19 May 2021	The registered person shall ensure client records are stored securely at all times. Ref: 5.2.1
	Response by registered person detailing the actions taken: We can confirm our client records are stored to RQIA guidelines in a locked unit in a locked office.
Area for improvement 4 **Ref:** Standard 48.9 **Stated:** First time **To be completed by:** 19 May 2021	The registered person shall ensure that the laser register is completed every time the IPL is operated. Ref: 5.2.1
	Response by registered person detailing the actions taken: Our LPS has been advised that she must inspect the IPL register on a weekly basis to ensure that the operators have completed the laser register for each IPL appointment.
Area for improvement 5 **Ref:** Standard 48.7 **Stated:** First time **To be completed by:** 30 June 2021	The registered person should ensure that an LPS is in place who is suitably experienced, knowledgeable and skilled to undertake this role. Ref: 5.2.1
	Response by registered person detailing the actions taken: Our newly appointed LPS, Sandra Brady has substantial knowledge and has been with our company for a number of years. She has completed Core Knowledge and holds Adult Safeguarding Level 2 Certificates, as well as Fire Safety and Basic Life Support. We will continue to support her and refresh her knowledge

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