

Announced Care and Variation to Registration Inspection Report 10 May 2019



La Bellezza

**Type of Service: Independent Hospital (IH) –
Cosmetic Laser and Intense Pulsed Light Service
Address: 131-133 North Street, Belfast, BT1 1NE
Tel No: 028 9024 2167
Inspector: Carmel McKeegan
RQIA's Medical Physics Advisor: Dr Ian Gillan**

www.rqia.org.uk

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

This is a cosmetic laser service providing treatments using an Intense Pulse Light (IPL) machine and Class 4 laser machines. La Bellezza provides a range of cosmetic/aesthetic treatments. This inspection focused solely on those proposed treatments that fall within regulated activity and the categories of care for which the establishment is registered and/or has made application to register with RQIA.

Laser and IPL equipment:

- Manufacturer: Ultrapulse/UK Beauty
- Model: Titan 3
- Serial Number: L2 15101502
- Laser Class: 4
- Wavelength: Nd YAG 532nm & 1064nm
- Manufacturer: UK Beauty
- Model: Voyager 3+
- Serial Number: 19030501X
- Laser Class: 4
- Wavelength: Nd YAG 532nm & 1064nm
IPL 400nm – 1200nm

The UK Beauty Voyager 3+ machine is a multi-platform machine that is capable of providing both laser and Intense Pulse Light (IPL) treatments by changing the treatment heads. Both laser and IPL treatments heads are available in the establishment.

Laser protection advisor (LPA):

- Mr Simon Wharmby, Lasersafe

Laser protection supervisor (LPS):

- Mr Paul Clarke

Medical support services:

- Dr Paul Myers

Authorised operators:

- Mr Paul Clarke

Proposed treatments using the laser treatment head

Hair removal
Tattoo removal
Skin rejuvenation
Vascular conditions – thread veins

Proposed treatments using the IPL treatment head

Hair removal
Skin rejuvenation
Acne

3.0 Service details

Organisation/Registered Provider: Mr Paul Clarke t/a Ink-Out Tattoo Removal Responsible Individual: Mr Paul Clarke	Registered Manager: Mr Paul Clarke
Person in charge at the time of inspection: Mr Paul Clarke	Date manager registered: 21 January 2016
Categories of care: Independent Hospital (IH) 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 (awaiting confirmation of variation application)	

4.0 Inspection summary

A combined announced and variation to registration inspection took place on 10 May 2019 from 10.30 to 12.45.

The inspector was accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor; the findings and report of Dr Gillan is appended to this report.

This inspection was underpinned by The Health and Personal Social Services (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 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

An application to vary the registration of the clinic was submitted to the Regulation and Quality Improvement Authority (RQIA) by Mr Paul Clarke, registered person. The application was for the approval of new premises for the provision of the services. During the inspection it was identified that a new laser machine was provided which is a multi-platform machine that is capable of providing both laser and Intense Pulse Light (IPL) treatments by changing the treatment heads. Both laser and IPL treatment heads are available in the establishment. Mr Clarke was informed that this requires an additional category of care in respect of the IPL treatments. Following the inspection Mr Clarke formally requested that the variation application is amended to include an additional category of care in respect of PT (IL) prescribed techniques or prescribed technology: establishments using intense light sources. Mr Clarke also informed RQIA that the cosmetic laser service is to be known as La Bellezza.

The inspection assessed progress with any areas for improvement identified since the last care inspection and determined if the establishment was delivering safe, effective and compassionate care and if the service was well led. The inspection also sought to assess the readiness of the new premises for the provision of the services.

Examples of good practice were evidenced in all four domains. These included the arrangements for managing medical emergencies; clinical records; the environment; infection prevention and control; maintaining client confidentiality; ensuring the core values of privacy and dignity were upheld; authorised operator training and providing the relevant information to allow clients to make informed choices.

Two areas for improvement were made against the regulations, one to complete a referral to the Northern Ireland Adverse Incident Centre (NIAIC) in respect of the identified laser and one to seek confirmation from the Laser Protection Advisor that in respect of the issues identified in relation to the identified laser machine, they remain satisfied with the clinic's laser safety arrangements.

Four areas for improvement were made against the standards; one to ensure the identified areas of mandatory training are undertaken by the authorised operator; one to remove the identified pair of protective laser operator's eyewear to prevent them being used by mistake; one to establish a separate and dedicated laser register for the UK Beauty Voyager 3+ laser which clearly states if the treatment has been given using the laser treatment head or the IPL treatment head and one to provide further detail when completing client treatment records.

The variation to registration is granted subject to submission to RQIA of a completed Quality Improvement Plan (QIP), confirming that the areas identified for improvement have been met and the requested supporting documentation has been provided to RQIA.

An RQIA estates inspector contacted Mr Clarke following this inspection and requested specific documents in relation to the premises to be submitted for review. Overall approval of the variation application is also dependent on the estate inspector's assessment and Mr Clarke will be informed in due course.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and clients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	2	4

Details of the Quality Improvement Plan (QIP) were discussed with Mr Paul Clarke, registered person, as part of the inspection process. The timescales for completion commence from the date of inspection.

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

4.2 Action/enforcement taken following the most recent care inspection dated 6 September 2018

No further actions were required to be taken following the most recent inspection on 06 September 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- application to vary the registration status

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned completed clients questionnaires were analysed prior to the inspection.

A poster informing clients that an inspection was being conducted was displayed.

During the inspection the inspector met with Mr Clarke, registered person.

The following records were examined during the inspection:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- information provision
- care pathway
- management and governance arrangements
- maintenance arrangements

The findings of the inspection were provided to Mr Clarke at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 6 September 2018

The most recent inspection of the establishment was an announced care inspection.

6.2 Review of areas for improvement from the last care inspection dated 6 September 2018

There were no areas for improvement made as a result of the last care inspection.

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Mr Clarke confirmed that he is the sole operator of the establishment and that he can fulfil the needs of the establishment and clients. Mr Clarke stated that should the business need grow he will employ another authorised operator.

Mr Clarke confirmed that in the event of appointing any new authorised operator, induction training would be provided on commencement of employment.

Mr Clarke confirmed that laser and IPL treatments are and will only be carried out by authorised operators. A register of authorised operators for the laser machines is maintained and kept up to date.

A review of training records evidenced that Mr Clarke as the only authorised operator has up to date training in core of knowledge training, application training for the equipment in use, basic life support, and protection of adults at risk of harm in keeping with the RQIA training guidance. Mr Clarke was aware that he needs to complete refresher training in fire safety and infection prevention and control. An area of improvement against the standards was made in this regard. All other staff employed at the establishment, but not directly involved in the use of the laser and IPL equipment, had received laser safety awareness training.

Recruitment and selection

As previously discussed there have been no authorised operators recruited since the previous inspection. During discussion Mr Clarke confirmed that should an authorised operator be recruited in the future robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

Mr Clarke confirmed that he has not yet recruited any new authorised operators, advice and guidance was provided and following the inspection a recruitment procedure checklist was provided to Mr Clarke by email. The recruitment procedure checklist, if followed, will ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be in place for any new staff member.

Safeguarding

It was confirmed that laser and IPL treatment is not provided to persons under the age of 18 years.

Mr Clarke was aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was confirmed that the safeguarding lead has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policy included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

Laser safety

A laser safety file was in place which contained all of the relevant information in relation to laser and IPL equipment.

There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA) which will be reviewed on an annual basis. The current service level agreement between the establishment and the LPA was reviewed and this expires on 12 April 2020.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers on 28 March 2019. Systems are in place to review the medical treatment protocols on an annual basis. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

Up to date local rules were in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser and IPL equipment being used.

RQIA's medical physics advisor identified that several aspects of the UK Beauty Voyager 3+ laser do not comply with the requirements of the European Standard EN 60825 in relation to labelling and the provision of an interlock socket. These observable areas of non-compliance indicate a failure by the manufacturer to meet the required European Standard; this may indicate that other aspects of relevant European standards may not have been complied with when achieving CE marking. An area for improvement was made against the regulations to raise these matters with the manufacturer and make a referral to the Northern Ireland Adverse Incident Centre (NIAIC).

The LPA has provided a risk assessment and local rules however reference is not made in either to the non-compliance of the UK Beauty Voyager 3+ laser with BS EN 60825. Mr Clarke should seek confirmation from the LPA that although aware of this non-compliance they remain content with the clinic's laser safety arrangements. An area for improvement has been made against the regulations in this regard.

It was noted that one pair of protective operator's eyewear for the laser did not conform to EN207 and it was agreed that these would be removed from the clinic to prevent them being used by mistake. An area of improvement has been made against the standards in this regard.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. The authorised operator had signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser or 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 laser and IPL equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. 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 keys when not in use. Protective eyewear is available for the client and operator as outlined in the local rules. As previously discussed an area of improvement has been made against the standards to remove unsuitable protective eyewear.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has a laser register for the Ultrapulse / UK Beauty Titan 3 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

Mr Clarke was advised that as the UK Beauty Voyager 3+ machine is capable of operating as a laser and IPL depending on the treatment head used, separate registers must be maintained to record the laser and IPL treatments. It was agreed that the same book would be used as the register and that a section of the book would be dedicated to laser treatments and a separate section dedicated to IPL treatments. An area of improvement had been made against the standards in this regard.

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

Management of emergencies

As discussed, Mr Clarke has up to date training in basic life support. Discussion with Mr Clarke confirmed he was aware of what action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

The treatment room was clean and clutter free.

Discussion with Mr Clarke evidenced that appropriate procedures were in place for the decontamination of equipment between use.

The laser room does not have a hand washing sink, however, a toilet facility with a hand washing sink is available adjacent to the laser room. An adequate supply of liquid soap and disposable hand towels was provided and a laminated hand hygiene poster was displayed near the hand washing facilities. Alcohol based hand gel and personal protective equipment were provided in the laser room.

As discussed previously, Mr Clarke was due to complete refresher training in infection prevention and control, and an area of improvement has already been identified.

Environment

The cosmetic laser service has been relocated to a new treatment room within a beauty salon.

The inspector undertook a tour of the premises, which had recently been completely refurbished and were maintained to a high standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Observations made evidenced that a carbon dioxide (CO2) fire extinguisher is available which has been serviced within the last year.

Mr Raymond Sayers RQIA estates inspector, contacted Mr Clarke following this inspection and requested specific documents in relation to the premises to be submitted for review. Mr Sayers has reviewed the documents and confirmed approval of the variation application from an estates perspective.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff recruitment, induction, adult safeguarding, management of emergencies, infection prevention and control, risk management and the environment.

Areas for improvement

Ensure authorised operators complete fire safety training annually and infection prevention and control training every two years.

Mr Clarke should make a referral to NIAIC to report the issues as identified.

Mr Clarke should seek confirmation from the LPA that although aware of the issues of non-compliance of the UK Beauty Voyager 3+ machine that they remain satisfied with the clinic's laser safety arrangements.

Ensure the pair of protective operator's eyewear for the laser which did not conform to EN207 is removed from the clinic to prevent them being used by mistake.

Establish a separate and dedicated laser register for the UK Beauty Voyager 3+ laser which clearly states if the treatment has been given using the laser treatment head or the IPL treatment head.

	Regulations	Standards
Areas for improvement	2	3

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

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 and 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.

During the initial consultation, 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.

A sample of 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)

An area of improvement was made against the standards that the client care record of treatment delivered should also include the number of shots and fluence settings (where appropriate).

Observations made evidenced that client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Discussion with Mr Clarke and review of the management of records policy confirmed that patients have the right to apply for access to their clinical records in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate ICO regulations and Freedom of Information legislation.

Mr Clarke confirmed that the establishment is not registered with the ICO as he had contacted the ICO a few years ago and was informed that he was not required to register. Discussion took place regarding the application of the new GDPR and Mr Clarke readily agreed to re-check with the ICO if the establishment was required to register.

Communication

As discussed, there is written information for clients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

Areas of good practice

There were examples of good practice found in relation to the range and quality of audits, health promotion strategies and ensuring effective communication between clients and staff.

Areas for improvement

Ensure the client care record of treatment delivered also includes the number of shots and fluence settings as appropriate.

	Regulations	Standards
Areas for improvement	0	1

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with Mr Clarke regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely in a locked filing cabinet within a locked store room.

Client satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a summary report which is made available to clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that clients were highly satisfied with the quality of treatment, information and care received.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining client confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

Mr Clarke has overall responsibility for the day to day management of the service and as previously stated does not employ any staff in relation to the delivery of the laser service.

Mr Clarke is the only authorised operator in this establishment. Policies and procedures were available outlining the arrangements associated with laser treatments. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on an annual basis.

Discussion with Mr Clarke demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Mr Clarke demonstrated good awareness of complaints management.

It was confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed.

Discussion with Mr Clarke confirmed that arrangements were in place to monitor and review the effectiveness and quality of care delivered to clients at appropriate intervals.

A whistleblowing/raising concerns policy was available.

Mr Clarke demonstrated a clear understanding of his role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. It was confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and are available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

Observation of insurance documentation confirmed that current insurance policies were in place.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to governance arrangements, management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 Equality data

Equality data

The arrangements in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients was discussed with Mr Clarke.

6.9 Client and staff views

Eight client questionnaire responses were submitted to RQIA. All eight clients indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All of the clients also indicated that they were very satisfied with each of these areas of their care. No comments were provided in the submitted questionnaires.

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mr Paul Clarke, registered person, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified 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 the establishment. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

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) (b) Stated: First time To be completed by: 30 June 2019	Mr Clarke should ensure that a referral is made to the Northern Ireland Adverse Incident Centre (NIAIC) to report that the UK Beauty Voyager 3+ laser does not have the required classification label, aperture label and does not have an interlock socket. Confirmation of this referral should be submitted to RQIA upon return of this Quality Improvement Plan (QIP). Ref: 6.4
	Response by registered person detailing the actions taken: Email sent

Area for improvement 2 Ref: Regulation 15 (2) (a) Stated: First time To be completed by: 30 June 2019	Mr Clarke should seek confirmation from the LPA that although aware of this non-compliance of the UK Beauty Voyager 3+ machine that they remain satisfied with the clinic's laser safety arrangements. Ref: 6.4 Response by registered person detailing the actions taken: LPA has no concerns at all
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)	
Area for improvement 1 Ref: Standard 13.1 Stated: First time To be completed by: 30 June 2019	The registered person shall ensure authorised operators complete fire safety training annually and infection prevention and control training every two years. Ref: 6.4 Response by registered person detailing the actions taken: Fire Safety and Infection control updated
Area for improvement 2 Ref: Standard 48.17 Stated: First time To be completed by: 30 June 2019	The registered person shall ensure the pair of protective operator's eyewear for the laser which did not conform to EN207 is removed from the clinic to prevent them being used by mistake. Ref: 6.4 Response by registered person detailing the actions taken: Eyewear disposed
Area for improvement 3 Ref: Standard 48.9 Stated: First time To be completed by: 30 June 2019	The registered person shall establish a separate and dedicated laser register for the UK Beauty Voyager 3+ laser which clearly states if the treatment has been given using the laser treatment head or the IPL treatment head. Ref: 6.4 Response by registered person detailing the actions taken: Additional laser register added to include IPL
Area for improvement 4 Ref: Standard 48.10 Stated: First time To be completed by: 30 June 2019	The registered person shall ensure the client care record of treatment delivered also includes the number of shots and fluence settings (where appropriate) Ref: 6.5 Response by registered person detailing the actions taken: Implemented

Please ensure this document is completed in full and returned via Web Portal



The Regulation and
Quality Improvement
Authority

The Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST
BT1 3BT

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
Twitter @RQIANews

10th May 2019

Ms Carmel McKeegan
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Ms McKeegan

Laser Protection Report

La Bellezza, 281/283 Woodstock Road, Belfast BT6 8PR

Introduction

Further to the inspection of the above premises earlier today this report summarises the main laser protection aspects where improvement may be required. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Comments

(1) Laser standard BS EN 60825 & CE compliance:-

Several aspects of both lasers do not comply with the requirements of the above standard, these include:

- Labelling requirements
- Interlock socket

The above easily observable areas of non-compliance indicate a failure by the manufacturer to meet the required European Standard; this may indicate that other aspects of relevant European standards may not have been complied with.

NIAIC have already been notified of the non-compliance of the Titan 3 laser. The clinic should now make a similar notification for the Voyager3+ laser.

(2) LPA Report

Although the LPA has provided draft risk assessment & Local Rules reference is not made in either to the non-compliance with BS EN 60825. It would be useful if the LPA could confirm in writing that although aware of this non-compliance remains content with the clinic's Laser safety arrangements.

(3) Treatment Log book

The required contents of the laser treatment logbook was discussed.

(4) Protective Eyewear

One pair of protective operator's eyewear for the laser did not conform to EN207 and it was agreed that these would be removed from the clinic to prevent them being used by mistake.

RQIA should be informed when the deficiencies noted above have been corrected.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix 1

La Bellezza, 281/283 Woodstock Road, Belfast BT6 8PR

Lasers

Manufacturer: Ultrapulse / UK Beauty
Model: Titan 3
Class: 4
Wavelength: Nd YAG 532nm & 1064nm
Serial no: L2 15101502

Manufacturer: UK Beauty
Model: Voyager 3+
Class: 4
Wavelength: Nd YAG 532nm & 1064nm
IPI 400nm – 1200nm
Serial no: 19030501X

Laser Protection Adviser

Simon Wharmby, Lasersafe