

## **Independent Healthcare Inspection (Announced)**

Lee Voltz Laser Removal

Inspection date: 08 October 2019

Publication date: 09 January 2020

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In writing:

**Communications Manager  
Healthcare Inspectorate Wales  
Welsh Government  
Rhydycar Business Park  
Merthyr Tydfil  
CF48 1UZ**

Or via

**Phone: 0300 062 8163  
Email: [hiw@gov.wales](mailto:hiw@gov.wales)  
Website: [www.hiw.org.uk](http://www.hiw.org.uk)**

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**Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales**

## **Our purpose**

**To check that people in Wales receive good quality healthcare**

## **Our values**

**We place patients at the heart of what we do. We are:**

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

## **Our priorities**

**Through our work we aim to:**

**Provide assurance:**

**Provide an independent view on the quality of care**

**Promote improvement:**

**Encourage improvement through reporting and sharing of good practice**

**Influence policy and standards:**

**Use what we find to influence policy, standards and practice**

# 1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Lee Voltz Laser Removal on the 8 October 2019.

Our team, for the inspection comprised of two HIW inspectors.

HIW explored how the service complied with the Care Standards Act 2000, requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards for Independent Health Care Services in Wales.

Further details about how we conduct independent service inspections can be found in Section 5 and on our website.

## 2. Summary of our inspection

We found that Lee Voltz Laser Removal was committed to providing a positive experience for patients.

The environment was visibly clean and tidy and we found processes in place to ensure the privacy and dignity of patients.

However, we found evidence that the service was not fully compliant with all standards, regulations and their conditions of registration with the HIW.

This is what we found the service did well:

- The registered manager was committed to providing a positive patient experience
- There was good evidence of recording consent and medical histories
- The premises were visibly clean and tidy.

This is what we recommend the service could improve:

- The registered manager must implement a method for patients to provide feedback
- The registered manager must provide evidence that a fire risk assessment has been completed, including evidence of completed fire training
- The registered manager must ensure that all policies and procedures are reviewed and enhanced, where necessary.

Please refer to Appendix B for a comprehensive list of improvements.

We identified the service was not compliant in the following areas:

- The service had not appointed a certified Laser Protection Adviser to provide the service with support on the safety of the laser machine.
- The registered manager had not ensured that the local rules for the safe use of the laser machine had been reviewed at least annually by a certified Laser Protection Adviser.

- The registered manager had not ensured that an updated risk assessment of hazards had been reviewed and, where necessary, updated.

These are serious matters and resulted in the issue of a non-compliance notice to the service. At the time of publication of this report, HIW have received sufficient assurance of the actions taken to address the improvements needed.

## 3. What we found

### Background of the service

Lee Voltz Laser Removal is registered as an independent hospital to provide Class 3B/4 laser and Intense Pulsed Light Technology (IPL)<sup>1</sup> treatments at 8 High Street, Caerleon, Newport, NP18 1AG

The service was re-registered with HIW on the 1 August 2017 to provide services at its registered location on High Street, Caerleon.

At the time of the inspection, the staff team included the registered manager as the sole laser operator.

The service is registered to provide the following service to patients over the age of 18 years old:

- Laser tattoo removal

Using an Eclipse Compact Nd:YAG Laser

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<sup>1</sup> IPL is a broad spectrum light source technology and is used by cosmetic and medical practitioners to perform various skin treatments for aesthetic and therapeutic uses



## Quality of patient experience

*We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.*

We found that the service was committed to providing a positive experience for patients.

Suitable arrangements were in place to protect the privacy and dignity of patients during their initial consultation and treatments.

Patients were provided with sufficient information pre and post treatment to help them make an informed decision about their treatment.

However, the service must implement a method for patients to provide feedback on the service and treatment that they have received.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of four were completed.

Overall, patient feedback was positive; all of the patients who completed a questionnaire said that they would rate the service provided by the practice as 'excellent'.

### Health promotion, protection and improvement

We saw evidence that patients were asked to complete a medical history prior to their initial treatment, and that this was checked for changes at any subsequent appointment. We also saw that medical histories were signed by the patient, which helps to ensure that appropriate treatments are provided in a safe way.

All patients who completed a HIW questionnaire confirmed that they had their medical histories taken prior to treatment.

## Dignity and respect

To ensure patient privacy, we were told that patient consultations are carried out in the treatment room.

To ensure patient privacy dignity pre and post treatment, we were told that patients are able to use the toilet facilities to change, if required, otherwise patients are free to use the treatment room in private. We saw that the treatment room door was lockable and a 'do not enter' sign was displayed to ensure patient dignity and safety during treatment.

The registered manager told us that a patient could attend with a chaperone or relative for part or all of the treatment, providing that advance notice is given so that additional safety glasses can be made available. However we did not consider this to be practical or reasonable on patients, therefore, the service must obtain an additional pair of safety glasses if it is to continue to provide a chaperone service.

All patients who completed a HIW questionnaire agreed that they had been treated with respect by staff.

## Patient information and consent

All patients who completed a HIW questionnaire agreed that they had been given enough information about their treatment, including the available treatment options, costs, risks and benefits.

We found evidence to confirm that patients had been provided with sufficient information in order to make an informed decision about their treatment. This is because all patients are provided with a verbal consultation prior to treatment and all patients had access to a patients' (clients') guide to read in their own time.

The registered manager told us that all patients are provided with a face-to-face consultation. This includes a discussion around the risks, benefits and likely outcome of the desired treatment. We were also told that written consent is also obtained prior to initial treatment and at any subsequent appointments. On the day of the inspection, we reviewed a sample of patient records to confirm they reflected the process described to us.

The registered manager also confirmed to us that following treatment all patients receive verbal aftercare advice and an aftercare leaflet to take away with them. All of the patients that completed a questionnaire told us that they had been given aftercare instructions about how to prevent infection and aid healing after their treatment.

## **Communicating effectively**

A copy of the patients' guide and statement of purpose was provided to us by the registered manager which we found contained the essential information required by the regulations.

The service also showed evidence of an active social media presence which outlined the services available and provided prospective patients with visual examples of the outcomes of the treatment offered.

All patients that completed a questionnaire agreed that they felt listened to by staff and that they were able to speak in their preferred language.

## **Care planning and provision**

The registered manager confirmed that all patients receive a face-to-face consultation prior to the start of any treatment. As part of this consultation we saw evidence to confirm that medical histories were being collected in order to ensure suitability of treatment.

In line with the service's treatment protocol and in the information supplied to patients, the registered manager confirmed to us that patch testing was required for all patients as a condition of their treatment. All patients who completed a questionnaire told us that they had received a patch test prior to treatment.

## **Equality, diversity and human rights**

The service is located on the ground floor with a small step into the waiting area and treatment room. The registered manager advised us that the service ensures that patients are aware of this prior to them attending the premises. A ground floor toilet was also provided for patient use.

## **Citizen engagement and feedback**

We were told that the service did not have a formal system for regularly gaining patient feedback as a way of monitoring the quality of service provided. The registered manager told us that patients provide verbal comments and feedback, but there was no system to record or evidence this. We were also told that patients can provide feedback and reviews on social media, therefore providing a means for the service to analyse feedback and identify any areas for improvement.

As indicated in the service's statement of purpose, we recommend that the service implements a method for patients to provide feedback on the service and

treatment that they have received. This should also include a mechanism for capturing verbal comments and feedback.

#### Improvement needed

The registered manager must implement a method for patients to provide feedback on the service and treatment that they have received

## Delivery of safe and effective care

*We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.*

The service was visibly clean and tidy, however, the service is required to review and enhance their health and safety / infection control policy to ensure that it contains the necessary details.

Patient records were stored securely to prevent unauthorised access.

The service must ensure that all aspects of fire safety and first aid have been reviewed in line with the relevant standards and regulations.

The service needs to establish more effective and proactive arrangements to monitor compliance with the relevant regulations and their conditions of registration; specifically in relation to the appointment of, and ongoing support from, a certified Laser Protection Advisor (LPA). This also includes a review of local rules<sup>2</sup> and a comprehensive risk assessment.

The service must ensure that the maintenance and service of its laser machine is appropriately logged and evidence of this retained on file.

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<sup>2</sup> Local rules (or safe working procedures) should reflect safe working practices and relate to the day-to-day safety management of lasers, IPL systems and LED's. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/474136/Laser\\_guidance\\_Oct\\_2015.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/474136/Laser_guidance_Oct_2015.pdf)

## Managing risk and health and safety

We found suitable arrangements were in place in some areas to protect the safety and well-being of the registered manager, visitors and patients. However improvements are required in a number of areas in order to appropriately manage and mitigate risk.

We saw evidence that Portable Appliance Testing (PAT) had been conducted to help ensure that electrical appliances were safe to use. We also saw evidence that there had been a building electrical wiring check conducted within the last five years.

We found that there were some arrangements in place to adequately protect the registered manager and people visiting the service in the event of a fire:

- Fire exits were appropriately signposted
- Fire extinguishers throughout the clinic had been serviced within the last twelve months to ensure the equipment was appropriate for use in an emergency
- Fire alarm checks were documented but we would advise that these are documented on a log sheet which indicates what checks have been undertaken

However some improvements are required:

- a fire risk assessment was not available for us to view on the day of the inspection. We therefore could not confirm whether any remedial actions had been identified and implemented by the registered manager
- the registered manager confirmed that fire training had been completed, but a certificate was not available for us to view on the day of the inspection.

In keeping with the service's policy, the registered manager described suitable procedures to follow in the event of an emergency, such as a patient collapse, and confirmed that he had undertaken first aid training in 2014. We were told that other staff on the premises did have current first aid training but we did not see evidence of these certificates on the day. We therefore advised the registered manager that they should consider attending a first aid refresher course.

We saw that a first aid kit was available and that the items within the kit were in date.

### Improvement needed

The registered manager must provide evidence that a fire risk assessment has been undertaken.

The registered manager must provide evidence that fire training has been completed.

### Infection prevention and control (IPC) and decontamination

We saw that the service was visibly clean and tidy. All patients who completed a HIW questionnaire felt that, in their opinion, the premises was very clean.

The registered manager described the infection control arrangements at the service. We also saw evidence to demonstrate how the service maintains hand hygiene, including a hand washing sink and availability of alcohol hand gel.

Whilst these arrangements were verbally explained to us we found that the health and safety / infection control policy did not detail these arrangements and that the policy overall required additional information in order to maintain a safe clinical environment. The policy must include:

- arrangements for cleaning treatment areas and equipment between patients
- cleaning schedules and regimes
- safe handling of clinical waste

We saw that a contract was in place for the safe transfer and disposal of hazardous (clinical) waste and general waste.

### Improvement needed

The registered manager must enhance their health and safety / infection control policy accordingly.

### Safeguarding children and safeguarding vulnerable adults

The service is registered to provide treatment to adults over the age of 18 years only. The registered manager confirmed this was complied with.

The registered manager confirmed that children are not allowed in the treatment room under any circumstances, but have in the past been allowed to wait in the

reception area. However the registered manager confirmed that this is no longer encouraged and we advised that this should be maintained.

An adult safeguarding policy was in place with procedures to follow in the event of a safeguarding concern. This included a local authority point of contact. However we recommended that this policy is updated and localised so it is clear what the service will do in the event of any safeguarding concern. The policy also needs to be dated to show when it was last reviewed.

The registered manager confirmed to us that adult safeguarding training had been completed, but was unable to provide evidence of this on the day of the inspection. The service must provide evidence to HIW that an appropriate level (level 2) of safeguarding training has been undertaken.

#### Improvement needed

The registered manager must review their adult safeguarding policy to make it clear what the service will do in the event of any safeguarding concern.

Evidence of an appropriate level of safeguarding training must be provided.

#### Medical devices, equipment and diagnostic systems

Overall, whilst the service was compliant in some areas, we found that the service did not have all of the necessary arrangements in place for safe and effective use of the laser machine at the service.

A treatment protocol setting out the procedures to follow to ensure treatment is delivered safely to patients was in place which was been overseen by an expert medical practitioner.

Routine quality assurance and maintenance checks were described to us, which included a deep clean of equipment, water tank changes and replacing parts of the laser equipment. However these checks were not documented. We advised the registered manager that these checks should be recorded on a log sheet to evidence regular maintenance of the laser machine.

Whilst the manager confirmed to us that the laser machine had been sent for a service and we saw evidence to see that the machine had been sent away, we were not provided with written confirmation of what work was undertaken, including whether or not a service in line with manufacturer's guidelines had taken place. The registered manager must provide evidence of what work was undertaken in order for HIW to confirm that the laser machine is operating safely and effectively.



The local rules are a key aspect of identifying, assessing and managing the risks associated with the operation of a Class 3B/4 laser or Intense Pulsed Light (IPL) machine. The service's conditions of registration state that these must be reviewed annually. During the inspection we saw evidence that the local rules in place at the service were last issued by a certified Laser Protection Advisor (LPA) in July 2017 and therefore were overdue for review.

We saw evidence that an annual contract with a Laser Protection Advisor (LPA) was last issued in July 2017. The registered manager advised us that he had paid an invoice for the services of a Laser Protection Advisor but was unable to provide evidence that a contract with a certified LPA was in place. We could therefore not be assured that the service was in receipt of continuous support on the safe and effective operation of the laser machine.

The absence of a risk assessment undertaken by the LPA in the last twelve months is further evidence that the arrangements for obtaining support and advice on the safe use of the laser were inadequate.

Our concerns regarding the above issues were dealt with under our non-compliance process. Details of the immediate improvements we identified are provided in Appendix B.

#### Improvement needed

The registered manager must provide evidence of what work was undertaken, including whether or not the laser machine has been serviced in line with manufacturer guidelines.

The registered manager must ensure:

- i) There is a contract in place with a Laser Protection Advisor (LPA)
- ii) That the local rules for the safe use of the laser machine are reviewed by a Laser Protection Advisor.
- iii) A risk assessment of hazards is reviewed and, where necessary, updated.

## Safe and clinically effective care

We saw evidence that the registered manager, as the sole authorised operator, had completed Core of Knowledge<sup>3</sup> training. The registered manager confirmed that they had completed manufacturer training in the use of the laser/IPL machines, but was unable to provide evidence of this on the day of the inspection. The service must provide evidence of this to HIW.

We saw that safety glasses was available for patients and the laser operator. Whilst the service stated that they do not actively encourage others to be present during treatments, as mentioned previously in this report, the service must ensure that an additional pair of safety glasses are available if it is to continue providing a chaperone service. We also saw eye shield in use which provides added eye protection for patients receiving laser treatments above the neck.

The eye protection was in visibly good condition and the service confirmed that eyewear is regularly checked for damage. However there was no evidence that these checks were being documented, therefore, it is advised that regular checks are undertaken and appropriately logged.

All treatment rooms were fitted with locks and a 'do not enter' sign was on display to prevent unauthorised access whilst the machine is in use. We confirmed that keys for the laser machine are kept securely in a locked box when not in use.

### Improvement needed

The registered manager must provide evidence that the manufacturer's training in the use of the laser machine has been undertaken.

The registered manager must ensure that a secondary pair of safety glasses are made available for use by chaperones.

The registered manager must ensure that eye wear is checked for damage on a regular basis and that these checks are logged.

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<sup>3</sup> Core of Knowledge training provides a foundation in the safe and effective use of laser and IPL machines

## Participating in quality improvement activities

As mentioned earlier within this report, the service must ensure that there are suitable systems in place to regularly assess and monitor the quality of the service provided. For example, the service should provide patients with the opportunity to provide feedback following treatment.

## Records management

We reviewed a sample of patient notes and found evidence of satisfactory record keeping. Hard copies of individual patient notes were retained on file, including consent forms, initial consultation forms and updated medical histories forms for patients who returned for additional courses of treatment.

We found hard copy files were kept securely at the service. However, we recommend that the registered manager reviews the regulations; specifically in relation to the retention of patient records, in order for old records to be securely disposed of.

We found that whilst the service kept individual patient records, there was no overarching treatment register in use, despite a template being available for us to see. The treatment register is needed to capture each time the laser is used and the nature of the treatment provided. This would enable the registered manager to maintain a system and audit trail in the event of any patient treatment or equipment issues. The registered manager agreed to re-implement this register.

### Improvement needed

The registered manager must begin to use a treatment register for all treatments.

The registered manager must review the retention schedule of patient records in the regulations and securely dispose of any outdated records.

## Quality of management and leadership

*We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Independent Health Care Regulations and National Minimum Standards.*

The registered manager demonstrated a commitment to providing a good service, but we advise that they familiarise themselves with the relevant regulations and supporting standards and guidance in order to ensure that they are fully aware of the regulatory requirements applicable to their service.

### Governance and accountability framework

Lee Voltz Laser Removal is run on a day-to-day basis by the registered manager who is the owner and solely authorised laser operator.

We saw a current HIW certificate of registration and public liability insurance certificate on display.

The service had a range of policies and procedures in place. We reviewed a sample of these and found that some of the policies were not localised / relevant to the service and others which need to be further enhanced, as outlined in the main body of this report. All policies must also be reviewed on a regular basis, with the appropriate version control and review dates listed.

The registered manager demonstrated a commitment to providing a good service, but we advise that they familiarise themselves with the relevant regulations and supporting standards and guidance in order to ensure that they are fully aware of the regulatory requirements applicable to their service.

Given the areas for improvement identified during this inspection, consideration should be given to ensuring that there are more effective and proactive arrangements in place at the service to monitor compliance with relevant regulations and standards. Whilst no specific recommendation has been made in this regard, the expectation is that there will be evidence of a notable improvement in this respect at the time of the next inspection.

### Improvement needed

The registered manager must review all policies and procedures, including the appropriate version control and review dates.

### Dealing with concerns and managing incidents

We found that the service had an appropriate complaints policy and procedure in place, and that this included the contact details for HIW. A summary of the complaints procedure was included in the statement of purpose and clients' guide.

As mentioned earlier in this report, we recommend that the service implements a mechanism for recording formal and informal complaints, including verbal feedback.

### Workforce planning, training and organisational development

As mentioned earlier in this report, we saw certificates showing that the registered manager, as the sole authorised laser operator, had completed Core of Knowledge training. The manager confirmed that they had also completed training on how to use the laser machine, but we require evidence of this to be submitted to HIW.

### Workforce recruitment and employment practices

We saw evidence that the registered manager had an appropriate Disclosure and Barring Service (DBS) check in place to help protect and safeguard patients.

## 4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a [non-compliance notice](#). The issuing of a non compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

## 5. How we inspect independent services

Our inspections of independent services may be announced or unannounced. We will always seek to conduct unannounced inspections because this allows us to see services in the way they usually operate. The service does not receive any advance warning of an unannounced inspection. In some circumstances, we will decide to undertake an announced inspection, meaning that the service will be given up to 12 weeks' notice of the inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

HIW inspections of independent healthcare services will look at how services:

- Comply with the [Care Standards Act 2000](#)
- Comply with the [Independent Health Care \(Wales\) Regulations 2011](#)
- Meet the [National Minimum Standards](#) for Independent Health Care Services in Wales.

We also consider other professional standards and guidance as applicable.

These inspections capture a snapshot of the standards of care within independent services.

Further detail about [how HIW inspects independent services](#) can be found on our website.

## Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection			



## Appendix B – Improvement plan

**Service:** Lee Voltz Laser Removal

**Date of inspection:** 08 October 2019

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
<b>Quality of the patient experience</b>				
The registered manager must implement a method for patients to provide feedback on the service and treatment that they have received	Independent Health Care (Wales) Regulations 2011 Regulation 19(1)a  National Minimum Standards for			

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
	Independent Health Care Services in Wales  Standard 5			
<b>Delivery of safe and effective care</b>				
<p>The registered manager must ensure that a secondary pair of eye protection is made available for use by chaperones.</p> <p>The registered manager must ensure that eye wear is checked for damage on a regular basis and that these checks are logged.</p>	<p>Regulation 19(1)</p> <p>Standard 22</p>			
<p>The registered manager must provide evidence that a fire risk assessment has been undertaken</p>	<p>Regulation 26(4)(f)</p> <p>Standard 22</p>			
<p>The registered manager must provide evidence that fire training has been completed.</p>	<p>Regulation 26(4)c</p> <p>Standard 22</p>			

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
The registered manager must enhance their health and safety / infection control policy.	Regulation 9(1) Standard 13 and 22			
The registered manager must review their adult safeguarding policy to make it clear what the service will do in the event of any safeguarding concern.	Regulation 16(1) Standard 11			
Evidence of an appropriate level of safeguarding training must be provided.				
The registered manager must provide evidence of what work was undertaken, including whether or not the laser machine has been serviced and calibrated in line with manufacturer guidelines.	Regulation 15(1) Standard 16			
The registered manager must provide evidence that manufacturer training in the use of the laser machine has been undertaken.	Regulation 45(3) Standard 16			
The registered manager must begin to use a treatment register for all treatments.	Regulation 45(2)			

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
	Standard 16 and 20			
The registered manager must review the retention schedule of patient records in the regulations and securely dispose of any outdated records	Regulation 23(1)(b) Standard 20			
Quality of management and leadership				
The registered manager must review all policies and procedures, including the appropriate version control and review dates.	Regulation 9(6) Standard 1			

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

### Service representative

**Name (print):**

**Job role:**

**Date:**