

Surgical CO₂ Lasers

White Paper

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Foreword

LuxarCare has been receiving numerous offers from several overseas surgical laser manufactures and importers to distribute and service their products in the USA and Canada. We studied such offers very seriously; we have inspected and evaluated five different imported surgical lasers that we have acquired as trade-ins during 2006-08.

In this white paper we describe the differences between the state-of-the-art American made surgical CO₂ lasers and imported (e.g. Chinese made, etc.) lasers. We present our findings and reasons why we do not recommend any of the inspected imported lasers neither to any Luxarcare customers nor any other surgeon in North America.

Introduction

Thousands of veterinarians around the globe are adopting [state-of-the-art CO₂ laser surgery](#) that is in high demand by their clients - the pet owners. Laser surgery brings tremendous clinical benefits to patients and also rewards with a very substantial additional revenues not available otherwise.

Ironically, *and largely unknown to general public*, North American veterinarians are being persuaded by countless importers and resellers into purchasing *low-quality* clones of antiquated and repackaged glass tube, articulated arm surgical CO₂ lasers of older American designs from the 1980's.

At the same time, *high-quality* state-of-the-art American made lasers (new www.aesculight.com and refurbished www.luxarcare.com) are making a strong comeback after a devastating series of Mergers and Acquisitions in Medical Laser Industry during 1997-2000, that have nearly decimated the surgical CO₂ lasers' manufacturing base in North America when all three major American surgical CO₂ laser manufacturers Surgilase, Luxar and Coherent Medical were purchased and shut down by Lumenis by 2001.

One could only wish that more North American veterinarians would evaluate American made lasers too when considering to purchase surgical lasers for their practices - the difference in technology and quality between the imported (mostly Chinese) and American-made lasers is vast.



Figure 1. The difference between old and new technologies is vast

Surgical CO₂ laser's building blocks

For decades, the CO₂ Laser undisputedly remains the Gold Standard of surgical lasers because of its unique wavelength, versatility, precision and mature technology. Tens of thousands of surgical CO₂ Lasers are used daily across North America in various specialties at veterinary and human medical facilities. Consider the world's most popular surgical CO₂ laser - Luxar's LX-20 series with the first ever flexible waveguide fiber beam delivery (www.luxarcare.com). This brand has the largest installed base (over 12,000 units), which testifies to its design as one of the best and the safest. This laser's design includes - see [Figure 2](#) - the following critical components:

- 1 *all-metal laser tube;*
- 2 *low voltage 32 Volts DC and RF power supplies;*
- 3 *heat exchanger;*
- 4 *beam delivery system;*

- 5 laser power meter;
- 6 beam attenuator - shutter;
- 7 devices monitoring the performance of all critical components 1 thru 6 above;
- 8 user control panel;
- 9 software program controlling all the hardware items 1 thru 8 above; and
- 10 safety 'watch-dog' software program monitoring items 1 thru 9 above.

Among the only negative features of Luxar laser design are the antiquated (1994 design) user control panel, limited average CW and SuperPulse laser powers (20 Watt and 10 Watt respectively) and inefficient heat exchanger (relying on natural air convection).

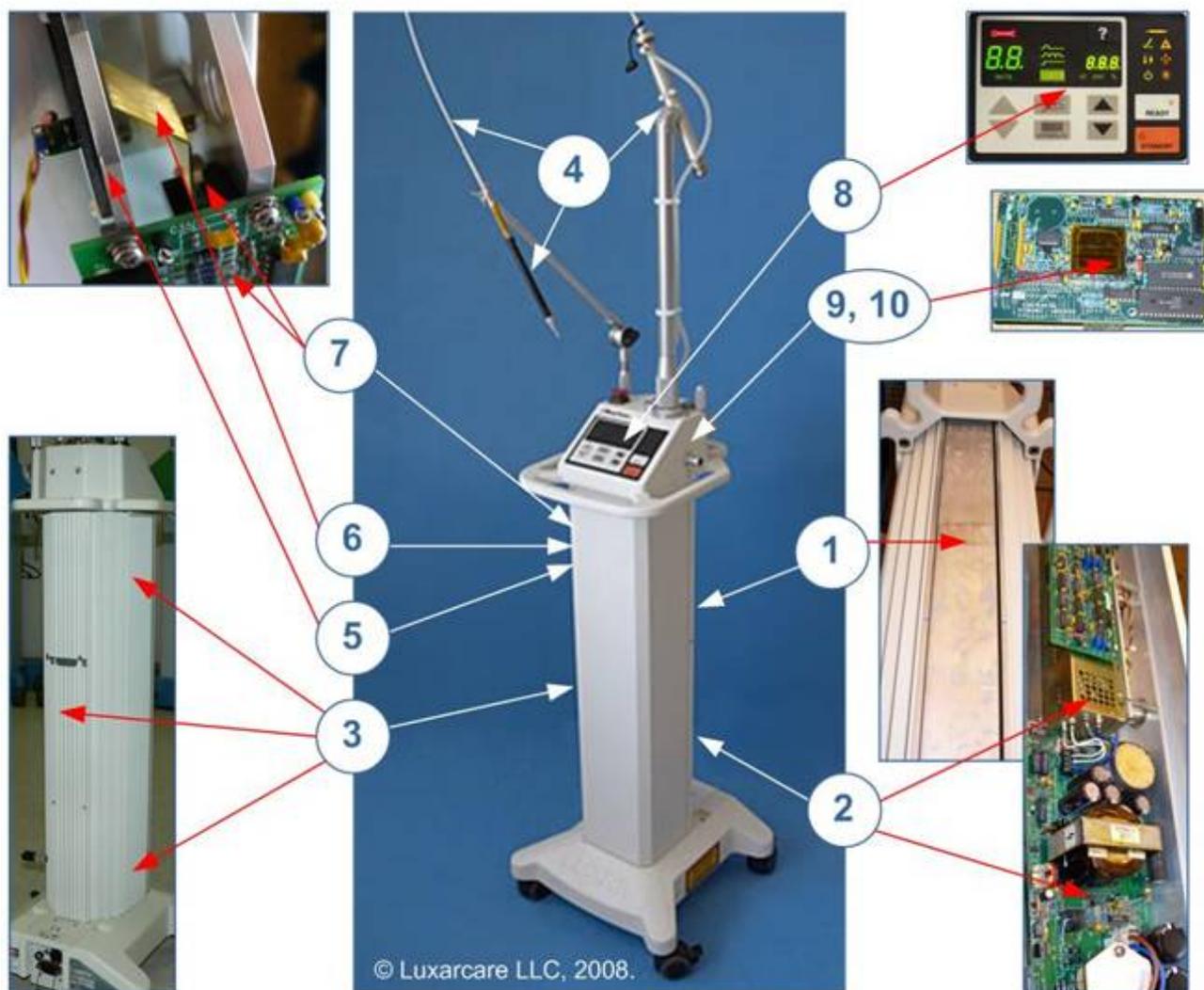


Figure 2. Luxar's 20 Watt surgical CO₂ laser. The best selling surgical lasers during 1995-2005

State-of-the-art American technology

Consider the [next generation of flexible fiber surgical CO₂ lasers](#) - [Aesculight](#) AE-10 and AE-20 ranging in power from 12 to 50 Watts (see [Figure 3](#)). Designed by many former Luxar laser engineers currently employed with Aesculight, these lasers feature a similar set of critical components 1 thru 10 above. Unlike the Luxar laser, Aesculight lasers feature a far more powerful laser source

(up to 50 Watt regular CW operation and 30 Watt SuperPulse mode) and an exclusive highly efficient active cooling heat exchanger. All models are covered by 3 year 'bumper-to-bumper' warranty. Among new features is unique touch-screen user control panel allowing for custom controls over laser, smoke evacuator, air purge, READY mode time-out delays, and user defined custom laser power settings. The icing on the cake is Aesculight built-in digital compendium of over 100 surgical laser procedures including text, images and videos. Aesculight lasers are sold as scalable and upgradeable surgical platform allowing for inexpensive future upgrades for just a price difference between the two respective models.

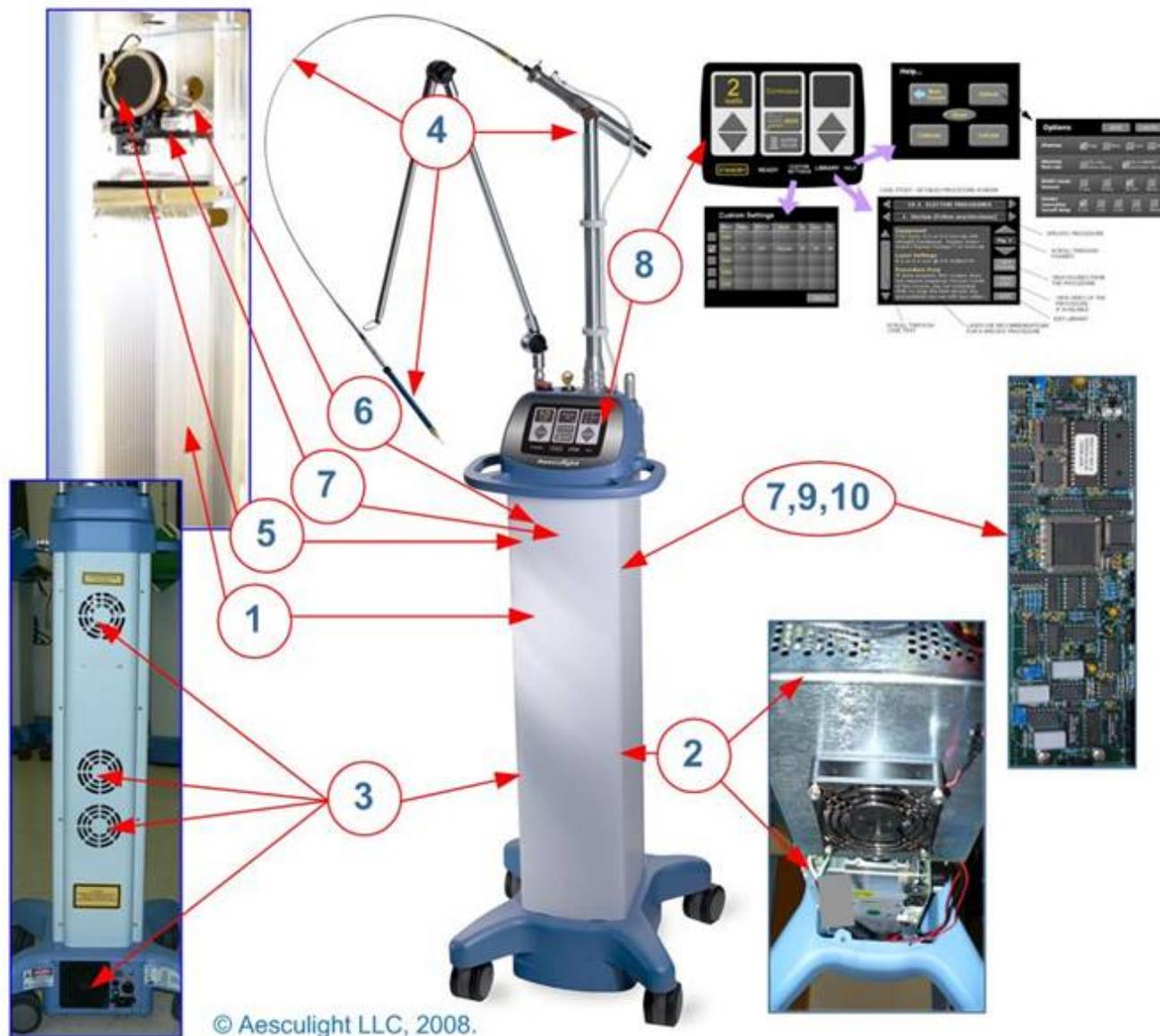


Figure 3. Aesculight 50 Watt surgical CO₂ laser. The only American made veterinary surgical CO₂ laser

How do imported lasers compare to American-made lasers?

We have inspected five different imported surgical lasers that we have acquired as trade-ins during 2006-08: two Korean-made lasers (one of which is shown in [Figure 4](#)) sold by **Union Medical Laser**; two Chinese-made table-top lasers shown in [Figure 5](#) distributed by **Union Medical Laser**, **Cutting Edge Surgical Lasers** and other importers; and one imported Italian made laser shown in [Figure 6](#) sold by **Cutting Edge Surgical Lasers**.

All five imported trade-in laser feature bulky antiquated (1980's technology) articulated arms and antiquated fragile high

voltage (over 10,000 Volts) glass laser tubes (1960s technology) with flowing liquid required to prevent the glass from cracking under the intense heat generated by the plasma inside the glass tube.

Upon inspecting the laser shown in [Figure 4](#), it was discovered that it was missing the beam attenuator (or shutter) and the laser power meter. And yet, in 2000 this laser model was approved by the FDA for use on human patients in spite of the fact that FDA's own regulations (CFR Title 21 Part 1040) mandates both the beam attenuator and the laser power meter to be an integral part of a medical laser. Upon inspecting yet another Korean-made trade-in laser, similar to the one shown in [Figure 4](#), it was discovered that beam shutter and laser power meter were also missing in its design. Our conclusion is that:

- 1 *These inspected imported lasers are unsafe for any medical, veterinary or industrial users (due to missing beam attenuator - shutter), and*
- 2 *FDA was wrong clearing these imported lasers for medical use (due to missing power meter and shutter).*

Upon inspecting two lasers shown in [Figure 5](#), it was discovered that they do have the beam-attenuator (shutter); however safety devices monitoring and verifying the performance of the shutter are absent. Also absent in these imported lasers is the laser power meter.

Upon inspecting the laser shown on the right-hand side in [Figure 6](#), it was discovered that both the laser power meter and the beam attenuator (shutter) are present, as well as shutter monitoring safety devices.

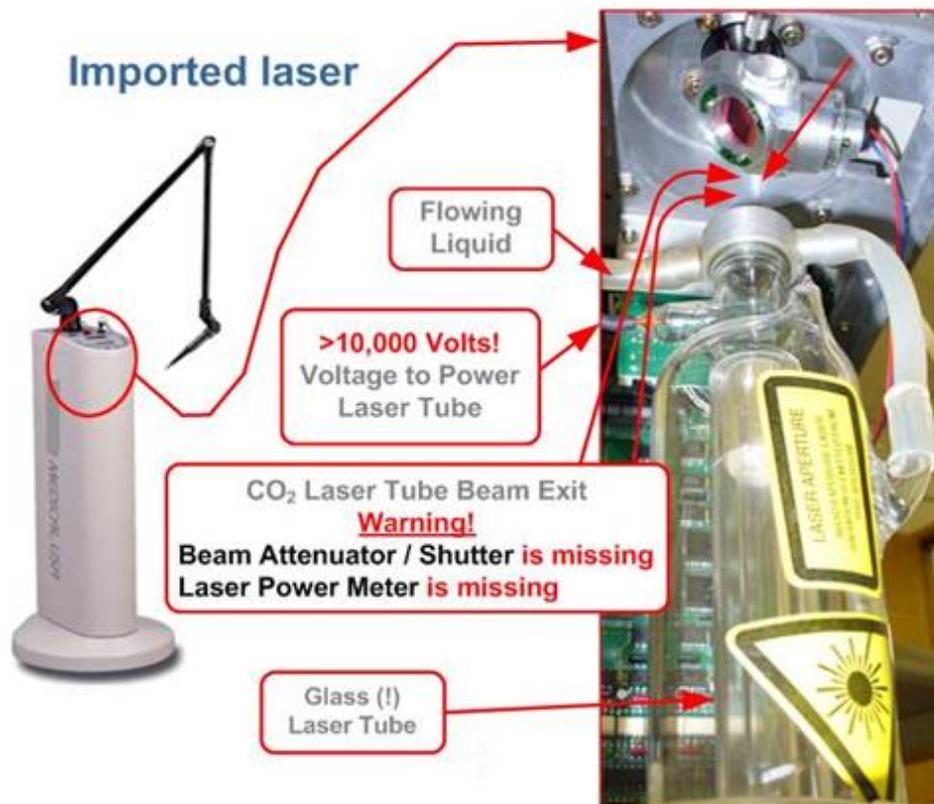


Figure 4. Imported 25 Watt surgical CO₂ laser. Model UM-L25 (and similar private labeled imports) is distributed in USA and Canada by Union Medical Laser and others

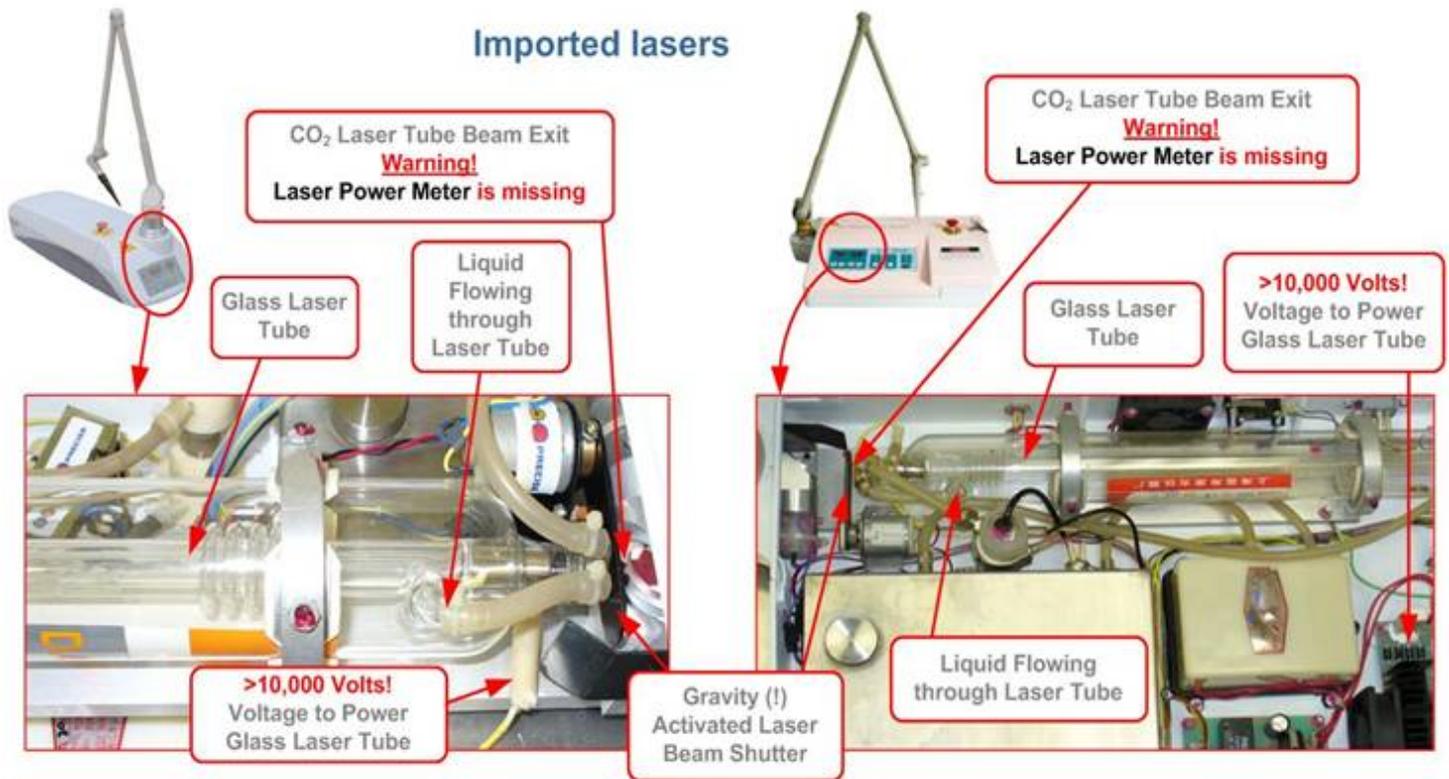


Figure 5. Imported table-top surgical CO₂ lasers.

Left - this and similar models are imported into USA and Canada by Union Medical Laser (UM-L15) and Cutting Edge Surgical Lasers and many other importers. Right - an older variation of the laser shown on the left; it is still being sold in the USA and Canada by many importers

Aesculight

USA made
50 Watt laser

Exclusive Patented Rugged Flexible Fiber

Pen-Like Sterilizable Handpiece

All Metal Laser Tube

Low Voltage 32 Volt DC Power Supply

Forced Air Cooling

US made state-of-the-art laser uses flexible fiber with pen-like handpiece and contains rugged air-cooled all-metal laser tube powered by low-voltage 32 Volts power supply

Flowing Liquid filled Glass Laser Tube

Glass Tube Laser with Articulated Arm

Imported
30 Watt laser

Articulated Arm Generic 1980's Technology

Bulky Handpiece

DANGER
HIGH VOLTAGE WHEN OPEN (20 KV)
Power Supply

Liquid Tank

Liquid Pump

Liquid Cooler

This imported laser uses bulky articulated arm with bulky handpiece and contains Glass Laser Tube filled with Flowing Liquid and is powered by 20,000 Volts Power Supply

Figure 6. Side by side comparison of all-metal tube fiber waveguide CO₂ laser:

Aesculight vs. imported glass-tube articulated arm laser distributed in the USA and Canada by Cutting Edge Surgical Lasers and other importers

How important a built-in laser power meter is for a surgical laser?

FDA regulations require laser power meter on medical lasers and do not require presence of laser power meter on non-medical laser (FDA CDRH Title 21 Part 1040.11 defines 'medical laser' as such used on humans). However, veterinary laser surgeons would surely understand that accurate control of laser power affects such important aspects of laser surgery as thermal damage to and charring of the soft tissue. **Therefore, those veterinarians who own imported lasers shown in [Figures 4 and 5](#) might not feel comfortable knowing that such lasers are not safe enough for use on human patients, and yet such lasers are used on animal patients.**

'Internal calibration'

One can certainly appreciate the joke in the claims by some importers that their glass tube, articulated arm lasers can be 'internally calibrated'. This is simply **technically impossible** for lasers shown in [Figures 4 and 5](#) **since these lasers don't have the laser power meter to measure the laser power with!** Even though the more expensive imported laser in [Figure 6](#) does include an on-board laser power meter, there is nothing in its design for the end-user to verify the integrity and functionality of the seven mirror articulated arm: the alignment and the integrity of all seven mirrors can only be verified at the factory or by the trained field service engineers.

Laser cooling technology

Notably missing on lasers shown in [Figures 4 and 5](#) are the heat exchangers. The CO₂ laser is only 10-20% efficient; hence 80-90% of electrical energy is transformed directly into the heat inside the laser tube and the laser system. This waste heat needs to be removed, otherwise the laser overheats and the laser power deteriorates during operation. Since lasers shown in [Figures 4 and 5](#) do not heat exchangers, these lasers cannot be operated for extended period of time without overheating and subsequent laser power deterioration! ***Ironically, designers of lasers shown in [Figures 4 and 5](#) have made laser overheating and laser power deterioration a 'non-issues' by simply removing laser power meter! Why bother measuring laser power!***

Beam delivery technology

Flexible fiber waveguide lasers shown in [Figures 2 and 3](#) became dominant technology since mid-1990s. Rugged and long-lasting flexible fibers enable compact and ergonomic handpieces to have scalpel-like feel and featuring pin-point accuracy as well as enhanced flexibility and accessibility for surgeons. On the contrary, articulated arms shown in [Figures 4, 5 and 6](#) are an old technology (developed during 1970s - 1980s) and are in use by surgical CO₂ laser manufacturers who do not have access to new proprietary flexible fiber waveguide technology. Besides convenience of using flexible fiber vs. bulky articulated arms, the flexible fiber has an added safety benefit and advantage: ***fiber can be conveniently and inexpensively calibrated at any time by the user. The articulated arm can only be calibrated at the factory or by trained field service engineers.***

Laser tube technology

Rugged and reliable all-metal RF excited CO₂ laser technology is the dominant technology in medical (tens of thousands installations) and industrial (hundreds of thousands installations) laser applications in power range from 10 - 500 Watts. This is the **ONLY** proven and reliable technology allowing for fast and inexpensive service in highly demanding (24-7-365) industrial settings for cutting, welding, engraving, printing, marking and coding etc. Since **all-metal technology** is almost exclusively owned and manufactured by USA-based companies (including [Aesculight](#)), **it is not available to the importers of lasers shown in [Figures 4, 5 and 6](#).** In contrast to all-metal CO₂ lasers, antiquated fragile glass tubes (1960s technology) are difficult to service and they cannot operate without flowing liquid needed to prevent the glass from cracking under the intense heat generated by electric discharge plasma inside the laser tube. A very high voltage, **over 10,000 Volts**, is required to operate plasma in such glass tubes; this very high electrical voltage presents a unique liability issue for laser service companies and their personnel. Neither eroded

electrodes nor metal sputtered glass tube walls are serviceable - which often necessitates laser tube replacement rather than repair! These and many other reasons (difficulties with glass tube plasma pulsing and turning on, severe limitations on laser pulse width, laser power stability, laser beam quality, etc) have allowed **all-metal lasers to replace glass tube lasers in virtually all industrial and most medical applications since mid-1990s.**

Laser Warranty

Some of the imported lasers, such as shown in [Figures 4](#) and [5](#), have laser power monitoring and other safety features simply *disabled*; this allows importers to claim an arbitrary long warranty period, since laser tube performance is not being monitored. As a result, the so called '**warranty**' for some imported lasers is often meaningless. Worth noting that the manufacturer of the more expensive glass tube laser shown in [Figure 6](#) provides an on-board laser power meter and its warranty is only 1 year. In contrast, the cheaper glass tube laser shown in [Figure 4](#) is sold with up to 5 years of warranty - the most likely explanation is that this laser simply lacks the laser power meter to even detect any deterioration of the laser tube power; one might wonder why its warranty is not 10 or 50 years since such warranty won't be affected by laser tube performance deterioration!

International Laser Safety Compliance Certifications

Some importers misrepresent their products as compliant with relevant international safety regulations. For instance, one Chinese manufacturer is representing its surgical CO₂ lasers as a CE certified product - see [Figure 7](#). Upon closer examination, however, one can easily uncover that 1) CE standards EN 60335-1 and 60335-2-23 quoted in such certificate are only applicable to *HOUSEHOLD* appliances such as curling combs and irons, hair- and hand-dryers, etc; and 2) quoted CE standards explicitly declare that they are not applicable to any 'appliances intended for medical use'. Sadly enough, there are numerous importers in North America already peddling these and other similar devices to many thousands of unsuspecting American veterinarians.

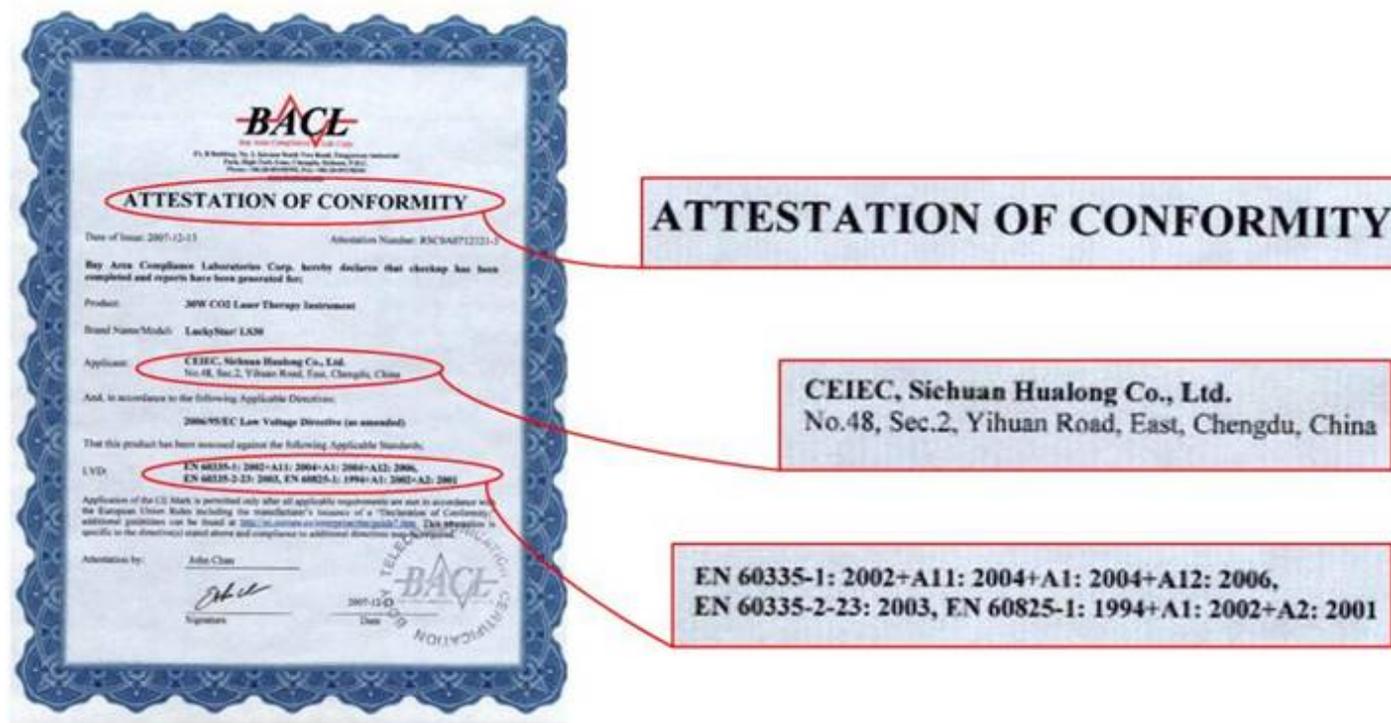


Figure 7. Chinese-made CO₂ laser's 'Attestation' certifying that it conforms to European Union (CE) standards for *HOUSEHOLD* appliances such as hair-dryers

Conclusion

One could only wish that more North American veterinary surgeons will recognize some of the foreign made glass-tube, articulated arm surgical lasers for what they truly are: poorly and sometimes unsafely (e.g. imported laser shown in

[Figure 4](#)) repackaged clones of antiquated and outdated designs from 1980's.

Appendix

The summary of specifications: imports vs. state-of-the-art American made

Brand	—	Accuvet (trademark of Lumenis)	Luxarcare	Aesculight
Laser System Technology	Articulated Arm / Glass Laser Tube	Flexible Fiber / All Metal Laser Tube		
Sold in the USA by	Importers	US subsidiary	Service Provider	Manufacturer
Manufacturing Location	China, Korea, Asia, Europe	Israel	Refurbished in USA	USA
Laser Tube Service Location ¹	China, Korea, Asia, Europe	Israel	USA	USA
Number of Models	1-2 per importer	3	3	9
Comply w USA CFR Title 21 Part 1040.10	some do not ²	Yes	Yes	Yes
Comply w USA CFR Title 21 Part 1040.11	some do not ²	Yes	Yes	Yes
Laser Power CW ³	No Distal Calibration	20 W	20 W	50 W
Laser Power SP ³	No Distal Calibration	10 W	10 W	25 W
Laser SuperPulse Peak Power ³	No Distal Calibration	> 50 Watt	> 50 Watt	> 100 Watt
Laser Tube Technology ⁴	Glass	All Metal	All Metal	All Metal
Laser Tube Cooling ⁴	Flowing Liquid	N / A	N / A	Forced Air
Laser Tube Voltage ⁴	>10,000 Volts	32 Volts	32 Volts	32 Volts
Beam Delivery Technology ⁵	Heavy & Bulky Arm	Flexible Fiber	Flexible Fiber	Flexible Fiber
Handpiece ⁵	Heavy and Bulky	Pen-size	Pen-size	Pen-size
Focal Spot Size(s), mm ⁵	One fixed size	.3, .4, .8, 1.4	.3, .4, .8, 1.4	.25, .4, .8, 1.4, .4x3
Laser Power Pulsing ⁶	Slow	Fast	Fast	Fast
Repeat, Single Pulse & Custom Programs ⁶	Very limited	Multiple	Multiple	Advanced
Super Heavy Duty SP Cutting Programs	No	No	No	Yes ⁷
Self-Diagnostic Test Program	No	No	No	Yes ⁷
Integrated Smoke Evacuator Controls	No	No	No	Yes ⁷
Custom Smoke Evacuator Time-Outs	No	No	No	Yes ⁷
Custom Air Purge Flow	No	No	No	Yes ⁷
Custom Air Purge Time-Outs	No	No	No	Yes ⁷
Custom "READY" Time-Outs	No	No	No	Yes ⁷
Power Upgrades without Trade-in	No	No	No	Yes ⁷
Software Upgrades without Trade-in	No	No	No	Yes ⁷

¹ Technical support for some imported lasers is often poor.

² Some imported articulated arm lasers in use today are inferior clones of 1970-80s American designs. Certain safety features on some imported lasers in use today are either absent or are of sub-standard quality, which may increase the risk of harming patients and medical staff.

³ Aesculight's greater power allows for faster cutting and ablation speed as well as for less char and thermal damage. Imported, articulated arm lasers in use today do not provide distal power calibration; some such lasers lack internal calibration – this may increase the risk of harming patients through thermal damage and excessive char.

⁴ Outdated and fragile glass laser tubes sold by importers need liquid coolant to avoid cracking under heat. Glass tube lasers are almost completely phased out of industrial CO₂ laser applications because fragile glass, liquid coolant and very high operating voltage (over 10,000 Volts) make these lasers difficult to operate and service.



⁵ Articulated arms were developed in the 1970s and are far less versatile than flexible fibers.

⁶ Glass tube lasers exhibit very poor pulsing performance.

⁷ Exclusively by Aesculight – many new and unique control features make laser surgery even easier and more enjoyable.

Figure 8. The summary of specifications of American-made and some imported surgical CO₂ lasers