EVALUATION OF CLINICAL DATA (excerpt) ACCORDING TO RECOMMENDATION NB-MED/2.7/Rec3

1. MEDICAL PROCEDURES FOR USE

Medical procedures for which Safe Laser 500 Infra soft laser appliance is intended:
"The biological effect of laser radiation is linked to its specific physical properties. 'Soft lasers' have two essential beneficial effects on human body:
– biostimulation (1, 4, 19), and
– relief of inflammatory pain (3, 12, 15, 20, 23)
By laying down the theoretical basis of biostimulation, Prof. Mester set the scientific background that has enabled the extensive introduction of soft laser therapy on different medical fields all over the world in order to stimulate healing processes. The term 'biostimulation' means the stimulative effect on the regeneration processes on cell and tissue level. The potential 'independent' use of anti-inflammatory and analgesic effect observed 'incidentally' during this biostimulation has been the basis for further areas of clinical applications."
Excerpt from Háziorvosi könyvek *(Books for General Medical Practitioners)* – Softlaser-terápia 3 *(Soft Laser Therapy Vol. III)*: p. 64-73 (1996). Softlaserek a klinikai gyakorlatban *(Soft Lasers in Clinical Application)*. Dr. Ádám Mester, Semmelweis University, Faculty of General Medicine, Department of Radiology and Oncotherapy, Budapest.

Diseases and Problems Treatable with Safe Laser 500 Infra

- Wounds – promotes regeneration *(7, 11, 12, 14, 16, 24, 25)*
- Ulcus cruris, non-healing ulcers – starts and promotes regeneration *(7, 11, 12, 16, 19, 24, 25)*
- Sports injuries – shortens recovery (muscle strains, bruises, tears, bone fractures, hematomas, etc.) *(5, 10, 15, 21, 28, 33, 34, 35, 39, 41)*
- Musculoskeletal complaints – relieves pain and inflammation (e.g. myositis, periostitis, tennis elbow, arthrosis, osteoarthritis, osteoporosis, arthrosis and arthritis, muscle pain, etc.) *(3, 5, 10, 13, 15, 20, 21, 22, 23, 26, 28, 34, 35, 39, 41, 42, 43, 44)*
- Toothache, gum atrophy and inflammation, bleeding gums – can greatly reduce the damage to the oral mucosa (i.e. aphthae), speeds up healing *(6, 9, 32, 44)*

Application Areas of Laser Phototherapy

Nowadays laser therapy is applied in several areas due to its beneficial biological effects listed above.

- Dermatology *(7, 8, 12, 14, 16, 19)*
- Sports medicine *(5, 10, 12, 13, 15, 20, 21, 22, 28, 33, 34, 39, 41, 42)*
- Rheumatology *(10, 20, 21, 22, 23, 26, 28, 33, 34, 35, 42, 43)*
- Dentistry *(6, 9, 32, 44)*
- Otolaryngology *(2, 7, 9, 29, 31, 36, 37, 38, 40)*
- Diabetology *(12, 17, 19)*

The treatment doses indicated in the “User Manual” have been determined based on Hungarian professional experience, protocols and WALT Recommendations. http://waltza.co.za/wp-content/uploads/2012/08/Dose_table_780-860nm_for_Low_Level_Laser_Therapy_WALT-2010.pdf

Contraindications:

- In case of pregnancy, irradiation of abdomen is forbidden because of (dangerous) increase of congestion!
- Usage of the instrument is forbidden in case of persons suffering from severe coagulation disorders as well!
- Do not treat with laser:
- tumour areas,
- thyroid (in case of superactivity) and
- breast area,
- skin surfaces affected by fungal infection,
- implanted pacemaker!
- Direct irradiation of coloured moles may be dangerous, because these qualify as pre-neoplastic skin lesions.
- It is forbidden to light into nostrils with Safe Laser® 500 Infra without nasal accessory!

Never treat yourself without a precise medical diagnosis, since Safe Laser® 500 Infra, although it can decrease your pain, is not always able to eliminate the root of your problem, and it may temporarily obscure grave diseases!

1. Mester E.: A lasersugár biomedikális hatásaira vonatkozó vizsgálatok. Doktori értekezés, Budapest, 1971
2. Szabó Gy.: Laserterápia a fül-orr-gégészetben. Kandidátusi értekezés, Budapest 1993
3. Sohajda Mária: Softlaserek hatásának összehasonlítása krónikus fájdalom syndromákban. Városi Kórház jubileumi kiadványa, Sátoraljaújhely, 1995
4. Horváth Z, Donkó Z.: Possible ab initio explanation of laser ”biostimulation” effect, Las. Appl. In Med. and Surgery, Bologna, 1992
5. Neduchalova, Kylov: Lézer alkalmazása gyermekek mozgásszervi rendellenessé-geinek átfogó terápiájában, Lágylézer Terápia 2001. január
6. Simunovic: Lasers in Medicine and Dentistry, EMLA, 2000
7. Schindl A, Schindl M, Schon H, Knobler R, Havelec L, Schindl L. Low-intensity laser irradiation improves skin circulation in participants with diabetic microangiopathy. Diabetes Care. 1998;21(4):580–584. doi: 10.2337/diacare.21.4.580. Division of Special and Environmental Dermatology, University of Vienna Medical School, Austria link

8. Riberio: Effects of low-intensity polarized visible laser radiation on skin burns: a light microscopy study, J. of Cl. Laser Medicine & Surg. 2004, 1Center for Lasers and Applications, IPEN-CNEN/SP, Cidade Universitária, Department of Histology, ICB/USP, Cidade Universitária, São Paulo, Brazil.
9. Jan Tuner és Lars Hode: Laser Therapy in Dentistry and Medicine (Prima Books Sweden, 1996, Stock- holm, 1–235.
10. Danhof G.: Lasertherapie in der Sportmedizin und Orthopadie, WBV Bio.-Med Verlag, Schorndorf, 1993
11. Hopkins J, Todd A, Jeff G, Seegmiller G, Baxter D. Low level laser therapy facilitates superficial wound healing in humans: a triple-blind, sham-controlled Study. J Athl Train. 2004;39(3):223–229. link
12. Enwemeka CS, Parker JC, Dowdy DC, Harkness EE, Sanford LE, Woodruff LD.: The efficacy of low-power lasers in tissue repair and pain control: a meta-analysis study. Photomed Laser Surg 2004; 22: 323–29 (CI=110, IF=1.785) link
13. Bjordal JM, Lopes-Martins RA, Joensen J.: A systematic review with procedural assessments and meta-analysis of low level laser therapy in lateral elbow tendinopathy (tennis elbow). BMC Musculoskelet Disord 2008; 9: 75
14. Pereira AN, Eduardo Cde P, Matson E, Marques MM. Effect of low power laser irradiation on cell growth and procollagen synthesis of cultured fibroblasts. Laser Surg Med. 2002;31:263–267. doi: 10.1002/lsm.10107. Department of Stomatology, School of Dentistry, University of São Paulo-SP, Brazil link
15. Chow RT, Barnsley L.: Systematic review of the literature of low-level laser therapy (LLLT) in the management of neck pain. Lasers Surg Med 37:46-52 2005 (CI=88, IF=2.455) link
16. Fulop MA, Dhimmer S, Deluca JR, Johanson DD, Lenz RV, Patel KB, Douris PC, Enwemeka CS.: A meta-analysis of the efficacy of phototherapy in tissue repair. Photomed Laser Surg 2009 (CI=10, IF=1.756) link
17. Gáspár L., Kásler M.: Laserek az orvosi gyakorlatban. Springer Hungarica, 1-252, Budapest 1993
18. Horváth Judit dr.: Lágylézerterápia a gyakorlatban, Wantex – Medical, 1993
19. Basavaraj M. Kajagar, Ashok S. Godhi, Archit Pandit and S. Khatri: Efficacy of Low Level Laser Therapy on Wound Healing in Patients with Chronic Diabetic Foot Ulcers— A Randomised Control Trial, Department of Surgery, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum, 590 010 Karnataka India link

20. Gür: Efficacy of low power laser therapy in Fibromyalgia: a single blind, placebo controlled trial, Lasers Medical Science 2002, Physical Medicine and Rehabilitation, School of Medicine, Dicle University, Diyarbakir, Turkey link
21. Ljubica M. Konstantinovic, Milisav R. Cutovic, Aleksandar N. Milovanovic: Low-Level Laser Therapy for Acute Neck Pain with Radiculopathy: A Double-Blind Placebo-Controlled Randomized Study, Institute for Rehabilitation, Medical School, University of Belgrade, Belgrade, Serbia link
22. Soriano F, Rios R, Pedrola M.: Acute cervical pain is relieved with Gallium Arsenide (GaAs) laser radiation. A double blind preliminary study. Laser Therapy 1996
23. Aimbire F, Albertini R, Pacheco MTT.: Low-level laser therapy induces dose-dependent reduction of TNFα levels in acute inflammation. Photomed Laser Surg 2006; 24: 33–37. (CI=103, IF=1.732) link
24. Wu X, Dmitriev AE, Cardoso MJ, et al. 810 nm Wavelength light: an effective therapy for transected or contused rat spinal cord. Lasers Surg Med. 2009;41:36–41. link
25. Tuner J, Hode L.: Medical Indications: Wound Healing, in 'Laser Therapy: Clinical Practice and Scientific Background' Prima Books:Grangesberg, pp.189- 196 2002
26. Brosseau L, Robinson V, Wells G.: Low-level laser therapy (classes I, II and III) for treating rheumatoid arthritis. Cochrane Database Syst Rev 2005; 4: CD002049. link
27. Hashmi JT, Huang YY, Osmani BZ, Sharma SK, Naeser MA, Hamblin MR.: Role of low-level laser therapy in neurorehabilitation. – Wellman Center for Photomedicine, Massachusetts General Hospital, Department of Dermatology, Harvard Medical School, Boston, MA 02114, USA. – 2010 American Academy of Physical Medicine and Rehabilitation. (CI=207, IF=1.731) link
28. Hübler R1, Blando E, Gaião L, Kreisner PE, Post LK, Xavier CB, de Oliveira MG.: Effects of low-level laser therapy on bone formed after distraction osteogenesis. School of Physics, Pontifícia Universidade Católica do Rio Grande do Sul, Brazil. link
29. Maleki S, Kamrava SK, Sharifi D, Jalessi M, Asghari A, Ghalehbaghi S, Yazdanifard P.: Effect of local irradiation with 630 and 860 nm low-level lasers on tympanic membrane perforation repair in guinea pigs. link

30. Dr. med. Lutz Wilden: On The Effectiveness of Low Level Laser Light in the Inner Ear. Kurallee 16, D-94072 Bad Füssing, link
31. Gungor A, Dogru S, Cincik H, Erkul E, Poyrazoglu E. Effectiveness of transmeatal low power laser irradiation for chronic tinnitus. J Laryngol Otol. 2008 May;122(5):447-51. Epub 2007 Jul 12. link
32. Gáspár L., Szabó Gy.: A laser alkalmazási lehetőségei a szájsebészetben. Fogorv. Szle. 89, 114, 1988
33. Stergioulas A.: Low-level laser treatment can reduce edema in second degree ankle sprains. University of Peloponnese, Attica, Greece, link
34. Pinheiro AL, Oliveira MG, Martins PP, Ramalho LM, Oliveira MA, Silva Júnior AN, et al. Biomodulation effects of LLLT on bone regeneration. Laser Ther 2001;13:73-9. link
35. Fujimoto K, Kiyosaki T, Mitsui N, Mayahara K, Omasa S, Suzuki N, et al.. Low-intensity laser irradiation stimulates mineralization via increased BMPs in MC3T3-E1 cells. Lasers Surg Med 2010;42:519-526. link
36. Naghdi S, Ansari NN, Fathali M, Bartley J, Varedi M, Honarpishe R. "A pilot study into the effect of low-level laser therapy in patients with chronic rhinosinusitis." Assistant Professor, Department of Physiotherapy, School of Rehabilitation , Tehran University of Medical Sciences Physiother Theory Pract. 2013 Mar 22. link
37. Moustsen, P.A., Vinter, N., Aas-Andersen, L., Kragstrup, J.: Laser Treatment of Sinusitis in General Practice Assessed by a Double-blind Controlled Study. Ugeskrift for Laeger, 153 (32), 1991 Aug 5., pg. 2232 – 4. link
38. Simunovic, Z.: Laser therapy in the diseases of ear, nose and throat. p.381-383. In Laser in Medicine and Dentistry. Editor Zlatko Simunovic, Rijeka: Vitagraf 2000, 544 pgs. link
39. Stergioulas A.: Effects of low-level laser and plyometric exercises in the treatment of lateral epicondylitis. Peloponnese University, Sparta, Greece link
40. Simunovic, Z. et al.: Lasers in medicine and dentistry, Vitagraf Rijeka, 2000. Hahn, A. et al.: Combined Laser – Egb 761 Tinnitus Therapy, Acta Otolaryngol 2001, Suppl. 545, 92-93.
41. Pertille A, Macedo A, Oliveira C.: Evaluation of muscle regeneration in aged animals after treatment with low-level laser therapy. Universidade Metodista de Piracicaba, Piracicaba, SP, Brazil, link
42. Michael R Hamblin: Can osteoarthritis be treated with light? Arthritis Res Ther. 2013; 15(5): 120. link

43. Oliveira P, Santos AA, Rodrigues T.: Effects of phototherapy on cartilage structure and inflammatory markers in an experimental model of osteoarthritis. Federal University of São Carlos, Department of Physiotherapy, Brazil. link

44. Moritz, N. Gutknecht, O. Doertbudak, K. Goharkhay, U. Schoop, P. Schauer, and W. Sperr.: Bacterial Reduction in Periodontal Pockets Through Irradiation with a Diode Laser: A Pilot Study Journal of Clinical Laser Medicine & Surgery. FEBRUARY 1997, 15(1): 33-37. doi:10.1089/clm.1997.15.33. link

Publications soft laser mechanism of action

- Tóth Tihamér dr.: A lézerek klinikai alkalmazása Medicina, Budapest, 1990
- Tunér J , Hode L.: Low Level Laser Therapy, Prima Books AB, 2002
- Rochkind S.: Lézerterápia – a perifériális idegsérülések kezelésének új módszere, 1-2. Lágylézer Terápia 2001. június
- Smith: The photobiological basis of low-level laser radiation therapy, Laser Therapy 1991
- Harrington J., Li Junheng: Biomedical optics and lasers: diagnostics and treatment. 16–18 September 1998, Beijing, China. Bellingham, Washington: SPIE. ISBN 0-8194-3009-9.
- Curtis Turchin: Light and Laser Therapy: Clinical Procedures, MA, DC, (third edition 2007)
- Moshkovska, T., Mayberry J.: It is time to test low level laser therapy in Great Britain. Postgraduate Medical Journal, 81 (957): 436–441. doi:10.1136/pgmj.2004.027755. PMC 1743298. PMID 15998818. (2005) (CI=43, IF=1.939)
- Harrington J., Li Junheng: Biomedical optics and lasers: diagnostics and treatment. 16–18 September 1998, Beijing, China. Bellingham, Washington: SPIE. ISBN 0-8194-3009-9.
- Tina Karu: Ten Lectures on Basic Science of Laser Phototherapy (Prima Books, Sweden, Stockholm, 2007, 1–414.
- Basford J. R.: Low Energy Laser Therapy – Lasers in Surgery and Medicine, 1989 (CI=133, IF=2.655)
- Nussbaum EL, Van Zuylen J.: Transmission of light through human skinfolds: effects of physical characteristics, irradiation wavelength and skin-diode coupling relevant to phototherapy. Physiother Can. 2007; 59: 194–207. (CI=86, IF=1.490)

- Fujimaki, Shimoyama T, Liu Q, Nakaji S, Sugawara K.: Low-level laser irradiation attenuates production of reactive oxygen species by human neutrophils. J Clin Laser Med Surg 21(4):165-170 2003 (CI=63, IF=2.594)
- Gulsoy M, Ozer GH, Bozkulak O, Tabakoglu HO, Aktas E, Deniz G, Ertan C.: The biological effects of 632.8-nm low energy He-Ne laser on peripheral blood mononuclear cells in vitro . J Photochem Photobiol B 8293):199-202. 2006 (CI=36, IF=2.691)
- Brosseau L.: Low level laser therapy for osteoarthritis and rheumatoid arthritis: a metaanalysis. J Rheumatol 27(8):1961-9 2000 (CI=97, IF=3.84)

Clinical use of the soft laser

- Kovács Lajos: A kis teljesítményű lézersugár hatása a portio fiziológiás gyógyulási folyamatára, Budapest, 1982
- Barabás Klára: Különböző típusú lézerek hatásainak vizsgálata kettős vak módszerrel, rheumatoid arthritisben, Budapest, 1991
- Szabó György: Laserterápia a fül-orr-gégészetben, Budapest 1993
- Jana Melková, M.D.: The significance of Low Level Laser Therapy for ambulatory treatment of burn trauma, Laser & Surgery Center Jevicko, Czech Republic
- Les Jonsson B.H.Sc (Podiatry): Preoperative Low Level Laser application to reduce post-operative pain in patients receiving winograd type of partial matrixectomy surgery of hallux , Dip. Pod. (Psy) Cert. L.L.T., Masterton, New Zealand
- Mary Dyson: How photons modulate wound healing via the immune system. King’s College London (KCL), University of London, Guy’s Hospital Campus, London SE1 9RT, UK.
- Simona Bedřichová M.D.: Biostimulation Laser Acne Treatment, Clinic of Laser, Aesthetic Dermatology and Plastic Surgery Prague
- Dundar E, Evcik D, Samli F, Pusak H, Kavuncu V.: The effect of gallium arsenide aluminum laser therapy in the management of cervical myofascial pain syndrome: a double blind, placebo- controlled. Clin Rheumatol 2007
- Roberta T Chow, Mark I Johnson, Rodrigo A B Lopes-Martins, Jan M Bjordal: Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomised placebo or active-treatment controlled trials Nerve Research Foundation, Brain and Mind Research Institute, University of Sydney, Sydney, NSW, Australia November 13, 2009

- Les Jonsson B.H.Sc (podiatry): Low level laser to reduce pain, pain medication and increase patient compliance in the treatment of lower limb ulceration (Psy) Cert. L.L.T., Masterton, New Zealand
- Oron A, Oron U, Chen J, Eilam A, Zhang C, Sadeh M, Lampl Y, Streeter J, DeTaboada L, Chopp M.: Low-level laser therapy applied transcranially to rats after induction of stroke significantly reduces long-term neurological deficits. Department of Orthopedics, Assaf Harofeh Medical Center, Zerifin 70300, Israel
- W. Babushkina, I.M. Korochkin, A.V. Kartelishev: Results of 10-Year Use of Low Intensity Laser Therapy and Conventional Treatment of Patients with Stenocardia. Bashkir Medical University, Ufa, Russian State Medical University, Moscow, RF