C.P.S.®

LASER SYSTEM

fisioline®

biomedical instrumentation

uni3®

NEW

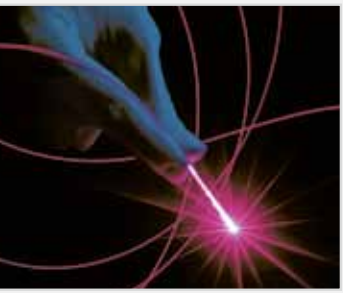
SOLID YAG DIODE

1064 nm

C.P.S.®
LASER SYSTEM

Lasertherapy

LASER is a coherent electromagnetic radiation source. Its abbreviation is the acronym for **Light Amplification by Stimulated Emission of Radiation**. It defines a physical mean to produce energy as a light wave after a stimulated emission of radiation. As the laser light is an electromagnetic wave crossing a non-homogeneous medium such as the biological substrate, it is important to remember the general features of light passing through the skin. Part of the electromagnetic wave passes through the tissues unchanged thanks to **transmission**, that is mainly seen in the red and infrared range because of the limited cellular absorption of these wavelengths. Part of the electromagnetic wave is scattered because of the heterogeneity of the tissues both in a retrograde sense (back-scattering), and with a simple change of direction of the ray, a **deviation**, part of it is **absorbed**. The interaction of laser light and biological tissues is determined by the physical processes controlling the yield of energy by the radiation to the substrate and the biological response of the tissue in question. The intensity of the biological reactions in the irradiated tissues depends on the characteristics of the tissue (energy absorbtion, transmission or reflectance) as well as on laser:



- **wavelength,**
- **power,**
- **emission modalities**

A laser device is a system consisting of three main elements: the active emitter, the activation source and the optical resonator.
The active emitter consists of a solid, liquid or gaseous material, that when properly stimulated produces a radiation: each material emits a specific wavelength.

The wavelength depends therefore on the active emitter being used and it has an influence on the ray penetration abilities. The UV rays (200-350 nm) are absorbed by the proteins and by the nucleic acids. The wavelengths of what is visible ranging from 400 to 750 nm are absorbed by the melanine and by tetrapyrrolic compounds and over 3000 nm the radiation is absorbed by water completely.
For wavelengths ranging from **600** to **1400** nm (near infrared) there is the so-called "therapeutic window" where laser radiation is not absorbed effectively by any specific element and consequently they have **better tissue penetration power**.
When treating the various pathologies of the locomotor apparatus several types of non-surgical or biostimulation lasers are used, defined based on laser emission average power, soft lasers with powers ranging between 1 and 50 mW; mid-laser 100 to 500 mW; power laser over 1000 mW.

The **power** is the quantity of energy (Joule) issued in a unit of time (second) and is measured in Watts (1W = 1J/s). However to better understand how important this parameter is we should distinguish between **peak power** (maximum emission power) **and average power**,recorded at the tip or aperture in one second.

Effects depend on the power as well as the volume of tissue involved because penetration and consequently the volume of tissue involved by the radiation depend on peak power. For instance: a continuous wave (CW) laser emitting **5W** will have an **average power** of 5W and a peak power also equal to 5W, in 1 second **5J** will be emitted.

A pulsed laser with a peak power of 100W emitted with pulses of 1 hundredth of second at 5 pulses per second will have an average power of 100X5/100 = 5W and in 1 second the same energy that is 5J will be produced. Two lasers with the same average power, but with radically different effectiveness and penetration. An important factor regarding superpulsed lasers is the high peak power, comparable to the maximum emission power of CW lasers.

It is important to remember that the average power is directly proportional to the peak power.
For example: if the average power of a laser with an impulse opening of 200 nanoseconds and an emission frequency of 100,000 pulses per second (Hz) is 2W, its minimum peak power will be 100W.

If the average power has a value that is also less than the peak power, it will suffer a significant variation downwards.

The amount of energy emitted at the source of the optical system can be calculated using the following formula:

$$E_{tot} = P_{out} \times T = t_p \times f \times P_{MAX} \times T$$

where:

E_{tot} = amount of energy

P_{out} = average power on leaving the optical unit [W].

t_p = duration of the impulse [s] (200 ns).

f = impulse repetition frequency [Hz] (1000 Hz-100000 Hz).

P_{MAX} = peak value of the output optical power [W].

T = total treatment time

Laser emission can be continuous, pulsed, superpulsed, superpulsed modulated (repeated discharges at higher frequencies), or C.P.S.® (CONTINUOUS, PULSED AND SUPERPULSED LASER), which represents the association of all three emission modes.
Pulsed and superpulsed emission represent an important possibility of modulating laser effects, as proven by the experimentations carried out with Fisioline lasers since 1980.

In fact different pulsing frequencies cause different effects in the substrate. In particular, with the same wavelength and power, the lower the frequency the higher the interaction with conduction structures while at higher frequencies a photochemical interaction prevails with a higher bio-metabolic stimulus.

C.P.S.®
LASER SYSTEM

Always state of the art

Fisioline® has been manufacturing vanguard laser devices since 1985.
The cooperation of its engineers to projects with internationally well known universities has allowed **Fisioline**® to become **the first Italian company that manufactured high power pulsed lasers** back in 1993, opening up a new horizon for this kind of devices.
Fisioline® keeps evolving from a technological standpoint and has been the first company worldwide to introduce the new:
HIGH POWER SUPERPULSED LASERS (H.F.P.L.® High Frequency Power Laser Fisioline®).

This new generation of laser equipment has the following main features:

- 3 **types of laser emission:** Continuous, Pulsed and Superpulsed
- 3 **different wavelengths** (650, 808, 910nm)
- **individual activation of the different laser sources**
- **synchronisation of activation of the laser sources**
- **optical overlapping of the laser sources spots**
- **high peak power** (from 100W to 250W)
- **high average powers** (from 5W to 7W)
- **high pulse repetition** (up to 100,000 per second)
- **the ability to interact therapeutically with different tissue depths.**

Having high peak powers available allows transferring the average power generated by the laser sources deeply inside human tissues.
An important feature of the new lasers **LUMIX**® 3 **with C.P.S.® technology** is a high peak power as well as a high average power.

The new LASERS lumix® 3

C.P.S.®
LASER SYSTEM

Two laser models with **C.P.S.®** technology able to satisfy any healthcare practitioner's.
The new **LUMIX® 3 Plus and LUMIX® 3 Ultra** lasers permit to work on the patient with any operating technique, both automatically and manually.

LUMIX® 3 Plus

A versatile laser:

- **3 pulsed-superpulsed diodes and 1 diode CW of 3,2W**;
- **600W:** maximum peak power;
- **100W:** minimum peak power;
- high average power equal to **5W**;
- excellent tissue penetration for fast treatments.

AVAILABLE SOLID YAG DIODE 1064nm VERSION

LUMIX® 3 Ultra

An innovative laser:

- **6 pulsed-superpulsed diodes and 1 diode CW of 3,2W**;
- **1200W:** maximum peak power;
- **250W:** minimum peak power;
- high average power over **7W**;
- best penetration in soft tissues;
- excellent results can be obtained in few short applications;
- immediate analgesic effects.

AVAILABLE SOLID YAG DIODE 1064nm VERSION

CE 0051

MECHANICAL ARM FOR AUTOMATIC TREATMENTS

BACKLIT GRAPHIC DISPLAY

ERGONOMIC HANDPIECE

FUNCTIONAL TROLLEY

PROTECTION LASER GLASSES

C.P.S.®

LASER SYSTEM

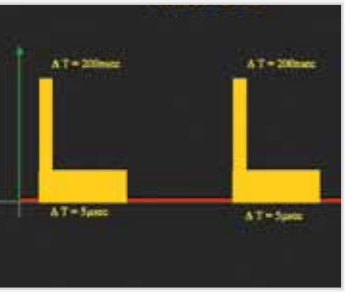
HIGH PENETRATION

Tissue penetration

Among the factors allowing a laser light to penetrate the human tissues, wavelength and peak power are essential.
It is important for the laser wavelength to fall within the so-called "therapeutic window" namely 600 to 1400 nanometers.
The lasers **LUMIX**® 3 emit in a wavelength of 650, 808, 904÷910 nanometers.
At the same wavelength the peak power is indispensable to reach deeply in the tissue. Using a laser with high peak powers is therefore absolutely necessary to reach the deep layers. The minimum peak power of the lasers **LUMIX**® 3 ranges from a minimum of 100 Watts to a maximum of 250 Watts.

C.P.S.® Laser System Fisioline®

Using high pulsation frequencies (over 40 KHz: super pulse) permits to exploit a physical phenomenon new for laser devices, that is the photomechanical effect i.e. the transformation, at a molecular level, of light EM energy into mechanical energy.
This can increase the effects on the conduction structures, that is on the muscular tissues (decontracturing), and on nervous tissues (antalgia), and also on fibrous tissues (improvement of the elasticity) with the same lambda and power.
The use of the 3.2W CW continuous laser diode, on the other hand, allows a **photomodulating effect** (analgesic, anti-oedemagenous, stimulating, in relation to the density of energy administered) to be achieved on the cutaneous receptors.
A wide frequency adjustment range (both manually and automatically) and **the association of the different emission modalities**, an exclusive feature of the **C.P.S.**® system, make the laser devices **LUMIX**® 3 extremely versatile.



SUPERPULSATION

Optical fibers

Fisioline® has been leader in Italy in the construction of optical fiber laser systems since 1993. Extensive experience has allowed us to acquire a good know-how in laser energy transmission through optical fibers with minimum losses due to the coupling of diode, fiber and collimator.
Optical fibers are processed entirely at **Fisioline**®'s from cutting to connections, from lapping to diode coupling.

FIBER OPTIC LASER TRANSMISSION

C.P.S.®
LASER SYSTEM

Multiple diode collimating

The output spot of multiple diode laser systems commonly in use actually consists of several mini spots, as many as there are source diodes. Each mini spot receives **peak power and average power from a single diode.**
The lasers **LUMIX**® 3 apply the innovative multielement technique, consisting in **converging several laser diodes to a single spot**, by using optical fiber beams and a final collimator.
This permits to **sum up both the peak and the average powers of a single diode** on anarea that is high energy and irradiated evenly.

MULTIPLE DIODE COLLIMATING

Large spots

The size of the output spot has a considerable importance. This is the surface where the laser radiation is evenly distributed (power density in W/cm^2). **The larger the spot size, with the same power density, the higher the laser penetration in the tissues, thanks to the scattering sum.**
The spot of **LUMIX**® 3 laser devices has a diameter ranging from about 2 cm to more than 10 cm. Independently from the position of the optical unit on the patient, the output angle should always less than 15° to avoid reflection (beyond 30° any laser or normal light would be almost entirely reflected).
Besides adopting the contact irradiation technique, these characteristics allow the laser devices **LUMIX**® 3 to carry laser and thermal energy deep in the tissues.

LARGE SPOTS

Therapeutic protocols with a high percentage of success

Fisioline® has always believed in **scientific experiments**. During the last few years a considerable library of laser treatment protocols has been developed with experiments carried out exclusively in hospitals or universities. These experiments supply the operator with the idea of the results that can be obtained with **Fisioline**® laser devices.
The company's commitment has also allowed **Fisioline**® laser devices to be sold anywhere in the world over including the very exacting and difficult American market. In fact, in November 2004 the **Fisioline**® **H.F.P.L.**® laser devices obtained the **FDA** approval in the USA.
The clinical experience and the medical advice of international experts have led to the therapeutic protocols of the new **Fisioline**® **H.F.P.L.**® laser devices.

PRESET THERAPEUTIC PROGRAMS

C.P.S.®

LASER SYSTEM

TREATMENT OF ACUTE INFLAMMATIONS

CHONDROPATHY

STIMULATION OF THE OSTEOGENESIS

MUSCULAR INJURY

MUSCLE CONTRACTURE

LUMIX® 3 advantages

Based on the type of pathology being treated, on the modalities and doses, laser radiation acts by increasing the pain threshold higher by acting directly on the algogenic nerve endings and by stimulating indirectly the liberation of endorphins "on the spot" and in the tissue fluids.
Moreover, the induced hyperemia and the macrophage activation, reducing ischemia and the local stasis of endogenous algogenic matters, exclude the onset of other possible sources of pain and inflammation.
Finally, the recovery of the cellular membrane potential contributes to interrupt the viscious circle of contracture-vasoconstriction-pain and to resolve the inflammation.
For what tissue lesions are concerned, experimental evidence has proven the regenerative biological stimulus determined by laser radiation. It is correct to think of lasertherapy in the same terms as a local infiltrative mesotherapy treatment. In mesotherapy
we establish the composition and proportion of the various drugs to infiltrate (such as FANS, cortisone, analgesics, fibrinolytics etc) while with a therapeutic laser we establish pulsation frequency, intensity and duration of the various phases of the treatment to obtain the same anti-inflammatory, analgesic and trophic-stimulating effects.

LASER LUMIX® 3 are appropriate in the following areas:

- **PAIN THERAPY**
  Cervicalgy, dorsalgia, backache and radicular syndromes in general, originated by both inflammation and irritation
  Articular and periarticular aches (direct and indirect antalgic effect by antiinflammatory action)
  Inflammatory and degenerative neuritis and neuropathies
  Muscular contractures and myofascial trigger areas

- **ACUTE INFLAMMATION**
  Acute tendonitis and new acute phases of chronic tendinopathies
  Capsular and ligament inflammation of either traumatic or degenerative origin
  Acute inflammatory arthritis in relapse phase (excellent antiedemigeneous effect) pain and phlogosis in case of chronic degenerative arthropaties (arthrosis, rheumatisms,etc)

- **DEGENERATIVE LESIONS**
  Acute lesions of ligaments and tendons (by exploiting the metabolic stimulus and the antiinflammatory effect to accelerate and improve fibroblasts and myofibroblasts)
  Muscular lesions (in a second phase at least 72 hours after the trauma)
  Condropathy
  Stimulation of osteogenesis

- **MYOFASCIAL SYNDROMES**
  Idiopathic Fibromyalgia
  Muscular contractures and/or first-degree distractions
  Neuroconnective syndromes

FDA
Food And Drug Administration

The Food and Drug Administration (FDA) is an American governmental agency for public health protection.
It is responsible for ensuring the safety and effectiveness of drugs for use on humans, of biologic products, medical devices, food, cosmetics and radiation-emitting products.
In a preliminary stage the agency technicians evaluate the petitions for new products to be offered on the American market.
After evaluating a sample, in order to prove the truthfulness of the technical characteristics declared by the manufacturer (electrical safety, output power and so on), the FDA starts a phase of scientific experimentation in order to validate the therapeutic efficacy with long-term tests in various Research Centers.
Obtaining the FDA approval is a tangible proof of the actual therapeutic value of a product.
The FDA approval is a confirmation that H.F.P.L.® Fisioline® lasers have an actual therapeutic value.

Guarantee in safety

Thanks to the safety features we have adopted, all superpulsed **Fisioline**® laser devices can be **used by the physician as well as by a physiotherapist and, depending on your local laws, by the clinic assistants.**
The destination of use is described specifically in the operating manual as required by European medical standards.
Furthermore **Fisioline**® laser devices, like any other appliances manufactured by **Fisioline**®, are covered by **FONDIARIA SAI product liability insurance policies** worldwide.

Our experimentation

Laser Therapy for the treatment of post surgical damages in breast cancer,
Breast and Pulmonary Surgey, Second World Week of Professional Updating in Surgery and in Surgical and Oncological Disciplines of The University of Milan. Page II/105-107. MONDUZZI EDITIONS.
D. Dini, D. Bertelli, G. Forno, M. Venturini, M.G. Vidili, G. Piccione, G.Rossi.
Functional reeducation service, National Institute for cancer research, Genoa (I)

1991
Lasertherapy in iatrogenic pathology in oncology, La Riabilitazione, di P. Farneti.
VOL 24 - N.2/1991.
D. Dini, D. Bertelli, G. Forno, M. Venturini, G. Piccione, M. Bianchini.
Functional Reeducation Service, National Institute for cancer research, Genoa (I)

1997
Treat to avoid illness chronicity, "Experiences of applications of a pulse laser in sports traumatology".
Sport e Medicina, number 3 May 1997, pages 48 and 49. EDI ERMES.
Marco Villa, Sport Physician, Center of Sports Medicine FMSI-CONI (Cuneo)

1998
Physical therapy, instrumental in sports traumatology, *"Application of pulsed lasers at 910nm in flogistic pathologies and pain syndroms in sportsmen",* Medicina dello Sport, Vol 51- N.3, pages 273-283 September 1998.
P. Mondardini, L. Verardi, R.Tanzi, S. Kanellopulu, E. Pagano, G.Roveran, E. Drago
Institute of Sports Medicine CONI-FMSI, Bologna • Interuniversity Center of studies and research in Sports Medicine, Bologna.

Laser therapy versus pharmacological therapy in knee pain, La Riabilitazione, di P. Farneti. VOL 31 N.4/1998. *A. Marchese, M. Cherubini, R. Forte. Algias Dept. Pro Juventute Foundation "Don Carlo Gnocchi" Rome.*
School of Specialization in Physical Medicine and Rehabilitation "Tor Vergata" University, Rome.

C.P.S.®
LASER SYSTEM

Our experimentation

1999

Use of pulsed laser 910 nm in the pathologies caused by traumas in sportsmen,
Records of the Meeting: Convegno triveneto, Rehab medicine, Belluno 13 November, 1999 – by Maurizio Del Borzo, pages 143-147.
DELL'OSTE P., BALDO M.**, ORTOLANI L.*, ORTOLANI M.**
* Orthopedic rehab service • Hospital - University of Padua. (Dir. Prof. M. Ortolani)
** Physiokinesiotherapy and Functional Reeducation Ambulatory Blucenter.

2001

Combination of ultrasound "class E"-lasertherapy in the treatment of chronic tendinities and peritendinities of the upper limbs,
Medicina dello Sport, Vol 54-N.1, pag 77-80.
R.Tanzi, L. Verardi, P. Mondardini, E. Drago • Istituto di Medicina dello Sport CONI-FMSI di Bologna Interuniversity Center for Studies and Research in Sports Medicine, Bologna.

New physiotherapy technologies,
Medicina dello Sport (Sports Medicine), Vol 54-suppl 1 to N.3, pages 37-38.
Dott. Paolo Mondardini • Institute for Sports Medicine CONI-FMSI, Bologna.
Interuniversity Center for Studies and Research in Sports Medicine, Bologna.

2005

Superpulsed high power-laser radiation induces cell proliferation and increased synthesis of the extracellular matrix components in cultured human chondrocytes,
RESULTS OF THE STUDY - Internal Report.
Prof. José A. Vega - Departamento de Ciencias Biomédicas, Sección de Anatomía y Embriología Humana, Facultad de Medicina, Universidad San Pablo – CEU, Madrid, Spain.

2007

Protocollo di impiego laser a infrarosso superpulsato ad alta potenza (H.F.P.L.®) ed ultrasuono ad alta potenza Fisiosonic® Plus nel trattamento della condropatia femoro–rotulea,
F. Verzini - Federazione Medico Sportiva- Comitato Regionale del Piemonte della FMSI – Atti del Congresso Nazionale: Torino 16 e 17 novembre 2007.

Effect of superpulsed laser irradiation on bone formation in a human osteoblast-like cell line,
MINERVA STOMATOLOGICA 2007;56;:27 - 30
G. Martinasso, M. Mozzati, R. Pol, R.A Canuto, G. Muzio – Department of Medicine and Experimental Oncology Turin University, Turin, Italy.

2009

Superpulsed laser irradiation increases osteoblast activity via modulation of bone morphogenetic factors,
LASER IN SURGERY AND MEDICINE 2009 Apr;41(4) :298-304.
Saracino S., Mozzati M., Martinasso G., Pol R., Canuto R.A., Muzio G. – Department of Experimental Medicine and Oncology, Turin University, Turin, Italy.

Biostimulation Effects of Superpulsed, High-Intensity, Low-Average Power Laser Application on the Timing of Orthodontic Aligner Sequencing of the Invisalign® System,
J LASER DENT 2009 17(3):139-145
Nelson Marquina, MSc, PhD, DC*; Fred Stalley, DDS**
**USA Laser Biotech Inc., Richmond, Virginia, United States*
***Redondo Beach Dental Group, Redondo Beach, California, United States*

Effect of Low-Level Laser Irradiation on Bisphosphonate-Induced Osteonecrosis of the Jaws: Preliminary Results of a Prospective Study,
PHOTOMEDICINE AND LASER SURGERY 2009; Volume 00, Number 00, Pp. 1–6
Matteo Scoletta, D.D.S., Paolo G. Arduino, D.D.S., M.Sc., Lucia Reggio, D.D.S., Paola Dalmasso, M.Sc., and Marco Mozzati, M.D., D.D.S. - Department of Clinical Physiopathology and Public Health and Microbiology, University of Turin, Turin, Italy.

technical features

C.P.S.®
LASER SYSTEM

Models:
LUMIX® 3 Plus
LUMIX® 3 Ultra
Commercial Classification: lasertherapy device (biostimulation).
Technical classification: electromedical device class I type B.
Medical device class: IIb (Dir. 93/42/EEC, modified by the Dir. 2007/47/EC)
Reference standards: EN 60601-1 (IEC 60601-1), EN 60601-2-22 (IEC 60601-2-22), EN 60825-1 (IEC 60825-1), EN 60601-1-2 (IEC 601-1-2).
Dimensions: 320 x 430 x 980 mm.
Weight: 30 Kg.
Power supply voltage: 230V single phase (115V available upon request).
Line frequency: 50-60 Hz.
Laser Classification: Class 4
Laser sources:
VISIBLE LASER RADIATION
Wavelength: 650nm (red)
Laser source: continuous CW
Average power (at the source): 15mW
LASER RADIATION I.R. CW
Wavelength: 808nm or option Solid Yag diode 1064nm
Laser source: continuous – frequenced or interrupted GaAs
Maximum power: 3,2W
Average power: 1,6W
LASER RADIATION I.R. PW
Wavelength: 904÷910nm
Laser source: pulsed-superpulsed GaAs
Peak power (maximum):
- LUMIX® 3 Plus: 600W
- LUMIX® 3 Ultra: 1200W

Peak power (aperture):
- LUMIX® 3 Plus: 100W
- LUMIX® 3 Ultra: 250W

AVERAGE POWER (at the source):
- LUMIX® 3 Plus: 5W
- LUMIX® 3 Ultra: 7W

Operating mode: continuous, pulsed, superpulsed or C.P.S.®
Duration of the CW diode impulse: from 5 ms to CW.
Duration of the PW diode impulse: 200ns.
Repetition frequency: can be selected up to 100.000 Hz.
Adjustable modulation: 10% to 100% depending on output frequency.
Beam diameter: approximately 20 mm.
The beam diameter can be increased by taking the optical group further away from the area to be treated.
Beam divergence: less than 15 degrees (240mrad).
Energy calculation based on the preset parameters.
Programmable electronic timer (1-60 min.).
Graphic display backlit 240x128 pixel for the visualization of parameters.
Acoustic (buzzer) and light (LED) signals to signal end of treatment.
Light and acoustic signals of laser source activation.
Laser power meter.
Red light guide (650nm). Collimated display of the area treated by the IR beam.
Mechanical arm for automated treatments.
Manual operation push button.
Interlock connection for remote control of the laser radiation.
Emergency stop key.
Therapeutic programs stored in memory.
Flexible operating procedures with modifiable parameters.
Microprocessor management.
Marking CE: the device complies with the requirements specified in the Directive 93/42/EEC, modified by the Directive 2007/47/EC, and in the Directive 2004/108/EC.

fisioline®
biomedical instrumentation

Fisioline® srl
Borgata Molino, 29 • 12060 VERDUNO (CN) • ITALY
Tel.: +39.0172.470432-0172.470433 • Fax.:+39.0172.470891
http://www.fisioline.com • e-mail:fisioline@fisioline.com

CERT. 9120. FISI CSQ UNI EN ISO 9001:2008
CERT.9124.FIS2 CSQ MED ISO 13485:2003

ED.05/10. Design and graphical project: Ego identità ed immagine, Dogliani (Cn)