MEDICAL LASER SERVICE - MYTHS vs REALITY

Gregory T. Absten
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www.LaserTraining.org, Absten@LaserTraining.org

This information represents personal opinions and experience of Gregory Absten who has worked and taught within the medical laser industry for more than 40 years, written many articles and books on medical laser use, served on the board of directors for the American Society for Laser Medicine and Surgery (ASLMS), received the ASLMS award for excellence in education, is a member of the ANSI 136.3 committee on Safe Use of Lasers in Health Care, and has consulted and trained on the development of medical laser use and laser centers from small office practices to major University Hospitals, and jointly started the first independent laser repair group in the early 80's. The opinions in this article are further supported with links to the U.S. Code of Federal Regulations, reference to Center for Medicare/Medicaid services statements, and a summary of ANSI 136.3 wording on service and repair of lasers.

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What motivated me to pen this information was my being contacted by some of our previous students who are biomedical engineers in hospitals who had received some very "official looking" information from a major laser manufacturer that essentially implied that only THE MANUFACTURER was qualified to perform service work on those lasers - that the Biomeds could not do it. They were misleading and intimidating. Other manufacturers have acted similarly. I am neither pro nor con with manufacturers providing service, but I do have a problem with intentionally misleading information being put out as an intimidating marketing practice. I also have an MBA degree in management and this is definitely NOT how I would want any company I was associated with to act. Since this is a potentially inflammatory article to a few manufacturers, let me take a minute to clarify my position on this. I've been in the industry since the late 70's, originally with an Allied Medical background, and have worked in laser sales and service prior to starting the nonprofit medical education group I still head. I have many friends in the industry, scattered across the many companies, whom I like and respect. I was the Exhibit Chairman for the ASLMS for more than 14 years working with all of the laser companies. There are MANY good people and companies out there to work with, so I don't want this to be a shotgun approach to imply that this is rampant in the laser industry. Like any aspect of life though, there are some individuals and companies that are more respectable than others, and sometimes even good people misbehave. No one is perfect. Most do a good job, and there is absolutely nothing wrong with trying to maximize profits - as long as misleading information is not intentionally used to generate those revenues. The "character" of a company is frequently just the ethical shadow of the person who runs it - so things trickle down through the corporate structure. OK - having said that I'll get off my soapbox and try to get on with a logical and straightforward discussion of who can provide service on your medical lasers and where points of confusion are created. We'll also talk a little about the pros and cons of cheap Chinese equipment, and the practice of some companies to charge very high "recertification" fees on used equipment before they will perform any maintenance on it.

Who can legally and legitimately perform the laser maintenance and repairs on your own lasers? ANYONE that is otherwise reasonably "qualified". That can of course be the laser manufacturer or

dealer, but it also includes highly qualified 3rd party service agents, hospital Biomeds and even YOURSELF if you want to learn to maintain your own lasers. Manufacturer authorization to do this is NOT a requirement - although it would certainly void your warranty if the laser was new and still covered. Once it's out of warranty it's entirely up to the owner of the equipment - just like your car. A few States (i.e. Tx & Az) require anyone providing laser service to register the service provider with the State. There is no prerequisite nor qualification - just register and pay the fee. Most States have no such requirement.

This wouldn't be such a big issue if it wasn't for the very high cost of maintenance contracts and service on this equipment. Of course, manufacturers offer a very high level of support and competency in maintenance of this equipment - after all they designed and built it. But the independents and third parties can also offer good service at very competitive rates.

You have the choice to take your personal auto in to either the dealership, or a local independent auto mechanic for repairs. This is common practice and there are benefits on both sides. You don't have to be the original manufacturer of the car in order to be able to perform quality tune-ups and repairs on it. Like only Ford can service Ford products ? Wake up! Lasers are generally no different.

Having said that, there are some lasers that are more "complex" than others. Most lasers are pretty straightforward to service. The complex ones are typically the multiple head devices that involve more complex alignments. Although many of the independents have this level of competence, most of the time it's probably better to have the manufacturer do it just because they do it all the time. Some manufacturers have also started embedding some very restrictive functions in their equipment (proprietary codes, special service chips, embedded RFID chips in their fibers and attachments, etc). Most of the time this is done under the name of "Safety" for the equipment, but most of us know that this is solely to control who can provide service, because it's so lucrative. As long as those are legal actions then I have no objection - unless I was a potential customer and I'd just buy from someone else that didn't intentionally lock me out of my own system. Competition - but most buyers are not aware of this before the purchase. Maybe we should start educating potential buyers on keys points before buying laser equipment. Since Federal Law, enforced through the FDA, requires the manufacturer to make full service, alignment and calibration information available to the user or ANYONE upon request, then some of these lock out practices are questionably legal, but to my knowledge it's not yet been litigated. The take-home from this is that a few of the lasers are much more complex than the others, and it starts to make more sense to have the manufacturer do this on those systems. This is a small minority of laser systems.

One confusing source of regulatory information that some manufacturers have intentionally used in a misleading fashion is the directive from the **Center for Medicare/Medicaid Services (CMS)** to follow certain maintenance regulations regarding medical equipment, including lasers. Hospitals have to follow this in order to continue to receive Medicare/Medicaid reimbursements. This CMS rule separates out lasers as its own class of equipment and imposes specific requirements on who can service it. Essentially they say that it can only be serviced by "Qualified" individuals, but they fail to define what that means. Some manufacturers exploit this confusion to imply that they are the only ones that are so "qualified". This is misleading and not true. I've written a summary article on these CMS requirements that explain this in more detail at https://www.lasertraining.org/Library/CMS_Svcs_LaserRequirements1501.pdf . It discusses aspects of what a "Qualified" individual is and also highlights some of the conflicting

information. Essentially anyone that can show evidence of formal training, or even better can show a National Certification in Laser Repair (not a requirement but a worthwhile credential) is the best way to evidence one's "qualification" to work on laser equipment. One of the "oxymorons" here is that CMS says that the service still needs to be done in accordance with manufacturer recommendations, and use their "schedule of maintenance", and they reference that Federal law requires them to make this information available. Even though Federal Law requires the manufacturers to have this list of scheduled maintenance, the truth is that most do not. They have complete information in their service manuals, but most do not publish the actual "schedule" of the maintenance. Service technicians just go through a routine set of preventive maintenance checks and then troubleshoot any specific issues using guidance from the service manual. The other confusing information is that the CMS directive uses the terms "service" and "maintenance" interchangeably, but the Federal Law that covers it does not. In federal law "Service" is technical repair work. "Maintenance" is normal user maintenance like wiping off the control panel with an alcohol swab. The CMS directive interchanges these terms and some manufacturers have capitalized on this source of confusion by providing the latter "maintenance" information to users (useless for service).

What do the American National Standards Institute Z136.3 standards on the Safe Use of Lasers for Health Care Facilities say? ..... no restrictions on who can perform laser service. They set out only two requirements for those that service lasers. The first is that they've had general laser safety training like everyone else working around lasers. The second is that they have adequate technical training commensurate only with the level of repairs they are providing. They don't have to be "Certified", and they don't have to be "authorized" by the manufacturer. In addition, the 2018 edition of the ANSI standards, in section 4.2.2 says this: (paraphrased) - *Added an entire section that clarifies the requirement of CMS (Medicare - Medicaid) Services that facility biomedical engineers and service agents are required to obtain written service, calibration and schedule of maintenance instructions from the manufacturer and that Federal law requires these procedures to be made available by the manufacturer to anyone, upon request, at the reasonable cost of reproduction of the service manuals, and it references the actual Federal Law at 21CFR 1040.10 H2II, and 21CFR 1040.11 A2.* This is an important addition to the ANSI standard because it draws this Federal law to the attention of laser owners, hospital administrators and Laser Safety Officers (LSO's) that they are supposed to have this service information and that manufacturers are required by law to provide it. Previously this was more vague because not all medical laser owners were actually aware of the legal requirement.

For the biomedical engineers and techs that have attended our repair or LSO classes, I had put together a summary of all of the items within the ANSI 2018 standards that deal with technical issues of repair or maintenance. You can find a copy of that summary article at https://www.lasertraining.org/Library/ANSI2018SynopsisBiomeds.pdf .

What about the actual FEDERAL LAW referenced by ANSI? Federal law that governs laser manufacturers is contained in the **Federal Laser Product Performance Standard.** This law spells out the requirements for manufacturers in order to build and sell lasers in the U.S.. It includes certain "performance" requirements which are the things like a key switch, covered foot switch, laser "ready" indicator lights, etc.. Within these requirements is the law that REQUIRES the manufacturer or distributor to make available, at the cost of reproduction, to anyone upon request, the full and complete service information on the laser. A separate section of that federal law further requires it to be complete

and also contain full and complete optical alignment and calibration information. This is supposed to be enforced by the Center for Devices and Radiological Health division of the FDA. Many of the companies simply ignore this or claim ignorance of the requirement, but it is Federal law. I had one person (laser owner) tell me that their laser manufacturer denied any obligation at all to provide such service information. When the customer confronted the company with this specific federal law, they were just flatly told that the company didn't care - that they weren't providing it anyway - and sue them if they didn't like it. This might be an isolated case but it's certainly not how I would want to grow my business.

Some companies are much more cooperative. I'm aware of one such request that was put in to ALCON as the manufacturer. Alcon asked for the person's email and immediately emailed them a full and complete PDF service manual on the laser at no charge whatsoever. Buy from ALCON. Those are the kinds of companies I want to deal with. There is a page on our website that walks you through the process of making this request for information from the manufacturer, and also how to contact the FDA to have it enforced if the company will not comply. That page on our site is located at https://www.lasertraining.org/CFRs-Service.html . That page also includes the link to the two specific sections of CFR that mandate this.

There is a movement at present by manufacturers to have this federal law changed. Of course they are citing reasons of "patient safety" but we all know that it is to protect the service revenue. If you are a biomedical engineer you should get involved and let your voice be heard. The FDA is already having hearings on this. 24x7 magazine has written a couple articles on the control of third party service, and these are located at:
https://www.lasertraining.org/Library/FDA_&_Third_Party_Service.html , and
https://www.lasertraining.org/Library/Revisiting_the_Right_to_Repair.html

OK .... if you follow all of those links and information, then I think I've beat this horse to death. Do what you want in terms of your own self interest with maintenance of your lasers. Use the manufacturer, third party agents, or even do a lot of it yourself. But don't be misled into thinking that you HAVE to use a manufacturer as the only authorized source.

While we're on a roll then, let's look at a couple of other laser technical issues that can be clarified:
1. Buying Cheapo Chinese Lasers, and
2. Sky high "Recertification" fees for used lasers.

CHEAPO CHINESE LASERS - To buy or not to buy, that is the question .....
Since we do independent inhouse training on laser use in physicians practices, we've seen many of these Chinese lasers out there. I've seen people buy brand new Chinese lasers for $3500 that would have cost $100,000 here in the U.S.. It's hard not to look at that price difference! What do I think about quality? First, they're all pretty and shiny. My issue with them is very inconsistent quality. People buy these things and then call us in to train on performing office procedures. Some of them work great! Others seem to hardly work at all (same makes/models). It seems that they have no consistency in manufacturing (i.e. quality control) so you take a big risk with that. I think they back them up though and will send you new ones if yours don't work. The other question people frequently bring up is whether the quality is enough to last. At a brand new price that is significantly less than a yearly service contract price on many U.S. lasers, I don't think this really matters. Even if it lasts you only a year you saved over $96,000 in that year! You can afford to buy a new one each year if you need. You can get many of the

independent service agents to do the routine maintenance on them for you, but you'll need to get the company to include the full service information (in English) when you buy the laser. Most of these Chinese lasers are not FDA approved and I've heard competitors try to scare off customers by implying that they would be in some type of trouble for using non-FDA approved devices. Not True. The FDA does not regulate end users. They only regulate the manufacturer or distributor here in the U.S.. The Chinese do not have a U.S. presence and you essentially buy them over the internet. It's perfectly legal and legitimate. Many hospitals won't do that because they don't want to get into a defensive position of defending a lawsuit that includes use of a non FDA approved device. It's not illegal but plaintiff's attorneys can try to use it as some indication of failure to meet a reasonable man standard. Individual practices are usually not as sensitive to this so you see them mostly in offices. Just remember that they do NOT have to be FDA approved in order for you to buy them. I'm personally a little ambivalent about these. Some of the places I've taught in are perfectly happy with them and they certainly got them cheap. if it were me though I think I'd be much more inclined to buy a used U.S. made laser (at least FDA approved) rather than a Chinese one. Yes, it will still cost a bit more - maybe $10-$20K instead of $3.5K - but I'm more confident in consistent quality and access to service - either third party or the original manufacturer. I'm also offended by the intrusiveness of these Chinese companies. Once they have your name and email you'll NEVER get rid of them. They'll never respond to your requests to remove you from lists, and they systematically change their incoming private email addresses so that you can't just block them. I do know people who are happy with them, but I just don't care to deal with them. (at least the way they behave now).

OK .... if you follow my train of thought here and choose a used U.S. Laser (at least FDA approved - there are many good Italian, Israeli, German and other lasers), then this leads us into the next issue:

Sky high "RECERTIFICATION" fees for used lasers.

This originally got my attention several years ago when the National Council on Laser Certification (NCLC - www.LaserCertification.org) started getting calls from office practices about getting their used lasers "Certified". What?? You don't "Certify" lasers, you only Certify operators such as Laser Safety Officers, Aesthetic Laser Operators, Laser Repair Technicians, etc.. After a few of these calls I was finally able to start putting the pieces together and figured out what was happening. Office practices were buying good used lasers for only $10-$15K (that would ordinarily cost them $85-$100K new). When they called to have routine service or repairs done on them by the manufacturer they were being told that the company could NOT work on their equipment unless it was "Recertified" first. The company would do this but the fee was more than $30,000 in many cases, and this is BEFORE any work was done. The implication to the people I spoke with was that this was some sort of regulatory legal requirement and had to be done first. Bull-crap (to be polite). I understand the market realities of having to compete against good used equipment with expensive new lasers (which are always better). However if the company wants charge these fees I'd be happier if they'd just call it for what it was - essentially just telling the customer that since they didn't buy it from the company, that the company first needed to recoup some of the losses in missing that sale and would therefore charge them $30K up front, and then sell them service calls at regular rates. They could even rationalize this in that their regular service rates were low because they came with a new or used laser sale, and without that they'd have to charge them more for the service. I wouldn't like that choice but at least it's honest. But then again competition kicks in. That doesn't happen with a used car, and it shouldn't happen with a laser either. My real problem with this is that people are being misled to believe that this is some sort of regulatory requirement that

must be met and this is not true. If you read through the Federal Laser Product Performance Standard (Federal Law on manufacturers), it does clearly state that manufacturers must CERTIFY their laser as to the ANSI hazard class of the device (i.e. class IV laser). This is a onetime deal however and once the manufacturer makes the laser and labels it as to ANSI hazard class - IT NEVER HAS TO BE DONE AGAIN. The people I've spoken with have been led to believe that this is some sort of process that has to be done if the laser goes outside the control of the company, but this is not true. If I were in charge of this (which of course I'm not) then I'd just be straightforward and a little more reasonable with the customer. I'd still make money - maybe charge them a $4 or $5K fee - to do an initial assessment and "tuneup" of the laser before I committed to taking it back under a service contract or otherwise. This would not be unreasonable and more importantly would not be misleading. By the way, I've never heard of an independent third party service agent charging a fee to "recertify", but they have charged assessment and/or refurbishment fees.

So what's the positive case for buying new from the manufacturer? PLENTY. It's not just getting a new laser - if you can get a used one that does the same thing then you're always better financially with that. The real reason (listen up manufacturers) is **ALL THE SUPPORT AND GUIDANCE THAT YOU CAN GET FROM THE MANUFACTURER WITH A NEW LASER PURHASE!** Get the entire package. Have them almost GUARANTEE that you'll succeed with the purchase. It's ongoing training, advice, resources, help with marketing, service manuals and access to any lockouts, reasonably priced service support and more. In this sense it's not just a one night stand - it's a marriage - make sure you find a good partner. People make the difference.

PREPARE YOURSELF for knowing what the rules and regulations really are, and then make an informed judgment about what serves YOU best with laser purchases, maintenance and repair.
KNOWLEDGE IS POWER.

A Parting Thought, and Modest Proposal -
What about a solution to this laser service and information issue that would help EVERYONE? - Manufacturer and customer alike? I think there is one but it partly depends on your world point of view and how you incorporate that into business. If you are one of the people that believe that "what goes around comes around", then all we have to do is help each other freely with this information and comply with existing laws and regulations in the process. What we need is a public collective information library for all of the laser operator manuals, service manuals and field service bulletins. Since it's already Federal law that they have to be made available upon request, why not just make it easy and cooperative and post them all on a publicly accessible website? There would be two obvious organizations to help facilitate this as a public service. One is the American Society for Laser Medicine and Surgery (ASLMS), and the other is the FDA itself. The ASLMS is the professional society for medical laser use so it would make some sense for them to organize and run this. It does take time and effort however so they'd need to find someone to spend the time to do it. The other obvious choice would be the FDA itself (the CDRH within the FDA) because they ALREADY require these companies to file these manuals with them when they seek FDA approval. It's all ALREADY there at the FDA and just needs to be organized for easy public access. Imagine that? Since the ASLMS and FDA cooperate with information sharing at the annual ASLMS meeting, maybe this should be formally presented. Just imagine that.