MEDICAL INNOVATION WITH NATURAL HEALING POWER

PAG-883-Y
BIOPTRON 2 with optional Y stand

PAG-880-SET
BIOPTRON 2 with optional professional stand

PAG-991
BIOPTRON Pro 1 with floor stand

PAG-960-SET
BIOPTRON MedAll with optional stand

BIOPTRON® LIGHT THERAPY SYSTEM By Zepter Group

www.bioptron.com

BIOPTRON AG
Sihleggstrasse 23
CH-8832 Wollerau
Switzerland
T: +41 43 888 28 00 F: +41 43 888 28 99
E-Mail: light@bioptron.com

CE 0124

zepter® INTERNATIONAL
LIVE BETTER • LIVE LONGER

www.zepter.com

BIOPTRON® LIGHT THERAPY SYSTEM By Zepter Group

BIOPTRON, a medical device for wound healing and pain relief:

CE 0124

BIOPTRON 2

BIOPTRON Pro 1

BIOPTRON MedAll

- Significantly reduced healing period
- Medically proven effectiveness
- Unique successes, confirmed by clinical studies

MADE IN SWITZERLAND

zepter® INTERNATIONAL
LIVE BETTER • LIVE LONGER

What does BIOPTRON Light Therapy actually do?

What is BIOPTRON Light?

BIOPTRON Light Therapy System emits light characterized by:

1) Polarization

BIOPTRON Light is polarized light, its waves move (oscillate) on parallel planes.
Linear polarization by reflection (the multi-layer mirror system, Brewster mirror), is very efficient and attains a polarization degree of 95%.

2) Polychromacy

BIOPTRON Light Therapy System encompasses the wavelength range from 480 nm to 3400 nm. This spectrum contains the visible light range and a proportion of infrared radiation.
The electromagnetic spectrum of BIOPTRON Light does not contain ultraviolet (UV) radiation.

3) Incoherency

BIOPTRON Light is incoherent or "out-of-phase" light. In other words, the light waves are not synchronized.

4) Low-energy

BIOPTRON Light Therapy System has a low energy density (fluency) of an average of 2.4 J/cm².
BIOPTRON Light reaches the area to be treated with a constant, steady intensity.
This energy density has biostimulative effects.

With BIOPTRON Light Therapy, the energy density dosage can be precisely determined.
Furthermore, the effect exerted by light is also defined by its power density. As it is measured at the skin's surface, it varies depending both on the intensity of the light's source and its distance from the area to be treated.
The specific power density of BIOPTRON Light is approximately 40 mW/cm² at a treatment distance of 10 cm. This is equivalent to an energy density (fluency) of an average of 2.4 J/cm² per minute.

These properties of BIOPTRON Light allow it to penetrate the surface of the skin with minimum heating effect, no damage to skin, and no known side-effects.

BIOPTRON Light Therapy System – medical devices, with expanding clinically proved efficacy both in the treatment of wounds and pain conditions and in the treatment of selective skin disorders (wound management).

BIOPTRON Light employs a combination of infrared and visible light wavelengths considered to be beneficial in the treatment of different types of problems and injuries. Both visible and infrared light have been shown to affect different positive changes at cellular level.

Biostimulative effects of BIOPTRON Light are the result of synergy between different mechanisms of action:

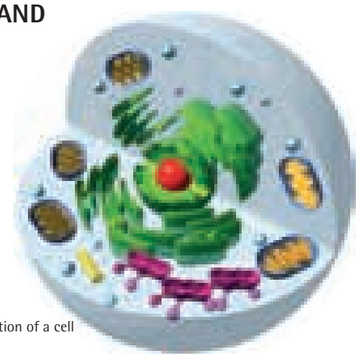
1) IMPROVE MICROCIRCULATION

2) REINFORCE THE HUMAN DEFENCE SYSTEM

3) STIMULATE REGENERATIVE AND REPARATIVE PROCESSES OF THE ENTIRE ORGANISM

4) PROMOTE WOUND HEALING

5) RELIEVE PAIN OR DECREASE ITS INTENSITY



Schematic illustration of a cell

Main mechanisms of the action of light therapy:

The scientific mechanisms underlying various light therapy treatments are still under investigation. However, in general scientists have identified various biological effects that can be initiated and achieved as a result of light stimulation. These include:

1) Stimulation of neoangiogenesis. Improvement of microcirculation.
2) Increasing the process of phagocytosis.
3) Stimulation and activation of ATP production.
4) Enhancement of important specific enzymes involved in cell regeneration.
5) Increasing the activity of lymphatic system.
6) Activation of fibroblast activity and increasing the production of collagen.
7) Increasing DNA and RNA production.
8) Reducing the excitability of nervous tissue and increasing the muscle relaxation.

BIOPTRON Light Therapy in wound healing and tissue repair

Care for population with chronic wounds is a growing challenge

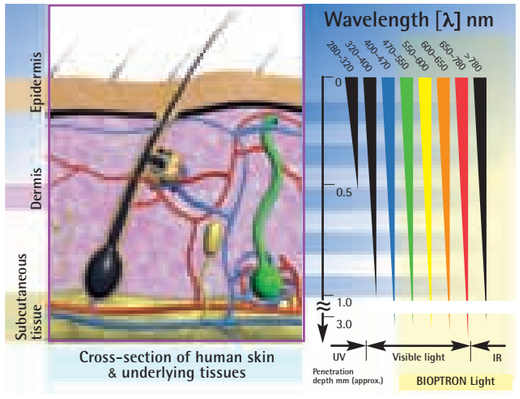
Wound healing

STASIS ULCERS (VENOUS LEG ULCERS)
BURNS
DECUBITUS (PRESSURE ULCERS)
GRAFTING
POST-TRAUMATIC WOUNDS
POST-SURGICAL WOUNDS

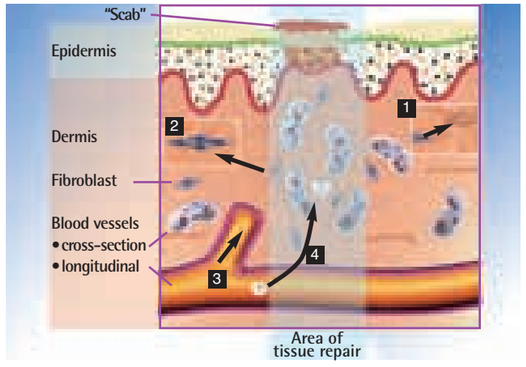
Chronic wounds are underestimated by physicians and general public alike, yet their prevalence continues to increase dramatically because of the steady growth of the elderly population and because the elderly are at increased risk in respect to the chronic condition predisposing to chronic wounds.
The need to care for population with chronic wounds is a growing challenge that requires innovative approaches.
We believe that the use of BIOPTRON Light Therapy and in conjunction with existing procedures could greatly enhance the natural wound-healing process. Furthermore, improved wound healing could reduce the risk of infection for the patient, decrease the number of costly dressings required, and more swiftly return the patient to a pre-injury/illness level of activity.

BIOPTRON Light Therapy System provides new insight into the management of venous leg ulcers, pressure ulcers, diabetic foot ulcers, burns, grafting and wounds following operation and injury. Patients are now able to receive innovative wound-care management. BIOPTRON Light Therapy could offer significant support in conjunction with standard wound-care.

Light penetration into tissues



Cross-section of healing processes in a skin wound



1. Collagen synthesis from fibroblasts / 2. Fibroblast proliferation
3. Growth of new blood vessels / 4. Migration of macrophages

Pain treatment

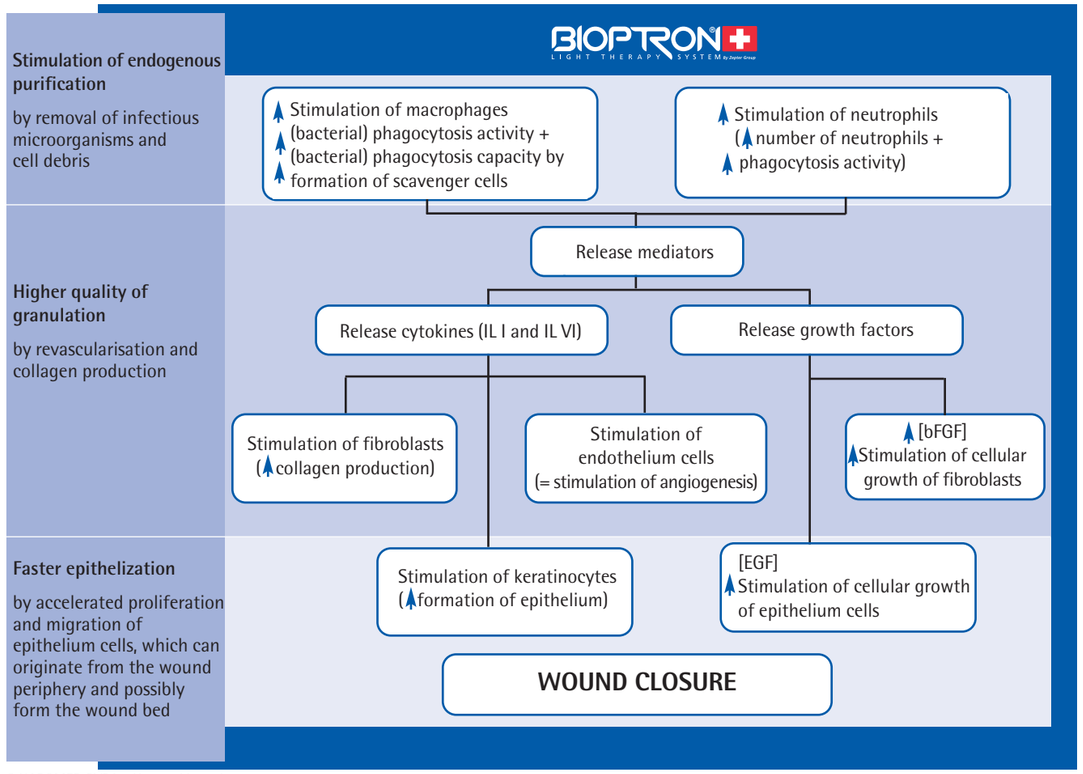
PHYSIOTHERAPY
RHEUMATOLOGY
SPORTS MEDICINE

The success of light therapy on pain and functions may be due to a number of mechanisms, one of which may be through its positive effect on chondrocyte proliferation and matrix's synthesis. Also, significant stimulatory effect on fibroblast action and enhanced connective tissue repair were noted. These effects seem to be related to the biostimulative effect of light therapy at the cellular level. Normalization of microcirculation and speed of nerve transmission achieved have been reported to interrupt the vicious circle of origin and development of pain.

Acute and chronic wounds

The complex process of wound healing can be influenced by BIOPTRON Light

Wound healing involves a highly complex set of physiological processes regulated by many different cellular and humoral factors.



Source: Bolton, P., Dyson, M., Young, S. The effect of polarized light on the release of growth factors from the U-937 macrophage-like cell line. Laser Therapy 1992; 33-37.

The complex process of wound healing can be influenced by BIOPTRON Light Therapy.

In spite of the positive clinical experiences reported in numerous publications, the mechanism of the biological effect of polarized light is still under investigation. It is assumed that, in the cell membranes, the polar heads of the lipid bilayer are reordered by polarized light and that, as a consequence, functional changes take place.[3]

Different biological effects have been observed after light therapy, including the stimulation of cell proliferation – especially in fibroblasts, the release of growth factors and the enhancement of collagen synthesis.[3,4,5] A number of clinical studies have revealed accelerated wound closure with increased wound epithelization and improved tensile strength of scars. [4-7]

One proposed mechanism of action of photobiostimulation is the absorption of visible light by mitochondria.[8] This may cause a chain of reactions on molecular level, leading to an increase in cell energy and activation of the nucleic acid synthesis, which is essential for wound repair. The second proposed mechanism is obtained by the infrared portion of the light spectrum. This initiates the response at the membrane level, probably through photophysical effects on Ca++ channels.[9] Light therapy has been shown to stimulate release of the growth factors from the irradiated cells. Growth factors stimulate angiogenesis, extracellular matrix production and degradation and cytokine release.[10] The key cells in skin ulcer contraction and collagen synthesis are fibroblasts and keratinocytes. A number of studies have demonstrated their activation and proliferation in response to low-energy laser/photon stimulation.

Other mechanisms that may be responsible for the light's therapeutic effect is the local peripheral vasodilatation, which may enhance skin blood flow and supply of oxygen to the ulcer area, thereby facilitating the transportation of the nutrients required for ulcer healing.[10]

Venous leg ulcers

It is widely known that light therapy could accelerate the healing of wounds and superficial skin ulcers.[1,2] The favorable effect of BIOPTRON Light Therapy on the healing rate of venous leg ulcers may be explained by the stimulation of epithelial growth and granular tissue regeneration.[10]

pt N° 4

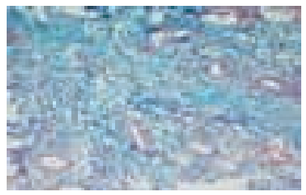
pt N° 15

Source: Institute of Dermatovenerology, Department of Dermatovenerology, Belgrade University, School of Medicine, Belgrade, Serbia and Montenegro.
Wound assessment: Measurements of wound surface area (ulcer size) by computerised planimetry (Planix 7 Digital Planimeter).

Histo-pathology findings

A) HE: Before BIOPTRON Light Therapy

Diffuse dermal inflammatory infiltrate and poor granulation.

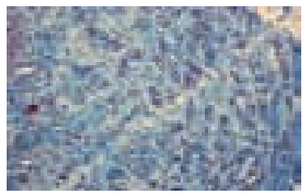


A) Masson's trichrom

Before BIOPTRON Light Therapy: Pronounced inflammatory infiltration and poor granulation

B) HE: After BIOPTRON Light Therapy

Granulation tissue composed of large number of fibroblasts, extensive collagen deposition and large number of blood vessels.



B) Masson's trichrom

After BIOPTRON Light Therapy: Tissue rich in capillaries, fibroblasts and fibrotic tissue

10) Medenica, L., Lens, M. The use of polarised polychromatic non-coherent light alone as a therapy for venous leg ulceration. Journal of Wound Care 2003; 12: 1, 37-40.

Deep second degree burns

Fig. 1

Start therapy | After 12 days | After 15 months

Fig. 1:
Single case (Source: Department of Plastic Surgery, University Hospital Gent, Belgium) showing the effect of BIOPTRON Light Therapy.

Fig. 2:
Monstrey, S., Hoeksema, H., Saelens, H., Depuydt, K., Hamdi, M., Van Landuyt, K., Blondeel, P. A conservative approach for deep dermal burn wounds using polarised-light therapy. British Journal of Plastic Surgery 2002; 55: 420-426.

Fig. 2

Start therapy 2 days after the accident

After 21 days

Appearance after 19 months

First-degree and superficial second-degree burns may be treated with conservative local medical treatments in combination with BIOPTRON Light Therapy treatment. Clinical studies have shown that the routine use of BIOPTRON Light Therapy may significantly reduce the time necessary for complete epithelization of the damaged skin, reducing the risk for the formation of the functionally and esthetically unacceptable scars.[11]

Start therapy | After 15 days | After 19 days | After 29 days | After 9 months

16) Monstrey , S., Hoeksema, H., Saelenes, H., Depuydt, K., Hamdi, M., Van Landuyt, K., Blondeel, P. The effect of polarized light on wound healing. European Journal of Plastic Surgery, 2002; 24 (8): 377-382.

Decubitus (pressure ulcers)

Clinical studies have demonstrated the effectiveness of polarized light therapy in healing 1st, 2nd and 3rd grade pressure ulcers. When polarized light treatment was added to conventional ulcer therapy, rapid changes in appearance and size with complete healing in half of the cases and accelerated partial healing in the remaining cases appeared within 1–2 weeks.[12]

Before BIOPTRON Therapy | After 12 days of BIOPTRON Therapy | After 27 days of BIOPTRON Therapy

Single case (Source: Department of Plastic Surgery, University Hospital Gent, Belgium) showing the effect of BIOPTRON Light Therapy.

Diabetic foot ulcers

BIOPTRON Light Therapy has been used to treat diabetic foot ulcers and clinical results have confirmed its positive influence on the affected and treated area. The ulcers gradually cleared, granulated and epithelized during treatment. Healing time was substantially shortened and ulcer pain was lower compared to treatment without BIOPTRON irradiation.[17]

Start BIOPTRON Therapy after amputation | After 3 months of BIOPTRON Therapy | Follow-up after 8 months of BIOPTRON Therapy

Single case (Source: Department of Plastic Surgery, University Hospital Gent, Belgium) showing the effect of BIOPTRON Light Therapy.

Post-traumatic wounds

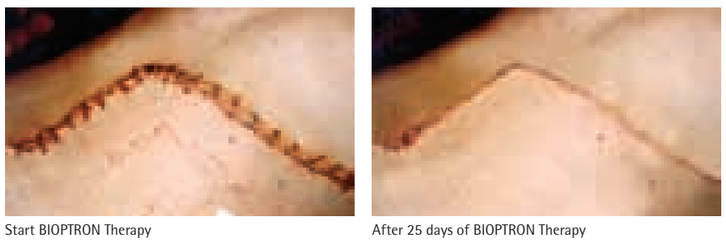
Residual defects after grafting and flap reconstruction of crushed foot.

Start BIOPTRON Therapy | After 21 days of BIOPTRON Therapy | After 8 months of BIOPTRON Therapy

Single case (Source: Department of Plastic Surgery, University Hospital Gent, Belgium) showing the effect of BIOPTRON Light Therapy.

Post-surgical wounds

BIOPTRON Light Therapy is a very simple and effective additional therapy in treatment of surgical wounds.

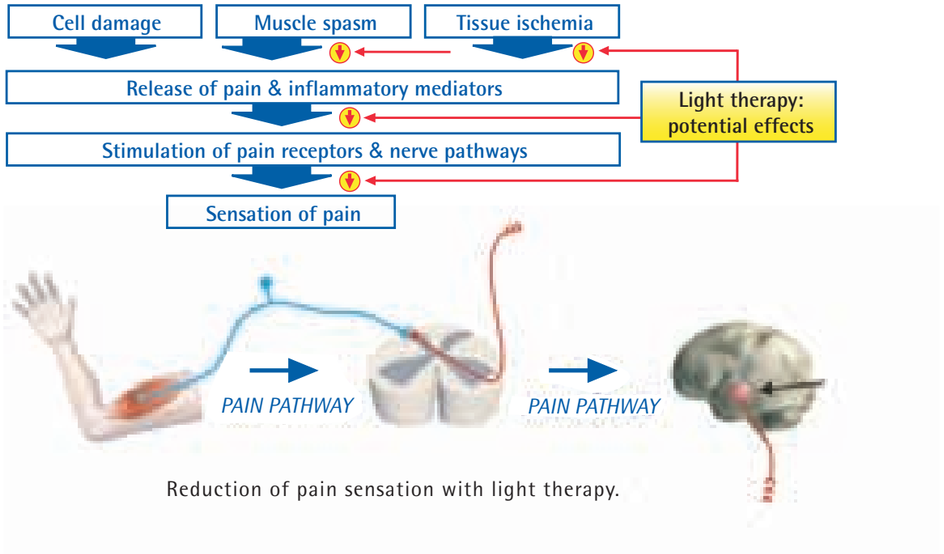


Start BIOPTRON Therapy | After 25 days of BIOPTRON Therapy

19) Simic, A., Pesko, P., Bjelovic, M., Stojakov, D., Todorovic, M., Jekic, I., Micev, M., Sabljak, P., Kontarak, M: Bioptron Light Therapy and Thoracophrenolaparotomy wound healing in patients operated due to cardiac carcinoma. Presented at the 4th International Gastric Congress, New York, USA, April 30-May 2, 2001

Pain treatment

Pain is unpleasant sensation associated with actual or potential tissue injury. Pain occurring after tissue injury has a protective role, alerting the body to damage and inducing rest to allow tissue regeneration. In chronic persistent pain this physiological function may be compromised. The pathophysiology of pain involves alteration of pain-transmission pathways. Thus knowledge of the normal physiology of these pathways is an essential prerequisite for understanding the mechanisms of acute and chronic pain.[18]

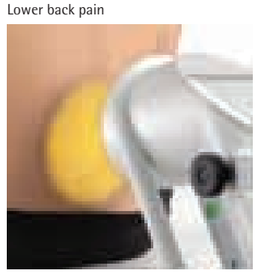


Reduction of pain sensation with light therapy.

Thanks to the ability of BIOPTRON Light Therapy to penetrate into live tissue this unit is suitable for the treatment of various conditions in RHEUMATOLOGY, SPORTS MEDICINE and PHYSIOTHERAPY. It has been reported that significant pain reduction in chronic painful conditions (rheumatoid arthritis, shoulder and neck pain) could be achieved.
In all these instances light therapy could help relieve pain and improve functionality. Very good results could be achieved in combination with classical treatment methods.
Its benefical influence could affect the patient's general condition, bringing relief from pain syndromes.

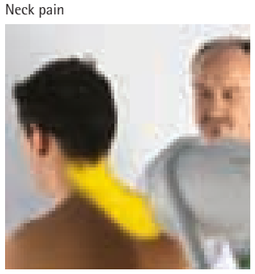
BIOPTRON Light Therapy is ideally suited as a complementary treatment in rehabilitation. It is often required with standard physiotherapeutic procedures and it can be successfully used as an integral part of complex physiotherapeutic procedures for sports injuries, burns, ankle and knee injuries, shoulder and elbow problems, stretching of tendons, bruises.
Musculosceletal pain can be caused by inflammation, degeneration, or trauma to the skeletal or myofascial tissues. Recent investigation in the field showed that BIOPTRON Light Therapy could be used for providing temporary relief of minor chronic and shoulder pain of musculoskeletal origin.

Lower back pain



Sport injury

Neck pain



Application

BIOPTRON step by step

Simple operation makes it easy to provide your patients with BIOPTRON Light Therapy:

1 Prepare the area to be treated by cleaning (for wounds by cleaning as prescribed by the treating physician).

2 Point the light beam at the area to be treated, holding the device at right angle (90°) and maintaining a distance of approx. 10 cm.

Apply the BIOPTRON Light Therapy for 4–10 minutes once or twice a day.

Cover larger areas by treating them point by point.
For wounds: apply the wound dressing as prescribed by the treating physician.

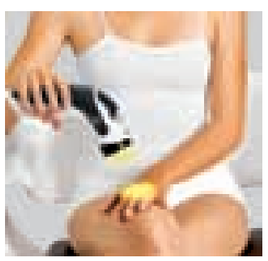
3 Unplug the device after use.
It is advisable to prolong the BIOPTRON Light Therapy for one to two weeks after closure of the wound in order to strengthen the treated area.

The BIOPTRON Light Therapy can be used both as a complementary treatment to support conventional medical methods and as a monotherapy for specific indications.

Needless to say, you are recommended to assure the clinical suitability of the BIOPTRON Light Therapy for your patient, by monitoring the effects of the treatment.

Fields of application

SURGERY • REHABILITATION • RHEUMATOLOGY • HOME CARE • SPORTS MEDICINE • TRAUMATOLOGY • GERIATRIC MEDICINE • DERMATOLOGY • NURSING HOMES • PHYSIOTHERAPY • PEDIATRICS • NEONATOLOGY



BIOPTRON Light Therapy

- A single unit emitting a broad range of light wavelengths at constant intensity for safe light therapy, thereby providing *effective, clinically proven solutions in wound healing and pain treatment.*
- *Innovative new technology* with clinically proven efficacy and visible results that encourage patient compliance.
- *Mobile, easily manageable* and *maintenance-free* device.
- *High patient throughput*: rapid 4 – 10 minutes full treatment can be administered by staff.
- Developed and produced by *BIOPTRON AG, Switzerland.*
- Technology *endorsed and used by leading physicians* in major universities and clinics across five continents.
- It can be applied both in the *medical practice* and in the *patient's home.*

Increasing health-care costs dictate the necessity of promoting the safe and effective treatments without long-term costs.

We could offer the use of the BIOPTRON Light Therapy in order to reduce health-care costs in wound healing and pain treatment.

Advantages of BIOPTRON Light Therapy

- Wide range of applications
- Conclusive therapeutic results
- Short treatment time
- Cost-effective (shortening hospitalization and rehabilitation periods; decreased use of wound-care materials)
- No known side effects
- Easy to use
- Continuation (rental/home care)
- Can be used both in the clinical setting and in the patient's home

The three devices BIOPTRON MedAll, BIOPTRON Pro 1 and BIOPTRON 2 differ in size, design and setting, but are featuring identical physical light characteristics. They are beeing used by medical professionals in hospitals and private surgeries as well as by home-users and patients themselves. The different types assure to find the best fitting solution for every individual need.

BIOPTRON MedAll

BIOPTRON Pro 1
with table stand

BIOPTRON 2

Filter diameter approx.	
- BIOPTRON MedAll	5 cm
- BIOPTRON Pro 1	11 cm
- BIOPTRON 2	15 cm
Power supply	
- BIOPTRON MedAll	100–240 V~ , 50 /60 Hz
- BIOPTRON Pro 1	100–240 V~ , 50 /60 Hz
- BIOPTRON 2	100–240 V~ , 50 /60 Hz
Power consumption	
- BIOPTRON MedAll	0.29-0.12 A
- BIOPTRON Pro 1	90 VA
- BIOPTRON 2	1.4–1.0 A
Fuse	
- BIOPTRON MedAll	-
- BIOPTRON Pro 1	-
- BIOPTRON 2	T2A / 250 V
Rated power of halogen	
- BIOPTRON MedAll	20 W
- BIOPTRON Pro 1	50 W
- BIOPTRON 2	90 W
Protective class	
- BIOPTRON MedAll	Class II ⧈, IP 20
- BIOPTRON Pro 1	Class II ⧈, IP 20
- BIOPTRON 2	Class I, IP 20
Weight	
- BIOPTRON MedAll	0.5 kg
- BIOPTRON Pro 1 (with table stand)	3.4 kg
- BIOPTRON Pro 1 (with floor stand)	7.8 kg
- BIOPTRON 2	4.3 kg
Ambient temperatures	
- Operation	+10 °C to +30 °C
- Storage	0 °C to +40 °C
Wavelength	480–3400 nm
Degree of polarization	>95% (590–1550 nm)
Light intensity	min. 10,000 lux
Specific power density	av. 40 mW/cm²
Light energy per minute	av. 2.4 Joule/cm²
CE labeling	CE 0124

References

1) Mester, E., Mester, A.F., Mester, A. The biomedical effects of laser application. Lasers Surg Med 1985; 5: 31-39.
2) Fenyo, M. Theoretical and experimental basis of biostimulation. Optics Laser Technol 1984; 16: 209-15.
3) Kertes, I., Fenyo, M., Mester, E., Bathory, G., Hypothetical physical model for laser biostimulation. Optics and Laser Technology, 1982; 16: 31-32.
4) Kubasova, T., Fenyo, M., Somosy, Z., Gazso, L., Kertesz. I. Investigations on biological effect of polarized light. Photochemistry and Photobiology, 1988; 48: 505-509.
5) Bolton, P., Dyson, M., Young, S. The effect of polarized light on the release of growth factors from the U-937 macrophage-like cell line. Laser Therapy 1992; 33-37.
6) Young, S., Bolton, P., Dyson, M. et al. Macrophage responsiveness to light therapy. Lasers Surg Med 1989; 9: 5, 497-505.
7) Depuydt, K., Monstrey, S., Hoeksema, H., The use of polarised light in the treatment of the burn wounds. Abstract. Presented at the 10th Annual EURAPS Meeting, Madrid, Spain, 21 May 1999.
8) Karu, T., Photobiology of low-power laser effects. Health Physics 1989; 56: 691-704.
9) Smith, K.C. The photobiological basis of low-level laser radiation therapy. Laser Therapy 1991; 3: 19-24.
10) Medenica, L., Lens, M. The use of polarised polychromatic non-coherent light alone as a therapy for venous leg ulceration. Journal of Wound Care 2003; 12: 1, 37-40.
11) Monstrey, S., Hoeksema, H., Saelens, H., Depuydt, K., Hamdi, M., Van Landuyt, K., Blondeel, P. A conservative approach for deep dermal burn wounds using polarised-light therapy. British Journal of Plastic Surgery 2002; 55: 420-426.
12) Iordanou, P., Baltopoulos, G., Giannakopoulou, M., Bellou, P., Ktenas, E. Effect of polarized light in the healing process of pressure ulcers. Int J Nurs Pract 2002; 8: 1, 49-55.
13) Kubasova, T., Horvath, M., Kocsis,K., Feny, M. Effect of visible light on some cellular and immune parameters. Immunology and Cell Biology 1995; 73: 239-244.
14) Young, S., Bolton, P., Dyson, M. et al. Macrophage responsiveness to light therapy. Lasers Surg Med 1989; 9: 5, 497-505.
15) Smith, K.C., The photobiological basis of low-level laser radiation therapy. Laser Therapy 1991; 3: 19-24.
16) Monstrey, S., Hoeksema, H., Saelenes, H., Depuydt, K., Hamdi, M., Van Landuyt, K., Blondeel, P. The effect of polarized light on wound healing. European Journal of Plastic Surgery, 2002; 24 (8): 377-382.
17) Coce, F., Korsic, M., Martinac, M. Approach to neuropathic and neuroishaemic foot ulcers in diabetic patients using lineary polarized light therapy. Presented on 18th International Diabetes Federal Congress, Paris 24-29 July, 2003.
18) Wulf, H., Baron, R., The theory of pain. Position Document, Pain at wound dressing changes, 2003.
19) Simic, A., Pesko, P., Bjelovic, M., Stojakov, D., Todorovic, M., Jekic, I., Micev, M., Sabljak, P., Kontarak, M: Bioptron Light Therapy and Thoracophrenolaparotomy wound healing in patients operated due to cardiac carcinoma. Presented at the 4th International Gastric Congress, New York, USA, April 30-May 2, 2001.