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## Control measurements for lasers in physiotherapy

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**ABSTRACT.** *In physical rehabilitation, is diffused the skin irradiation with near infrared laser at a fluence below 140 J/cm<sup>2</sup>, achieving a bio-stimulating effect that is due to the absorption of radiation in mitochondria rather than the simple heating of tissues. In order to deliver radiation without thermal damage of the skin, are used radiation pulses which duration does not allow heat accumulation and propagation far from the irradiated target; this requires laser sources with average power below 10 W implying a safety classification as “potentially dangerous for eye and skin”, or “class 4” according to the applicable international standards. In this paper, 6 laser therapy devices, of 5 different manufactures and models have been analyzed from the point of view of actual radiation output and user safety. In each case, one or more of the characteristic declared by the manufacturer in the user manual have been found different from the actual measured value. The actual accessible energy levels have been found to be complying with risk class 3B. The impact of the new version of the Standard IEC 60825-1 (2014), is also discussed, considering in particular the possible classification in the new class 1C, and the maximum permissible levels for pulsed lasers. An extension of the measurement protocols is proposed in order to assure effective and safe use of laser in physical therapy.*

**Key words:** laser therapy, infra-red, safety.

**RIASSUNTO.** MISURE DI CONTROLLO PER I LASER IN FISIOTERAPIA. Nella riabilitazione fisica viene fatto un certo uso dell'irradiazione della cute mediante laser nell'infrarosso vicino con fluenze inferiori a 140 J/cm<sup>2</sup>, ottenendo un effetto di biostimolazione dovuto all'assorbimento della radiazione nei mitocondri più che al semplice riscaldamento dei tessuti. Per erogare la radiazione senza danneggiamento termico della cute si usano impulsi la cui durata non permette l'accumulo del calore e la propagazione dello stesso a distanza dal bersaglio irradiato, il che richiede sorgenti laser con potenze medie inferiori a 10 W che implicano una classificazione di sicurezza come “potenzialmente pericolose per l'occhio e la pelle” o “classe 4” secondo le norme internazionali applicabili. In questo lavoro sono stati analizzati 6 apparecchi per laser terapia di 5 costruttori e modelli diversi dal punto di vista della radiazione effettivamente erogata rispetto alla sicurezza per l'operatore. In ciascun caso una o più delle caratteristiche dichiarate dal costruttore sono state riscontrate difformi dai valori effettivamente misurati. I livelli di energia accessibile reali sono risultati compatibili con la classe di rischio 3B. L'impatto della nuova versione della Norma IEC 60825-1 (2014) è discusso, considerando in particolare la possibile classificazione nella classe 1C e i livelli massimi permessi per i laser a impulsi. Viene infine proposta un'estensione dei protocolli di misura allo scopo di garantire un uso sicuro ed efficace del laser in terapia fisica.

**Parole chiave:** laser terapia, infrarosso, sicurezza.

### Introduction

In physical rehabilitation is diffused the skin irradiation with near infrared laser radiation as ambulatory treatment.

A bio-stimulation effect, due to the absorption of radiation in mitochondria, is described in literature; the chromophores involved seem to be porphyrin and cytochrome-c-oxidase (1) and the production of reactive oxygen species (ROS) seems to play a fundamental role. In high concentration, ROS are toxic for cells but in low doses inflammatory processes appear to be modulated.

Accordingly, in vitro studies showed (2) that a valuable bio-stimulating effect can be observed when the delivered fluence ranges from 2 to 5 J/cm<sup>2</sup>; cell death is reported when this value is exceeded.

Pain relief can also be obtained (3), actually depending on the absorption of radiation in the visible-near infrared range rather than on particular effects at a given wave length.

It is well established (4) that also light emitting diodes (led) sources can achieve the same effect; indeed it should be noted that leds share with lasers the ability to deliver light with a narrow emission spectrum even if not with the same high energy pulses.

The role of wavelength is another focal point in this discussion.

The maximum penetration depth in human skin is known to occur at about 660 nm, corresponding to red light (5). Shorter wave lengths can induce higher ROS production but with even toxically high concentration (6), photochemical injury to skin and poorer penetration depth as in the case of ultra violet.

Interaction models (6) and clinical evidence (7) encourage the use of near infrared, namely in the range 800 - 950 nm but we have found no definitive evidence in literature of the reason why actually most of physical therapy laser devices operate in this range rather than in visible.

Since the healing effect does not depend on the temperature increasing (8), it is important to limit the heat accumulation.

An excess energy absorption in the healthy skin could actually lead to an overheating of the irradiated target; a way to increase energy without accumulating heat in excess, is to

deliver radiation in pulses, as can be shown considering well known aspects of light-tissue interaction for human epidermis (9, 10).

Further heat sparing can be achieved in two ways: delivering the radiation over a wide area in a fixed position, thus reducing irradiance, or moving the treatment beam, by a motorized mirrors system, to sweep back and forth over the target area, the latter is often referred to as “scanning treatment”.

Treatment parameters such as target extension, energy, power density and treatment time must be set depending also on clinical considerations taking into account the condition of single patient including skin pigmentation that influences the reflectance of radiation (11).

As a result, the lasers used in physical therapy have typically these characteristics:

Active medium	diode, normally GaAs
Wavelength	800 - 950 nm
Mean power	1 - 5 W
Pulse Repetition Factor (PRF):	continuous to 100 kHz
Irradiance on target	0,05 - 2 W/cm <sup>2</sup>

Comparing these parameters with power and energy densities delivered by lasers in surgery, has brought to refer to laser physiotherapy as Low Level Laser Therapy (LLT), this definition is widely used also in the references.

Nonetheless, most of LLT sources, according to the IEC Standard 60825-1 about laser safety (12), are classified by the manufacturers in the risk class 4. Such lasers are dangerous for eye and skin and could cause fire and explosions if improperly used.

For this reason, the same standard recommends the appointment, within the organization that uses the device, of a “Laser Safety Officer” (LSO) “*who has the responsibility for oversight of the control of laser hazards*”.

Another IEC Standard, IEC 601-2-22 (13), applies to the “*safety of diagnostic and therapeutic laser equipment*” indicating a number of parameters to be controlled.

However, LLT devices are devised to be applied far from the patient’s eye, in close contact to skin, in such a way that, if correct operating procedures are followed, there is no risk for the therapist.

Accordingly, following the new edition, of the IEC 60825-1 (12), these lasers could be classified as 1C provided they were equipped with a switch turning off the beam when not in contact with the skin.

It must be pointed out that the quoted standards require the control of some issues, such as power output and aiming beam alignment, relevant for the safety of the user and the patient as well, however other aspects, such as pulse duration and frequency repetition, that seem to be important for LLT effectiveness are not considered.

In this work, 6 physiotherapy lasers, currently in use in the Fondazione Salvatore Maugeri rehabilitation centres in northern Italy, have been evaluated, verifying the compliance of the radiation output with the information supplied from the manufacturers in the user’s manuals and with the applicable standards; the possible 1C classification of each laser is discussed as well.

Finally, an extension of the periodic checking protocol aimed at the performance test of laser therapy devices is suggested.

## Materials and methods

The laser sources listed in Table I have been considered. All the lasers have been in use in the physiotherapy departments of each centre from several years as indicated in the table.

Having considered the reference values recommended in the standards, the instruments and methods have been chosen more to be easily applied by the LSO in his routine activity than to obtain a reference laboratory measurement of each parameter.

To obtain the geometrical characteristic of the beam, a simple and safe way to visualize the infrared beam spot is to use cameras having a good sensitivity also in the region around 1100 nm useful for near infrared laser visualization, like the ones mounted on current mobile phones.

It must be pointed out that, for normal photographic imaging, the infrared sensitivity is an unwanted effect due to poor detector filtration, so higher cost and quality mobile phones could be less useful than older or low cost models.

**Table I. Physiotherapy laser devices analyzed in the work**

	Fondazione Maugeri Site	Manufacturer	Model	Manufacturer’s classification EN60825-1	In use from
Laser 1	Genova	FISIOLINE Veruno (CN), Italy	ICL 60 plus	4	07/04/05
Laser 3	Tradate (VA)				20/03/07
Laser 2	Pavia	Easytech srl Borgo San Lorenzo (FI), Italy	Laser <sup>3</sup>	4	31/01/02
Laser 4	Castelgoffredo (MN)	Mectronic Medica S.r.l. Grassobbio (BG), Italy	Opton FCZ	4	05/06/02
Laser 5	Lumezzane (BS)	ASA s.r.l. Arcugnano (VI), Italy	Comby 3	4	22/12/03
Laser 6	Lumezzane (BS)	FISIOLINE Veruno (CN), Italy	ICL 60 micro	3B	21/12/99

To verify the feasibility of measurements in the current health organizations, the beam shape has been checked with an IR camera as well. The camera used was a Point Grey Chameleon BW, with high sensitivity Sony EXview HAD CCD sensor ICX445.

According to the sensor data sheet (15), the Chameleon camera has a sensitivity at 900 nm which is worth 1/5 of that in the visible range.

For Typical mobile phone cameras (16), the sensitivity in the IR range is 1/7 of that in visible.

As a result, the professional camera generates an image of the scattered laser beam too saturated to be useful.

Anyway, whatever the camera used, it should allow to record also short movies, because some lasers have a fixed duty cycle causing the treatment spot to blink.

The beam spot, both of treatment infrared beam and, when available, of visible aiming beam, have been projected on a squared chart and recorded with the camera. This is the simplest method to use, because putting the camera directly in front of the beam implies the use of condensing lenses, properly aligned. This is quite difficult to achieve in a medical environment.

The divergence  $\theta$  of the beam has been estimated evaluating spot diameter at two different values of source to target distance:

$$\theta = 2 \arctg \left( \frac{d_{63} - d_{63}^1}{2r} \right) \quad [1]$$

where

$d_{63}$  diameter containing 63% of the beam power in the target in position 0

$d_{63}^1$  diameter containing 63% of the beam power in the target position 1

$r$  difference in distance from the two positions.

Considering the uncertainties in the diameter determination, beam divergence can be determined with an estimated accuracy of 30%, especially when the treatment spot can only blink and the spot diameter must be evaluated extracting a single frame from a movie.

The alternative, would have required the  $d_{63}$  measurement by the knife-edge method (17) with a power meter

and the source mounted on an optical bench, but this is not practical for the scope of this work and conversely a beam profiler is even of more difficult availability.

Beam power has been measured by a Nova II power meter (Ophir Optronics Solutions Ltd Jerusalem, Israel) with thermopile detector 30A-P-DIF-V.

The detector is 16 mm in diameter with  $\pm 5\%$  accuracy and flat wavelength response from 200 to 6000 nm.

Aluminum frames with 3.5 and 7 mm diameter holes have been used to partialize the detector to evaluate AELs for eye and skin.

The wavelength has been checked diffusing the beam with a Bruel & Kjaer Type 1100 white sample (Brüel & Kjør Nørsum, Denmark) and measuring the diffused spectrum with an Ocean Optics HR4000 spectroradiometer (Ocean Optics Inc., Dunedin, FL - USA).

The beam time profile has been determined with an ET2000 photodiode (Electro-Optics Technology Inc. Traverse City MI - USA) connected to a GW Instek GDS-2104 digital storage oscilloscope (Good Will Instrument Co., Ltd. New Taipei City Taiwan).

## Results

Beam divergence and wavelength actual values have been found to be in accordance with the data declared by the manufacturer in the user's manual.

Incompliance has been found in aiming and treatment beam alignment.

In Figure 1 aiming beam and treatment beam alignment is shown for laser 2 at different target distances. In case of fixed spot, short distance treatment, which would involve a safer condition, the aiming beam does not points out correctly the irradiated area.

This condition would pose a safety problem for the patient in case of treatment near a critical region such as a nevus, skin tumor, tattoo or other counter indicated region.

In this case, there is no compliance with IEC 601-2-22 standard (13) at least in case of fixed treatment. In scanning treatments has been found that the beams are aligned as in Figure 1 b).



**Figure 1. Treatment beam and alignment beam for laser 2, at 3 cm a) and at 38 cm b); the blue lines have been traced to evaluate spot diameter**

In Figure 2, aiming beam and treatment beam are shown for laser 5, in case of fixed treatment. There is compliance to the standard as for the beams alignment but the spot shape is not uniform, probably due to a fault in one or more diodes of the array that makes the laser source.

In Figure 3 the two beams of laser 6 are aligned, the treatment spot is uniform but to take the picture has been necessary to turn off the room illumination.

The standard fixes the maximum AELs for laser aiming beam, thus fixing an upper value to the aiming beam irradiance which in this case is surely respected. Nonetheless, the user does not have a correct indication of the irradiated area.

The data supplied by the manufacturers about the wave-form can be lacking as well.

In Figure 4 is reported the pulse shape recorded setting the laser 2 in “continuous mode”.

Far to be continuous, the output is made of 100 ms pulses spaced by 600 ms, this type of output is often referred to in the user’s manuals as “duty cycle” and is used to limit the average power. For this particular laser, no mention was made in the manual of this fixed duty cycle while was indicated the possibility of setting a “pulse mode”.

The wavelength is 780 nm.

In Figure 5, the pulse mode wave form is shown. Instead of 100 ms pulses, the output is made of 100 ms trains or bursts, each made of triangular pulses with the set frequency.

This is a key information for the calculation of the MPE according to the IEC 60825-1 standard (12).

Since, as seen above, for laser 2 it is possible to be exposed to the treatment beam with the aiming beam pointing out of the eye, a time base of 10 s must be assumed.

a)

b)



Figure 2. a) aiming beam (in the circle) and treatment beam are aligned but the treatment spot is not uniform, b) same laser spot captured by an IR camera

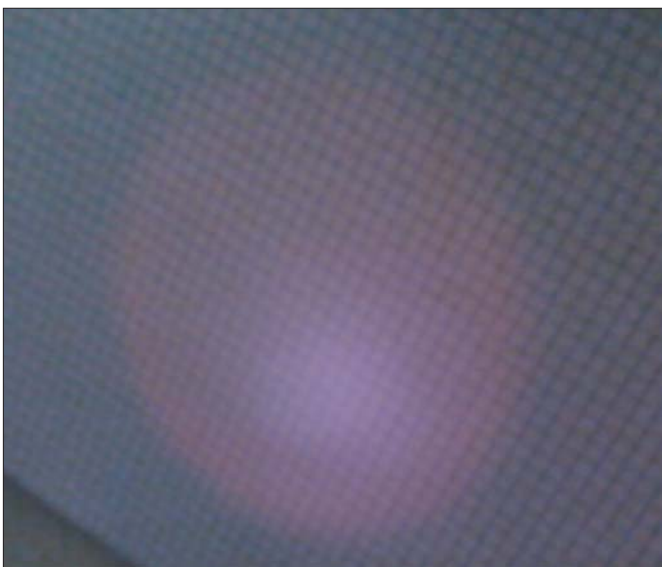


Figure 3. The aiming beam intensity of laser 6 complies with the IEC 60601 standard but the user does not have a correct information about the irradiated area

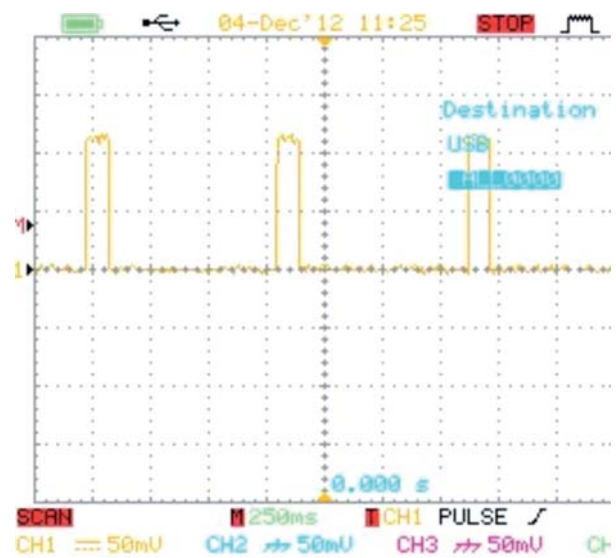


Figure 4. Wave-form output for laser 2 in “continuous mode”, the spacing of 600 ms between 100 ms pulses was not reported in the manual

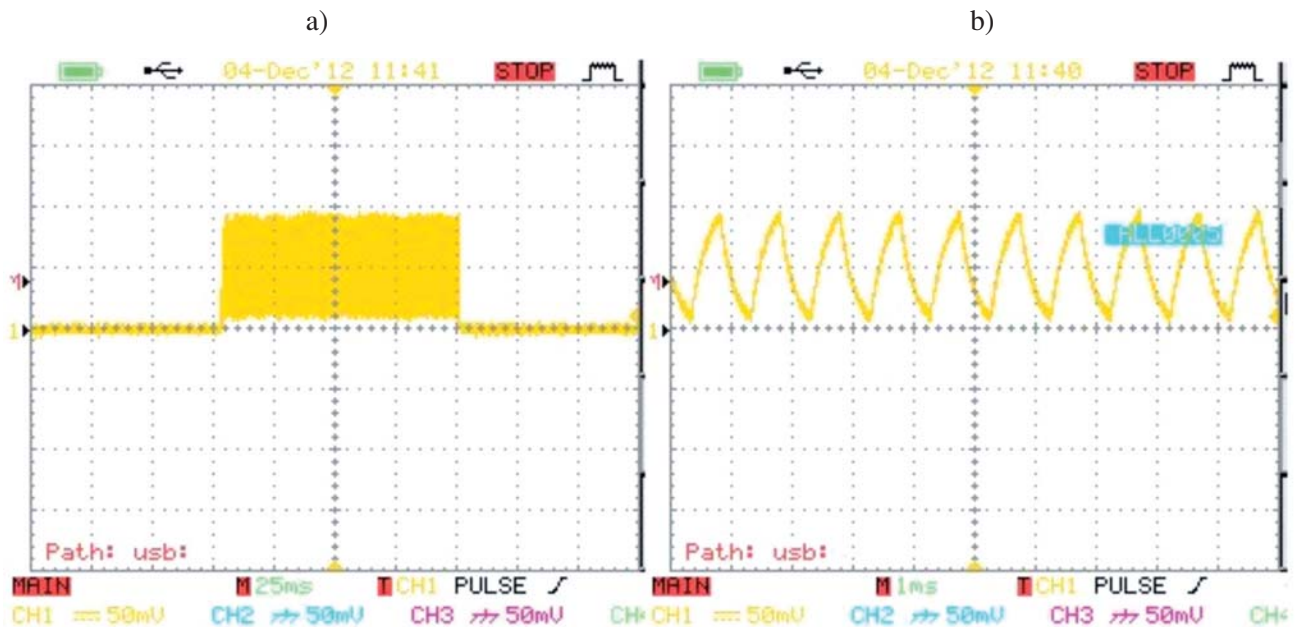


Figure 5. In pulse mode each 100 ms pulse becomes a burst, a) of short pulses of the set frequency b), here at 1 kHz

The Maximum Permissible Energy (MPE) according to the IEC 60825-1 is given by.

$$MPE = C_4 \cdot C_6 \cdot 18 \cdot t^{0.75} \text{ J/m}^2 \quad [2]$$

where  $C_4$  and  $C_6$  depends on wave-length and viewing distance as can be found in the standard.

Let's assume that an unattended patient stares into the source: this can occur at 30 cm distance which, with a 5 mm source diameter, the Standard gives  $C_6 = 11,1$ ; at 780 nm  $C_4 = 1,44$ .

Applying expression [2] for a 10 s exposure to a continuous beam,  $MPE = 97,5 \text{ J/m}^2$  however, if the energy is instead delivered in 100 ms pulses, the MPE must be found comparing the exposure to a single pulse, the mean radiant exposure of the pulses absorbed in the exposure time, and the radiant exposure of a single pulse, multiplied for a coefficient  $C_5$  which depends on the number of the pulses and taking the lowest value.

The resulting MPEs are reported in Table II, where was considered that delivering a 100 ms pulses every 600 ms, leads to a pulse repetition frequency PRF = 1/0,6 = 1,67 Hz.

Therefore, in a 10 s exposure,  $10 \times 1,67 = 17$  pulses are absorbed.

The lowest value is obtained considering the cumulative effect of the pulses in the train by  $H_{\text{sing}} * C_5$ .

Table II. Comparison of the three criteria for MPE, for 100 ms pulses spaced of 600 ms, according to IEC 60825-1:2014

Condition	Exposure time	N of pulses	MPE J/m <sup>2</sup>
Single pulse $H_{\text{sing}}$	100 ms	1	51,41
Mean irradiance	10 s	17	97,54
Pulse train, $H_{\text{sing}} * C_5$	100 ms	17	25,44

Notice that, when, instead of delivering the laser energy by a continuous beam, a so called “duty cycle” is introduced, the delivered energy is actually reduced, however, as was shown above, the applicable MPE must be reduced as well. Moreover, when pulses are introduced, also the values of the coefficients  $C_4$  and  $C_6$  have a dependence from the exposure time so that the calculation must be performed following the standard carefully in a way which cannot be shown here.

When the laser is operated in the declared “pulsed mode”, Figure 5 shows that every 600 ms, a train of 100 pulses of 1 ms is delivered, therefore in 10 s can be absorbed 1667 pulses; the calculation is shown in Table III.

Again, the lowest value is obtained for the pulse train, but more relevant is the comparison with the 2006/25/EC Directive “on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)”.

This Directive, that in the EU countries has the force of law, reports, in Annex II exposure limit values (ELVs) for laser radiation that are coincident with the MPEs contained in the 2007 issue of IEC.

The calculation for 100 ms pulses results in the same values, while for the case of 1 ms pulses, the application of the Directive overestimates the MPE for a factor about two.

Table III. Comparison of the three criteria for MPE, for trains of 100 pulses of 1 ms spaced of 600 ms

Condition	Exposure time	N of pulses	MPE J/m <sup>2</sup>
Single pulse $H_{\text{sing}}$	1 ms	1	0,62
Mean irradiance	10 s	1667	0,37
Pulse train	$H_{\text{sing}} * C_5$	1667	0,12

The operation of a laser in pulsed mode, therefore is very relevant for the risk assessment and should always be characterized.

Since each LLT laser has its own protocol to control power, it is not so easy to compare set and actual power. On device's display, a set of parameters derived from the design values of power and, when applicable, frequency is shown. These parameters can be:

- mean power;
- delivered energy of the whole treatment;
- delivered energy in treatment progress;
- set energy of the whole treatment;
- a combination of all.

However, they are normally higher than the actual value depending on the maintenance state.

With the aim at making a comparison, the following quantity, for each laser, has been calculated:

$$\Delta P_{\%} = 100 \cdot \frac{P_m - P_{th}}{P_{th}} \quad [3]$$

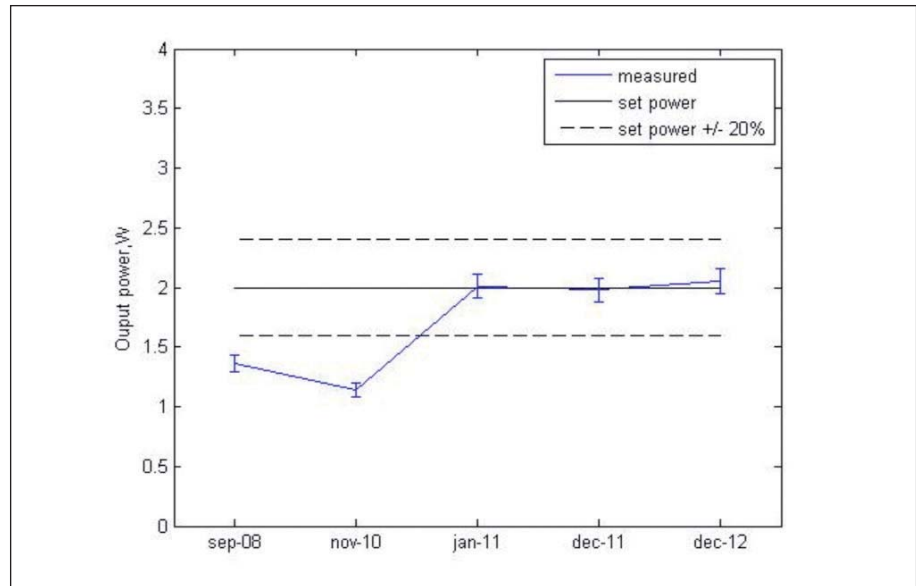
where  $P_{th}$  is the theoretical power value, set on the console or resulting from a calculation based on the set values of PRF, duty cycle and nominal peak power;  $P_m$  is the actual measured value of mean power output.

Since the actual  $\Delta P_{\%}$  for each laser is different varying the level of the set power output, in Table II, are reported the best and worst values of  $\Delta P_{\%}$  obtained for each device; notice that the standard (13) would require this parameter to be  $\pm 20\%$ .

**Table IV. Difference between theoretical and actual power output for each laser, reference is  $\pm 20\%$**

	Best $\Delta P_{\%}$	Worst $\Delta P_{\%}$
Laser 1	- 114	- 120
Laser 2	- 197	- 198
Laser 3	8	- 123
Laser 4	3	127
Laser 5	- 37	- 140
Laser 6	3	- 142

The power output depends also on the maintenance state of the laser: in Figure 6, is shown, as measured in different years, the output power measured setting laser 4 at 2 W. In this setting, the best  $\Delta P_{\%}$  shown in Table IV has been obtained. The power increasing between 2010 and 2011 is due to an extraordinary maintenance of the source that restored original power output.



**Figure 6. Actual power output of laser 2 at 2 W; between 2010 and 2011 the laser source has been replaced**

In Table V, the results obtained for the six lasers are summarized, comparing actual measured parameters with the information supplied in the user's manual.

At least one parameter for each laser does not comply.

**Table V. Comparison between measured and declared parameters**

	Spot shape	$\lambda$	Safety class	Pulse length	Output power within $\pm 20\%$	Aiming and treatment beams alignment
Laser 1	Yes	Yes	No	Yes	Yes	Yes
Laser 2	No	Yes	No	Not reported	Not reported	Not aligned at short range
Laser 3	Yes	Yes	No	Yes	Yes	Yes
Laser 4	Yes	Yes	No	Yes	Yes	Yes
Laser 5	Not reported	Yes	Yes	Not reported	No	Small aiming beam spot
Laser 6	Not reported	No	Yes	Not reported	No	Low aiming light brilliance

### Discussion

The simple mean power measurement required by the standard (13) would not have allowed to detect meaningful deviations of the wave form from design parameters; otherwise, only when power is well below - 20% of nominal output, as shown in Figure 6, clinical staff realizes that the laser could have some problem.

From a safety point of view, the critical issue is that when power is restored to theoretical value, a sudden increasing in laser output occurs, if laser staff is not aware of this, an over irradiation of the patient could result.

**Table VI. Proposal of physiotherapy laser controls in advance of what recommended by IEC 60601-2-22 standard**

Control	Method	Reference value
Aiming beam	Near IR sensible camera	Aiming beam shall be clearly visible under illuminance > 300 lx
Aiming and treatment beam coincidence	Near IR sensible camera	Distance between the centre of the two spots < 50% of the diameter of the larger one
Continuous or pulsed operating mode	Digital storage oscilloscope and photodiode	Compliance to what reported in the user's manual
Pulse duration	Digital storage oscilloscope and photodiode	Difference between theoretical and actual value within $\pm 10\%$
Wavelength	With spectroradiometer on the radiation diffused by a near lambertian diffuser	Difference between theoretical and actual value within $\pm 10\%$
Wavelength stability	With spectroradiometer and diffuser, measure wavelength just after a 2 hour shut off and at the end of other output controls	Difference between the two values within $\pm 5\%$
Beam divergence	Projecting the spot on graph paper, record with camera if needed	Difference between theoretical and actual value within $\pm 30\%$

Considering actual power output, only laser 5 should require a safety class 4, AELs of class 3B being respected for all other lasers.

It could be hypothesized to classify LLT lasers as 1C as they could be used in contact to skin.

The standard requires the respect of AEL of 3B class at 5 mm distance when measured with a 3.5 mm aperture, when the applicator moves laterally (12) and of the AEL of class 1 on a 7 mm aperture at 100 mm distance.

Lasers 4 and 6 have been found to comply with these requirements however the main requirement is the presence of a switch turning off the beam when the applicator is lifted from the skin.

Lasers 2 and 5 do not meet these requirements because of the use in scanning mode implies a finite source to target distance, while laser 1, (same as laser 3) can be used in contact to skin but the shape of the lens allows the escape of radiation exceeding class 1 AEL.

Manufactures should supply all the information about the laser output, not only in order to deliver effective treatments as routine activity, but also to do experiments in real controlled conditions.

At this aim, it is worth that a periodical checking of LLT devices concern not only laser safety but also other relevant properties for the treatment such as the pulse shape.

A basic check-list is available in standard (13), further useful controls are proposed in Table VI; in grey are outlined the measurement useful basically as acceptance tests that can be skipped in performance tests, except in the case the laser has undergone a part substitution.

Periodicity of tests is established by the LSO in dependence of the use of the LLT device.

## Conclusions

Even if careful consideration must be posed to pulsed sources, Low Level Laser Therapy involve a low risk for

trained and educated clinical staff since only the exposure to the direct beam is expected to exceed the exposure limit values for the eye.

Further research is needed to proof which parameters are effective in laser treatments and clinicians should be well aware about the bio-physical meaning of each of them.

Manufactures should supply all the information about the laser output, not only in order to deliver effective treatments as routine activity, but also to do experiments in real controlled conditions.

The use of 1C devices could represent a further increase in safety and easy management of these sources, avoiding the need of laser safety check; however the compliance between declared and actual treatment parameters would still to be proven.

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