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A radiant power intercomparison of medical equipment

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Abstract: This work presents the result of an intercomparison of radiant power from lasers source among laboratories, mainly from medical equipment manufacturing industries. The intercomparison was the round-robin type and used lasers sources in 3 wavelengths 405nm, 638nm and 785nm as traveling standards. The reference values were determined by the pilot laboratory, IPT, before and after each participant using an electrical calibrated pyroelectric radiometry and the normalized error was used as quality criteria. About 30% of the results were out of the acceptable limit, where the most critical results came from the laser 405nm (about 16% of the total). Theses misled measurements are related to lake of calibration according ISO 17025; need of specialized training in optical radiation measurement and deep knowledge of measurement instrumentation limits and behavior

Key words: intercomparison, laser, medical equipment, traceability.

1. INTRODUCTION

Intercomparison measurements are a fundamental tool to quality evaluation and metrological process trustfulness. It is carried out in many levels of metrological chain, from National Metrology Institutes (NMI) key comparisons [1] down to industrial laboratories.

In optical laser field, one BIPM (Bureau International des Poids at Mesures) supplementary comparison is in progress [2] and two bilateral laser power intercomparisons were performed between the Germany NMI, PTB (Physikalisch-Technische Bundesanstalt), and the USA NMI, NIST (National Institute of Standard and Technology). One of bilateral intercomparisons was carried out on near infrared with power value of 100 μW and a relative error less than 0,1% [3]. The other was carried out on far infrared with power value in order to 100W and a relative error less than 0,7% [4]. The IPT has made an effort to guarantee the trustfulness of its power measures by intercomparisons, which resulted in a relative error from 2% to 2,5% at a power value from 8 mW to 40 mW [5,6].

After IPT´s intercomparisons and the results of IPT perform tests for the medical equipment certification program of Brazilian National Healthy Agency (ANVISA), it was possible to realize that industrial laboratories mainly in medical equipment manufactory field need some kind of intercomparison program for radiant power as a tool to improve and monitor their production. This matter is highlighted because the Brazilian NMI (INMETRO) power meter calibration facility is on development [7]; so that many companies have to take their equipment abroad for calibration.

This intercomparison aims the assessment of measurement quality of radiant power done by manufactures and other laboratories when they fabricate or evaluate laser medical equipment according ABNT/IEC standardization such as: NBR/IEC 60601-2-22. In addition, the intercomparison results should furnish further information for Brazilian governmental politics.

2. EXPERIMENTAL METHOD

The intercomparison was done in the round-robin model. Three characterized traveling standards lasers sources [8] circulated among the participants laboratories. The wavelengths of traveling standard source were chosen to be very close to major commercial medical equipment using for analgesic or dental therapy. Before and after each participant measurement the pilot laboratory, IPT, took a reference value in its measurement setup [8]. This procedure allowed the evaluation of drift in the laser radiant power, ensured that the source was working well and contributed to reference values uncertainty estimation. The Table 1 shows the sources used in the intercomparison.

Table 1. Lasers used in the intercomparison.

Serial	Wavelength (nm)
92614501	405
91888601	638
92594201	785

The laboratories had to use their own routine radiant power measurement methods and should follow measurements protocol. The measurements protocol specified the power measurement should to be done under temperature of (21±3)°C, supplied voltage of (115±7)V and after 1 hour of laser source warm-up. In addition, the laser beam should under fill the detector area and be normal to detector surface, except for detectors with high specular reflection in which the laser beam should be slightly inclined (not more than 5º) to avoid reflection into the laser's cavity.

The IPT technicians observed all steps in order to guarantee the integrity and to collect further information from the measurement process. The pilot laboratory was also responsible for the dataset analysis comparing the measurement result, calculating errors, charting and giving the feedback to the participants.

The measurements agreement was checked using the normalized error (E_N) which is a parameter used to evaluate the results from the intercomparison [9]. This parameter is calculated according to equation (1).

$$E_N = \frac{M_{Lab} - M_{Ref}}{\sqrt{U_{Lab}^2 + U_{Ref}^2}} \qquad (1)$$

Where:

M_{Lab} is the participant laboratory's measurement;
M_{Ref} is the pilot laboratory's measurement;
U_{Lab} is the participant laboratory's uncertainty;
U_{Ref} is the pilot laboratory's reference uncertainty.

The criteria for participant measurement evaluation using the normalized error are the following:

$| E_n | \leq 1$ the result is satisfactory;

$| E_n | > 1$ the result is doubtful.

The participants' invitation was done using the medical equipment manufactures list from ABIMO which is a manufacture association and from the list of manufactures which had used IPT evaluation service according NBR/IEC 60601-2-22 standard. All together 14 participants were invited which are divided in 11 medical manufactures companies and 3 independent laboratories.

3 RESULTS

The participants of this radiant power intercomparison are listed in Table 2.

Table 2. List of participants laboratories.

Company Name
CARCI INDÚSTRIA E COMERCIO LTDA
CLEAN LINE
ESCOLA POLITÉCNICA DA USP (DEC-LEB/EPUSP)
IBRAMED IND. BRASILEIRA DE EQUIPAMENTOS MÉDICOS LTDA
INSTITUTO DE FÍSICA USP
OPTO ELETRÔNICA S/A

3.1. Pilot Laboratory Measurement

The pilot laboratory measurement for each traveling standard was determined using a electrical calibrated pyroelectric radiometer (ECPR) [8,10] before and after each participant laboratory. The final reference value was the mean of the values measured during the intercomparison. The reference's value uncertainty was determined according ISO guide to expression of uncertainty in measurement [11]. The reference value and its uncertainty are presented in Table 3 and the uncertainty components are presented in Table 4.

Table 3. Reference value for radiant power.

Wavelength (nm)	Radiant Power (mW)
405	52,5 ± 1,4
635	30,47 ± 0,88
785	49,6 ± 1,6

Table 4. Uncertainty's components of radiant power from reference value.

Source of uncertainty	Power's uncertainty (mW)					
	405 nm		635 nm		785 nm	
	Type A	Type B	Type A	Type B	Type A	Type B
Standard Deviation	0,05		0,06		0,14	
Difference between maximum and minimum		0.14		0.17		0.43
Calibration with electrical standards		0.1575		0.0914		0.1487
Equipment uncertainty		0.3150		0.1828		0.2975
Equipment resolution		0.0039		0.0023		0.0037
Variation of reflectance in the detector's surface		0.6062		0.3518		0.05724
Uncertainty combined	0.71		0.44		0.79	
Extended Uncertainty (k ≅ 2)	1.43		0.88		1.58	

3.2. Intercomparison Results

The result's diagrams presented in the Figures 1 to 3 identify the laboratories by theirs codes and brings the information below:

- **the laboratories mean** is the mean of the individuals results of the laboratory and is represented by an empty circle with the uncertainty bar. It is associated with left side diagram scale;
- **the reference value** is the pilot laboratory mean value and is represented by the band composed by the estimated value in dashed line, superior and inferior limits in solid line, considering the uncertainty (k=2). It is associated with left side diagram scale;
- **the normalized error** is described by Equation (1) and is represented in the diagram by a filled circle. The dot line indicated En = 1. It is associated with right side diagram scale.

The number of laboratories codes is bigger than the number of participants because of each participant could use one or more measurement equipment.

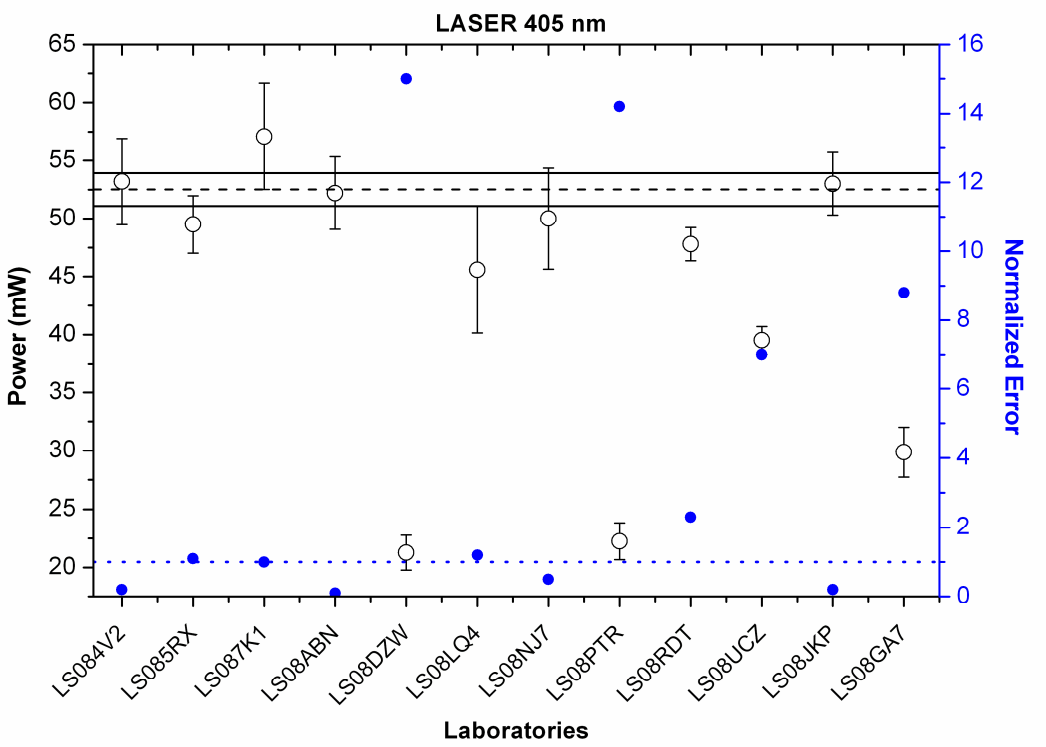

Fig 1. Intercomparison results for 405 nm laser source.

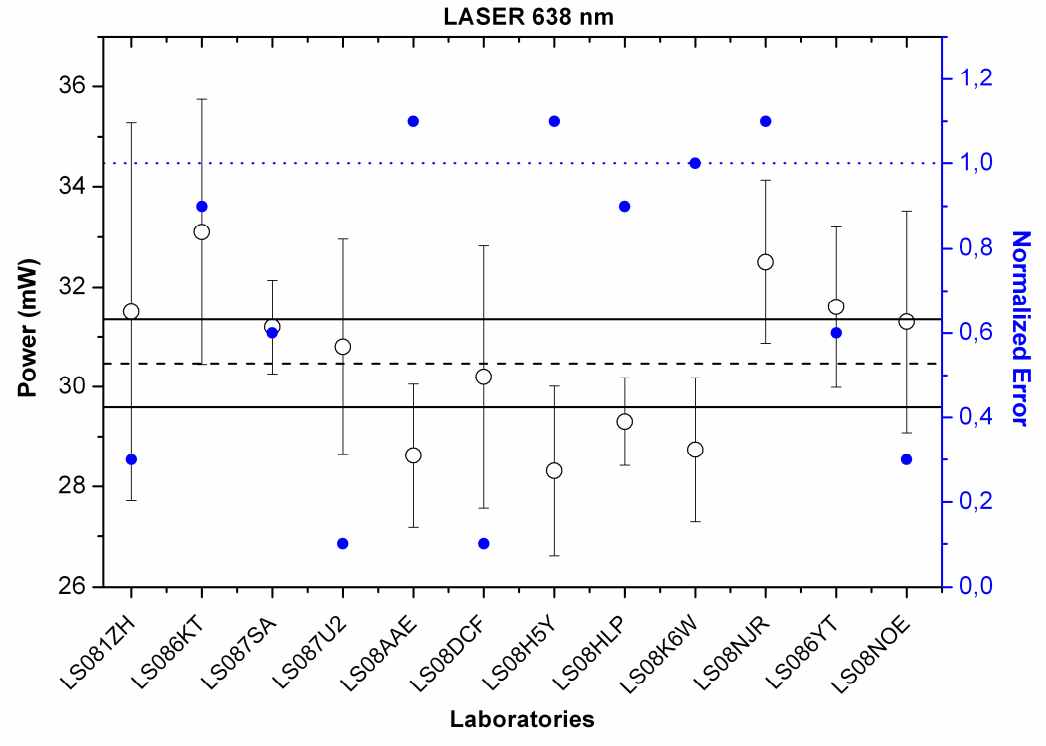

Fig 2. Intercomparison results for 638 nm laser source.

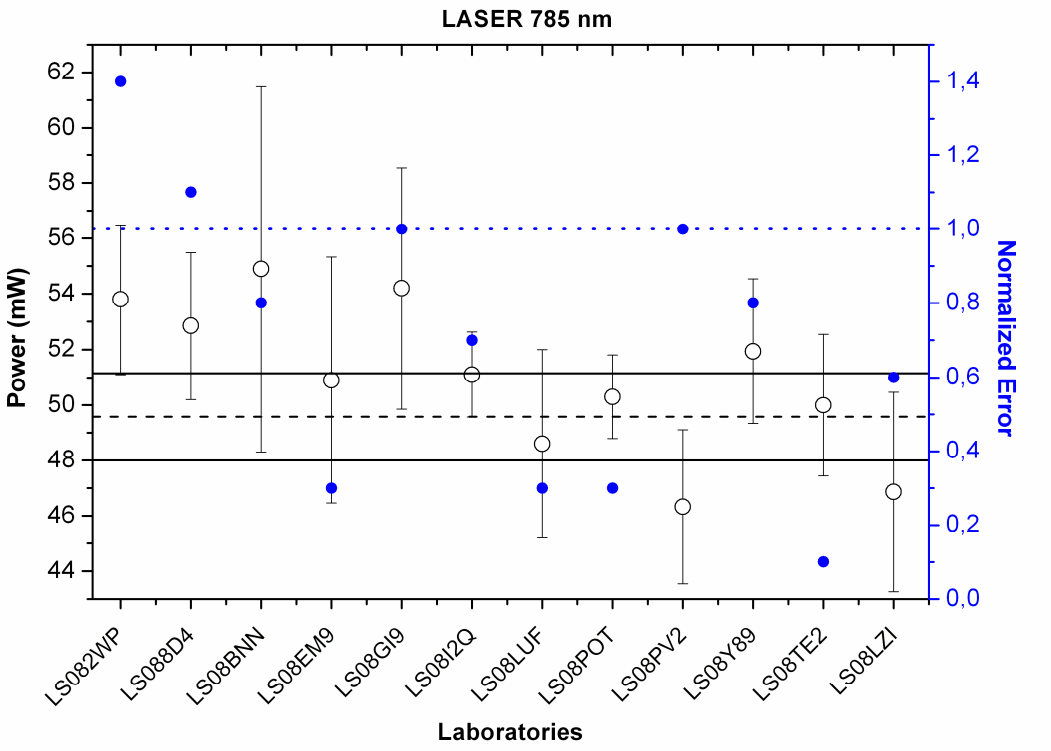

Fig 3. Intercomparison results for 785 nm laser source.

4 DISCUSSIONS

About 30% of the measurements had unacceptable results for the radiant power measures, being most of them (around 16% of total) for the laser of 405 nm. The following points discussed gives allowance to explain these results.

Considering the equipment issues it was noted that not all users pay attention to detector or filter radiation over exposure; allow a warm-up period for the measurement equipment; take care of environmental conditions of the detector and its accessories. In addition, it was observed that participants do not have internal measurement check procedures and, in some cases, very simple radiant power measurement equipment. The effect of ultraviolet (UV) radiation exposure in silicon detector was evaluated by Werne [12] and it could be a reason to explain the high percentage unacceptable results for the laser in 405 nm which is near the UV spectrum. The final major problem linked to the equipment is the calibration. Although all the participants have some kind of calibration, none of them has a calibration according ISO 17025 or done in National Institute of Metrology.

A second issue point is the participants' measurement procedure. A lake of a well defined measurement procedure, the knowledge of power measurement equipment and specialized training in optical radiation measurement contributed in the deviation of participants' results. Besides, only one third of laboratories technicians had read the intercomparison measurement protocol.

The NBR/IEC 60601-2-22 establishes and acceptable limit for radiant power measurements of 20%, however it was observed that some results attained a relative error of approximately 60% in the 405 nm laser source. Moreover, some participants' uncertainties reach more than half of the NBR/IEC 60601-2-22 which is the case for the LS08BNN with uncertainty of 12%.

5 CONCLUSIONS

An intercomparison of radiant power was established in 3 wavelengths and its results showed that about 30 % of the measurements are out of acceptable criteria. Most of out of limit measurements, 16%, occurred in the 405 nm laser sources. A possible reason for this behavior could be changes in responsivity of detector cause by radiation exposure.

Other factors that contributed for this misled measurements are lake of measurement equipment calibration according ISO 17025; specialized training in optical radiation measurement and deep knowledge of measurement instrumentation limits.

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Note: Specific firms and trade names are identified in this paper to describe the experimental procedure adequately. Such identification does not imply recommendation or endorsement by the authors, nor does it imply that the materials or equipment identified are necessarily the best available for the purpose.

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