

Evaluation Of Clinical Data and Literature Review Low Level Laser Therapy for

B-CURE LASER LLLT808 of GOOD ENERGIES

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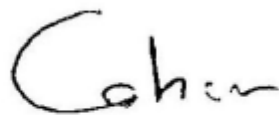
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For

B-Cure Laser - LLLT 808

Erika-Carmel LTD.

www.gd-energies.com

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Abstract

- **B-CURE LASER (LLLT808 of GOOD ENERGIES)** is a powerful hand held soft-laser medical device, with a peak power of 250 mW at wavelength of 808 nm.
- In the following document we present evidence for the clinical use of the low level laser therapy the following diseases: **carpal tunnel syndrome, fibromyalgia, myofascial pain syndromes** (e.g knee pain, low back pain, neck/upper back pain, muscle pain etc.), **joint disorders/arthritis** (e.g achilles tendinitis, tennis elbow etc.), **medical skin conditions** (e.g acne, vitiligo, herpes simplex, lymphedema, wound healing, fresh and old surgical wounds or scars, skin wounds, burns etc.), **cosmetic skin conditions** (e.g. post-pregnancy stretch marks (striae gravidarum), skin rejuvenation, wrinkles and skin aging, skin sensitivity, etc.), **inflammation, hemorrhoids, headache** and **dental diseases**.
- **A literature review** has demonstrated the beneficial effect of LLLT in high quality clinical studies in all the above mentioned indications.
- B-Cure Laser is approved by the **Standards Institution** of Israel and by the Israeli Ministry of Health.
- B-Cure Laser is being used in **major hospitals and medical centers in Israel** as will be shown in the manuscript.
- Several **other LLLT devices with similar technical specification have a CE mark** (Timelas Vital, Mo-dulas Handy CW100, EKKy Lite and Power Laser 105) as will be shown in the manuscript.
- The current application of B-Cure Laser device has **superior power of 250 mW** as compared to lower power applied by the other CE approved devices cited above.

Index

Cover page.....	1
Abstract	2
Index.....	3
Introduction	4
LLLT Devices.....	4
Therapeutic Mechanisms of LLLT.....	4
Indications for LLLT Use	5
B-Cure Laser – Product Description	6
B-Cure Laser – Technical Specifications	7
B-Cure Laser – Safety	7
Experience in B-Cure Laser Clinical Use in Israel	9
Literature review of the Indications for LLLT Use.....	11
CONCLUSION	11
Reference List.....	12
Appendix 1: Table summarizing literature search	16

Introduction

Low level laser therapy (LLLT), also called "cold laser therapy" and "low-power laser therapy" (LPLT) is a light source treatment that generates a coherent light of a single wavelength. LLLT uses red-beam or near-infrared lasers with a wavelength between 600 and 1,000 nanometers (nm) and from 5 to 500 milliwatts. LLLT emits no heat, sound, or vibration. Instead of producing a thermal effect, LLLT acts by photochemical reactions in the cells (bio-stimulation).

LLLT Devices

There are 2 kinds of LLLT devices:

1. Point Lasers – with a treatment area of approximately 0.5 cm².
2. Clusters (shower type lasers) with generally 3 – 8 diodes covering larger areas, irradiating an area of 0.5 cm² times the number of laser diodes

LLLT devices include the following laser types:

1. Gallium arsenide (GaAs) laser
2. Gallium aluminum arsenide infrared semiconductor (GaAlAs) laser
3. Helium neon (HeNe) laser

Therapeutic Mechanisms of LLLT

LLLT promotes healing and reduces pain through several therapeutic mechanisms:

1. Stimulation of collagen production
2. Alteration of DNA synthesis
3. Improves the function of damaged neurological tissue
4. Increased ATP production by the mitochondria and increased oxygen consumption on the cellular level, which may result in muscle relaxation
5. Increased serotonin and increased endorphins
6. Increased anti-inflammatory effects through reduced prostaglandin synthesis
7. Improved blood circulation to the skin in cases like neuralgia and diabetes mellitus
8. Decreases permeability of the membrane of the nerve cells for Na/K causing hyperpolarisation
9. Increased lymphatic flow and decreased edema

Indications for LLLT Use

The literature review supports the following indications for LLLT use (page 10, appendix 1)

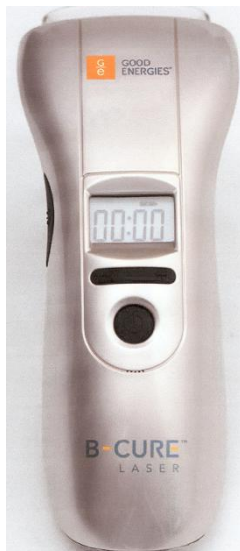
1. Carpal tunnel syndrome
2. Fibromyalgia
3. Myofascial pain syndromes
 - a. Knee pain
 - b. Low back pain
 - c. Neck/upper back pain
 - d. Muscle pain
4. Joint disorders (Arthritis)
 - a. Achilles Tendinitis
 - b. Tennis elbow
5. Skin – Medical conditions
 - a. Acne
 - b. Vitiligo
 - c. Herpes simplex
 - d. Lymphedema
 - e. Wound healing
 - f. Fresh and old surgical wounds or scars
 - g. Skin wounds
 - h. Burns
6. Skin – Cosmetic conditions
 - a. Post-pregnancy stretch marks (striae gravidarum)
 - b. Skin rejuvenation
 - c. Wrinkles and skin aging
 - d. Skin sensitivity
7. Inflammation
8. Hemorrhoids
9. Headache
10. Dental diseases

B-Cure Laser – Product Description

The LLLT device LLLT808 (Good Energies, B-Cure Laser) is a powerful portable (hand held) soft-laser medical device, with a peak power of 250 mW. B-Cure Laser 808 wavelength is 808 nm, which is within the range of wavelengths known for best tissue penetration ability 800 – 830 nm.

An innovative electro-optical mechanism, restricted to B-Cure Laser enables the production of an effective, homogenous, and very large coherent laser beam – with the area of 4.5 cm² (Patent Pending).

The combination of the relatively high power with the wavelength of 808 nm, and the unique treatment area of 4.5 cm², enables high quality and fast recovery in shorter individual treatment times.



In order to enable the device to treat the different kind of indications, two operation methods were developed, unique to B-Cure Laser.

1. Open wounds, burns, acne etc.: Pressing the treatment start button enables to operate B-Cure Laser device without touching the skin. This method is indicated for lesions without direct contact of the treated area.

2. Articular or muscle pain etc.: Pressing the device directly onto the skin or treatment area for a deeper effective treatment

B-Cure Laser – Technical Specifications

GaAIAs Infra-Red Laser	Wavelength: 808 nm (810nm max)
Optical power	250 mW (Peak)
Laser Indicator	Green Color LED
Beam Size	45 mm x 5 mm (Effective Beam Area)
Beam Divergence	+/- 3.0 degree
Pulse Time	20 micro second
Duty Cycle	25%
LCD Display Timer	30 min Timer with 30 second interval setting
Power Supply	AC/DC Adaptor for charging (115/230VAC, 60 / 50 Hz) Output 9V, 500mA
Battery	3x 1.2V AAA Rechargeable batteries (Metal Hybrid NiCd or NiMH)
Frequency	Standby 32,768Hz Active 2.0 MHz
Power	Max. 3.2W
Dimension	200 x 70 x 40 mm
Weight	650 g

B-Cure Laser – Safety

Laser Safety: The LLLT 808 is certified as CLASS 1 LASER PRODUCT by Standard Institution of Israel (Certificate no.: 8412320697 Rev.1, Date of issue: 19/06/2008) according to the requirements of the standard: IEC 60825-1 "Safety of laser products" Part 1: "Equipment classification, Requirements and user's guide" Ed. 1.2; 2001.

Electromagnetic Compatibility: Positive Test Report # 200SJ 10-30-107026 of Shanghai Institute of Measurement and Testing Technology EMC Lab (NVLAP Lab Code: 200632-0) according to the following standards: EN 55011:1998 A1:1999 A2:2002 Information technology equipment – Radio disturbance characteristics - Limits and methods of measurement; IEC 61000-4-2:2001 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test; IEC 61000-4-3: 2006 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques · Radiated, radio-frequency, electromagnetic field immunity test; Refer to: IEC 60601-1-2:2001/A1:2004 Medical

Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility Requirements and Tests (with Amendment 1:2004).

General safety: According to the standard: IEC/EN 60601-1 (1988) A1 (1991) A2 (1995) Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (tested by Electronics & Telematics Laboratory of Standards Institution of Israel):
Class II medical equipment while connected with AC/DC Adaptor
Internally powered equipment while not connected with AC/DC Adaptor
Applied part BF

Experience in B-Cure Laser Clinical Use in Israel

B-Cure Laser is approved by the Standards Institution of Israel, and by the Israeli Ministry of Health. B-Cure Laser is being used in 4 major hospitals in Israel: Tel-Aviv Medical Center, Hadassah Medical Center, Rambam Medical Center, and Sheba Medical Center. The following table describes the clinical use of B-Cure Laser in the medical centers in Israel, having applied it for 6 minutes per treatment.

Name	Title/Hospital/City	Disease	Number of patients	Results
Dr. Ana sajin	Specialist in Rehabilitation and Physical Medical Hadassa Jerusalem	Sub-acute articular Pains, Carpal Tunnel Syndrome, MCI in Patients W/ sub-acute Inflammation.	40	"The treatments for all the mentioned indications were very successful; The reduction of pain was very significant". "No negative side effects".
Prof. Elon Eisenberg Dr. V. Shabshayevitz	Director of the pain clinic. A Dr. in the pain Clinic. Rambam/ Haifa	Acute and chronic neck pain, low back pain knee and other Articular pains.	400	"The apparatus exerted a positive effect on a substantial number of treated patients. It is our Intention to continue using this equipment in the Rambam Pain Clinic.
Dr. Ittay Gur-Arieh	Director, unit for pain treatment. Sheba Hospital Tel-Aviv President of the Israeli Pain Association.	Articular pains and peripheral nerve pains – occipital neuralgia.	50	"There was a significant pain reduction in the majority of patients treated with the apparatus (pain reduction by 30% is considered significant)". "No negative side effects occurred."
Rachel Tiktinsky MPT Prof. Michael Heim Prof. Uri Martinowitz	The directors of Hemophilia Center. Sheba Medical Center. Tel Aviv	Hemophilia A Severe and Willebrandt type 3	8	Reduced pain on the VAS Scale from 9-10 to 5-6. Reduced swelling in the knee by 0.5-2.5 cm. A substantial range of motion improvement."The laser is almost an exclusive modality that is allowed to be used on a joint that has undergone arthroplasty."There were no ill side effects reported." "The laser adds a huge step forward for these patients; no other reported modality has shown improvement in so many musculoskeletal areas in such a short time frame."
Dr. Avi Reyhanian	Owns a private clinic, a member of the ALD-Academy of laser dentistry, a reviewer of dental Journals. Netanya	Periodontal disease, insertion of implants, surgical procedures with stitches.	8	"Normally, a day after surgical procedure such as implants, Periimplantitis, epicoectomy, surgical extraction,, periodontal surgery etc. the patient presents swelling and pain. With the use of the Good Energies B-CURE laser, 6

Name	Title/Hospital/City	Disease	Number of patients	Results
				<p>minutes before and after and a day after, there was a positive influence on the healing process of the hard and soft tissue, in the mean of less pain less swelling and the healing process was better and faster" "No side effects." There was hardly a need for pain killers.</p>
<p>Dr. Le-On Gilead</p>	<p>Head of wound clinic Certified Dermatologist and MOHS Surgeon.Dpt. Of Dermatology, Hadassah university Hospital / Jerusalem</p>	<p>Chondrodermatitis helicis nodularis</p>	<p>15</p>	<p>After the positive results – the final report relates to one case only: a 56 years old lady. "I performed surgery and removed the involved skin and Cartilage. The wound's healing process got very long despite systemic and local antibiotic treatment. After no improvement for weeks," I decided to treat her with LLLT 808. Within a number of days – two treatments a day, there was a substantial improvement. After two weeks there was at least 50% retreat in redness and pain, and a week later it was all gone – a complete healing and no sensitivity. In four month follow up – an affliction did not return. "In light of the long procedure and the condition of patient at the beginning of treatment I have no doubt that the recovery is only due to the treatment with the device."</p>

Literature review of the Indications for LLLT Use

The strategy of literature review is as follows: PubMed (PubMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: <http://www.pubmed.gov/>) was searched for publications relevant to LLT use using the following terms: laser therapy, low-level laser [MeSH], lasers, LLLT, randomized controlled trial, clinical trial and all the following clinical possible indications: carpal tunnel syndrome, fibromyalgia, myofascial pain, knee pain, low back pain, neck pain, upper back pain, muscle pain, arthritis, achilles tendinitis, tennis elbow, acne, vitiligo, herpes simplex, lymphedema, wound healing, surgical wounds, surgical scars, skin wounds, burns, post-pregnancy stretch marks, striae gravidarum, skin rejuvenation, wrinkles, skin aging, skin sensitivity, inflammation, hemorrhoids, headache and dental diseases.

According the literature review, the beneficial effect of LLLT has been demonstrated in high quality clinical studies, in all the above mentioned indications. The results of the literature review appear in Appendix 1.

Conclusion: The above mentioned literature review provide evidence base which indicates that B-Cure Laser LLLT 808 treatment is clinically effective in the treatment of the following diseases: carpal tunnel syndrome, fibromyalgia, myofascial pain syndromes (e.g knee pain, low back pain, neck/upper back pain, muscle pain etc.), joint disorders/arthritis (e.g achilles tendinitis, tennis elbow etc.), medical skin conditions (e.g acne, vitiligo, herpes simplex, lymphedema, wound healing, fresh and old surgical wounds or scars, skin wounds, burns etc.), cosmetic skin conditions (e.g. post-pregnancy stretch marks (striae gravidarum), skin rejuvenation, wrinkles and skin aging, skin sensitivity, etc.), inflammation, hemorrhoids, headache and dental diseases.

Reference List

1. Altan L, Bingol U, Aykac M, Yurtkuran M. Investigation of the effect of GaAs laser therapy on cervical myofascial pain syndrome. *Rheumatol Int* 2005; 25(1):23-27.
2. Amorim JC, de Sousa GR, de Barros SL, Prates RA, Pinotti M, Ribeiro MS. Clinical study of the gingiva healing after gingivectomy and low-level laser therapy. *Photomed Laser Surg* 2006; 24(5):588-594.
3. Bakhtiary AH, Rashidy-Pour A. Ultrasound and laser therapy in the treatment of carpal tunnel syndrome. *Aust J Physiother* 2004; 50(3):147-151.
4. Basford JR, Sheffield CG, Harmsen WS. Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain. *Arch Phys Med Rehabil* 1999; 80(6):647-652.
5. Bayat M, Azari A, Golmohammadi MG. Effects of 780-nm Low-level Laser Therapy with a Pulsed Gallium Aluminum Arsenide Laser on the Healing of a Surgically Induced Open Skin Wound of Rat. *Photomed Laser Surg* 2009.
6. Bingol U, Altan L, Yurtkuran M. Low-power laser treatment for shoulder pain. *Photomed Laser Surg* 2005; 23(5):459-464.
7. Bjordal JM, Lopes-Martins RA, Iversen VV. A randomised, placebo controlled trial of low level laser therapy for activated Achilles tendinitis with microdialysis measurement of peritendinous prostaglandin E2 concentrations. *Br J Sports Med* 2006; 40(1):76-80.
8. Bjordal JM. Re: "low-level laser therapy and lateral epicondylitis" Maher S. *Phys Ther.* 2006;86:1161-1167. *Phys Ther* 2007; 87(2):224-225.
9. Bjordal JM, Lopes-Martins RA, Joensen J et al. 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.
10. Brosseau L, Welch V, Wells G et al. Low level laser therapy for osteoarthritis and rheumatoid arthritis: a metaanalysis. *J Rheumatol* 2000; 27(8):1961-1969.
11. Brosseau L, Welch V, Wells G et al. Low level laser therapy (Classes I, II and III) for treating osteoarthritis. *Cochrane Database Syst Rev* 2004;(3):CD002046.
12. Brosseau L, Wells G, Marchand S et al. Randomized controlled trial on low level laser therapy (LLLTT) in the treatment of osteoarthritis (OA) of the hand. *Lasers Surg Med* 2005; 36(3):210-219.
13. Brosseau L, Wells G, Marchand S et al. Randomized controlled trial on low level laser therapy (LLLTT) in the treatment of osteoarthritis (OA) of the hand. *Lasers Surg Med* 2005; 36(3):210-219.

14. Brosseau L, Robinson V, Wells G et al. Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis. *Cochrane Database Syst Rev* 2005;(4):CD002049.
15. Carati CJ, Anderson SN, Gannon BJ, Piller NB. Treatment of postmastectomy lymphedema with low-level laser therapy: a double blind, placebo-controlled trial. *Cancer* 2003; 98(6):1114-1122.
16. Chang WD, Wu JH, Jiang JA, Yeh CY, Tsai CT. Carpal tunnel syndrome treated with a diode laser: a controlled treatment of the transverse carpal ligament. *Photomed Laser Surg* 2008; 26(6):551-557.
17. Chow RT, Heller GZ, Barnsley L. The effect of 300 mW, 830 nm laser on chronic neck pain: a double-blind, randomized, placebo-controlled study. *Pain* 2006; 124(1-2):201-210.
18. de Bie RA, de Vet HC, Lenssen TF, van den Wildenberg FA, Kootstra G, Knipschild PG. Low-level laser therapy in ankle sprains: a randomized clinical trial. *Arch Phys Med Rehabil* 1998; 79(11):1415-1420.
19. de Paiva Carvalho RL, Alcantara PS, Kamamoto F, Cressoni MD, Casarotto RA. Effects of Low-Level Laser Therapy on Pain and Scar Formation after Inguinal Herniation Surgery: A Randomized Controlled Single-Blind Study. *Photomed Laser Surg* 2009.
20. Djavid GE, Mehrdad R, Ghasemi M, Hasan-Zadeh H, Sotoodeh-Manesh A, Pouryaghoub G. In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomised trial. *Aust J Physiother* 2007; 53(3):155-160.
21. Dundar U, 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 study. *Clin Rheumatol* 2007; 26(6):930-934.
22. Ekim A, Armagan O, Tascioglu F, Oner C, Colak M. Effect of low level laser therapy in rheumatoid arthritis patients with carpal tunnel syndrome. *Swiss Med Wkly* 2007; 137(23-24):347-352.
23. Evcik D, Kavuncu V, Cakir T, Subasi V, Yaman M. Laser therapy in the treatment of carpal tunnel syndrome: a randomized controlled trial. *Photomed Laser Surg* 2007; 25(1):34-39.
24. Flemming K, Cullum N. Laser therapy for the treatment of venous leg ulcers. *J Tissue Viability* 1999; 9(2):67.
25. Franek A, Krol P, Kucharzewski M. Does low output laser stimulation enhance the healing of crural ulceration? Some critical remarks. *Med Eng Phys* 2002; 24(9):607-615.
26. Gaida K, Koller R, Isler C et al. Low Level Laser Therapy--a conservative approach to the burn scar? *Burns* 2004; 30(4):362-367.
27. Gur A, Karakoc M, Nas K, Cevik R, Sarac J, Ataoglu S. Effects of low power laser and low dose amitriptyline therapy on clinical symptoms and quality of

life in fibromyalgia: a single-blind, placebo-controlled trial. *Rheumatol Int* 2002; 22(5):188-193.

28. Gur A, Karakoc M, Nas K, Cevik R, Sarac J, Demir E. Efficacy of low power laser therapy in fibromyalgia: a single-blind, placebo-controlled trial. *Lasers Med Sci* 2002; 17(1):57-61.
29. Gur A, Cosut A, Sarac AJ, Cevik R, Nas K, Uyar A. Efficacy of different therapy regimes of low-power laser in painful osteoarthritis of the knee: a double-blind and randomized-controlled trial. *Lasers Surg Med* 2003; 33(5):330-338.
30. Gur A, Sarac AJ, Cevik R, Altindag O, Sarac S. Efficacy of 904 nm gallium arsenide low level laser therapy in the management of chronic myofascial pain in the neck: a double-blind and randomize-controlled trial. *Lasers Surg Med* 2004; 35(3):229-235.
31. Hakguder A, Birtane M, Gurcan S, Kokino S, Turan FN. Efficacy of low level laser therapy in myofascial pain syndrome: an algometric and thermographic evaluation. *Lasers Surg Med* 2003; 33(5):339-343.
32. Harto A, Garcia-Morales I, Belmar P, Jaen P. [Pulsed dye laser treatment of acne. Study of clinical efficacy and mechanism of action]. *Actas Dermosifiliogr* 2007; 98(6):415-419.
33. Ilbuldu E, Cakmak A, Disci R, Aydin R. Comparison of laser, dry needling, and placebo laser treatments in myofascial pain syndrome. *Photomed Laser Surg* 2004; 22(4):306-311.
34. Irvine J, Chong SL, Amirjani N, Chan KM. Double-blind randomized controlled trial of low-level laser therapy in carpal tunnel syndrome. *Muscle Nerve* 2004; 30(2):182-187.
35. Jih MH, Friedman PM, Goldberg LH, Robles M, Glaich AS, Kimyai-Asadi A. The 1450-nm diode laser for facial inflammatory acne vulgaris: dose-response and 12-month follow-up study. *J Am Acad Dermatol* 2006; 55(1):80-87.
36. Lam LK, Cheing GL. Effects of 904-nm low-level laser therapy in the management of lateral epicondylitis: a randomized controlled trial. *Photomed Laser Surg* 2007; 25(2):65-71.
37. Leal Junior EC, Lopes-Martins RA, Baroni BM et al. Effect of 830 nm low-level laser therapy applied before high-intensity exercises on skeletal muscle recovery in athletes. *Lasers Med Sci* 2009; 24(6):857-863.
38. Lee SY, Park KH, Choi JW et al. A prospective, randomized, placebo-controlled, double-blinded, and split-face clinical study on LED phototherapy for skin rejuvenation: clinical, profilometric, histologic, ultrastructural, and biochemical evaluations and comparison of three different treatment settings. *J Photochem Photobiol B* 2007; 88(1):51-67.
39. Matsutani LA, Marques AP, Ferreira EA et al. Effectiveness of muscle stretching exercises with and without laser therapy at tender points for patients with fibromyalgia. *Clin Exp Rheumatol* 2007; 25(3):410-415.

40. Montes-Molina R, Madronero-Agreda MA, Romojaro-Rodriguez AB et al. Efficacy of interferential low-level laser therapy using two independent sources in the treatment of knee pain. *Photomed Laser Surg* 2009; 27(3):467-471.
41. Naeser MA, Hahn KA, Lieberman BE, Branco KF. Carpal tunnel syndrome pain treated with low-level laser and microamperes transcutaneous electric nerve stimulation: A controlled study. *Arch Phys Med Rehabil* 2002; 83(7):978-988.
42. Oken O, Kahraman Y, Ayhan F, Canpolat S, Yorgancioglu ZR, Oken OF. The short-term efficacy of laser, brace, and ultrasound treatment in lateral epicondylitis: a prospective, randomized, controlled trial. *J Hand Ther* 2008; 21(1):63-67.
43. Plapler H, Hage R, Duarte J et al. A new method for hemorrhoid surgery: intrahemorrhoidal diode laser, does it work? *Photomed Laser Surg* 2009; 27(5):819-823.
44. Saltmarche AE. Low level laser therapy for healing acute and chronic wounds - the extendicare experience. *Int Wound J* 2008; 5(2):351-360.
45. Schindl A, Neumann R. Low-intensity laser therapy is an effective treatment for recurrent herpes simplex infection. Results from a randomized double-blind placebo-controlled study. *J Invest Dermatol* 1999; 113(2):221-223.
46. Stergioulas A. Effects of low-level laser and plyometric exercises in the treatment of lateral epicondylitis. *Photomed Laser Surg* 2007; 25(3):205-213.
47. Stergioulas A. Low-power laser treatment in patients with frozen shoulder: preliminary results. *Photomed Laser Surg* 2008; 26(2):99-105.
48. Stergioulas A, Stergioula M, Aarskog R, Lopes-Martins RA, Bjordal JM. Effects of low-level laser therapy and eccentric exercises in the treatment of recreational athletes with chronic achilles tendinopathy. *Am J Sports Med* 2008; 36(5):881-887.
49. Trelles MA, Levy JL, Ghersetich I. Effects achieved on stretch marks by a nonfractional broadband infrared light system treatment. *Aesthetic Plast Surg* 2008; 32(3):523-530.
50. Tullberg M, Alstergren PJ, Ernberg MM. Effects of low-power laser exposure on masseter muscle pain and microcirculation. *Pain* 2003; 105(1-2):89-96.

Appendix 1: Table summarizing literature search on double blind clinical trials in LLLT devices with similar specifications to B-Cure Laser LLLT 808

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Arthritis	Achilles tendinitis	Stergioulas	2008	52	820	60	12 sessions in 8 weeks – LLLT + exercise vs. sham LLLT + exercise	Greater improvement in pain levels and tendon function in LLLT group
Arthritis	Knee osteoarthritis	Gur	2003	90	Not stated	Not stated	5 minutes, 3 J total dose low-power laser vs. 3 minutes, 2 J total dose low-power laser vs. sham low-power laser. All patients received 10 treatments and also exercised.	Both low-power laser regimens were safe and effective treatments for knee osteoarthritis.
Arthritis	Temporomandibular Joint disorders	Fikácková	2007	80	830	Not stated	LLLT 10 J/cm(2) or 15 J/cm(2) vs. LLLT 0.1 J/cm(2)	LLLT (application of 10 J/cm(2) and 15 J/cm(2)) can be considered as a useful method for the treatment of TMD-related pain, especially long lasting pain
Arthritis	Tennis elbow	Lam	2007	39	904	25	3 weeks of 3 sessions per week – laser vs. placebo treatment	LLT decreased the pain reported by subjects and the disabilities associated with work.
Carpal Tunnel Syndrome	Carpal Tunnel Syndrome	Chang	2008	36	830	60	10 sessions in 2 weeks – LLLT vs. sham LLLT	LLLT was effective in alleviating pain and symptoms, and in improving functional ability and finger and hand strength for mild and moderate CTS patients

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
								with no side effects
Carpal Tunnel Syndrome	Carpal tunnel syndrome	Ekim	2007	19	780	50	LLLT vs. placebo laser in rheumatoid arthritis patients with CTS Once daily on week days for a 10 days	Improvements significantly better in LLLT group compared to placebo group
Carpal Tunnel Syndrome	Carpal tunnel syndrome	Naeser	2002	11	632.8	15	LLLT plus transcutaneous electrical nerve stimulation (TENS) vs. sham LLLT plus TENS applied to acupuncture points	Significant decreases in pain score after LLLT plus TENS treatment but not after sham treatment.
Dentistry	Dentistry	Faria Amorim	2006	20	685	50	Patients received treatment after having a gingivectomy – half mouth receiving LLLT vs. half mouth receiving sham laser	LLLT was an effective adjunctive treatment that appeared to promote healing following gingivectomy
Hemorrhoids	Hemorrhoids	Plapler	2009	25	810	5	Intrahemorrhoidal laser therapy vs. Placebo 'cold scalpel' hemorrhoidectomy	The diode laser energy delivered into small to median hemorrhoidal piles caused little pain and led to a partial to complete resolution within a short time compared to open hemorrhoidectomy

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Pain	Knee Pain	Montes-Molina	2009	152	810	100	LLT in two identical laser probes + exercise vs. one LLLT probe and one dummy probe + exercise	LLT is safe and effective in reducing knee pain. LLLT is not superior to single conventional laser.
Pain	Low back pain	Djavid	2007	61	810	50	Twice a week for 6 weeks – LLLT vs. LLLT + exercise vs. sham LLLT + exercise	The LLLT + exercise group showed a significantly greater improvement in lower back pain.
Pain	Muscle pain	Leal Junior	2009	20	830	100	LLLT or placebo laser were administered on athletes	LLLT irradiation seemed to inhibit an expected post-exercise increase in Creatine Kinase (CK) level and to accelerate post-exercise lactate removal and may be of benefit in accelerating post-exercise recovery.
Pain	Neck pain	Dundar	2007	64	830	Not stated	LLLT vs. Sham LLLT	Both the treatment and control group improved on all outcomes at the end of the study. LLLT had no superiority over placebo.
Pain	Neck pain	Chow	2006	90	830	300	LLLT vs. sham LLLT	LLLT was efficacious in providing pain relief for patients with chronic neck pain over a period of 3 months.
Pain	Neck pain	Gur	2004	60	904	Not stated	LLLT vs. Sham LLLT	LLLT is effective in pain relief and in the improvement of functional ability and quality of life

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Pain	Shoulder pain	Stergioulas	2008	63	904	40	LLLT vs. Sham LLLT	LLLT was more effective than placebo in reducing pain and disability scores
Pain	Shoulder pain	Bingol	2005	40	904	Not stated	LLLT + exercise vs. Sham laser + exercise	Significant results in favor of the LLLT group in palpation sensitivity and passive extension. No significant improvement in pain, active range, and algometric sensitivity was observed in the LLLT group compared to control.
Pain	Shoulder pain	Sterjioulas	2008	63	810	60	LLLT vs. sham LLLT	LLLT was more effective in reducing pain and disability scores than sham treatment.
Pain	Upper back pain	Chow	2006	90	830	300	14 treatments in 7 weeks (twice a week) – LLLT vs. Placebo treatment.	LLLT was efficacious in providing pain relief for patients with chronic neck pain over a period of 3 months.
Skin	Burns	Gaida	2004	19	670	400	Twice a week for 8 weeks treatment	Comparing to a non-treated control area, the LLLT treated area showed a greater improvement in burn scars macroscopic appearance, pruritus and pain
Skin	Herpes Simplex	Schindl	1999	48	690	80	Daily 2 weeks treatment – LLLT vs. Placebo	Average reactivation of HSV in LLLT group after 34 weeks comparing to 3 weeks in placebo group

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Skin	Lymphedema	Carati	2003	61	904	5	Patients suffering from Postmastectomy Lymphedema were given the following treatments: Placebo laser vs. 1 cycle of LLLT treatment vs. 2 cycles of LLLT treatment (cycle = 9 sessions in 3 weeks)	Two cycles of laser treatment were found to be effective in reducing the volume of the affected arm, extracellular fluid, and tissue hardness at 3 months after treatment
Skin	Skin Rejuvenation	Lee	2007	76	830 + 633	Not stated	Twice a week for 4 weeks – 830 LLLT vs. 633 LLLT vs. 830 LLLT+ 633 LLLT vs. sham laser	objectively measured data showed significant reductions of wrinkles and increases of skin elasticity compared to baseline on the treated face in the three treatment groups
Skin	Vitiligo	Wu	2008	40	632.8	Not stated	1-2 LLLT treatment sessions a week	After an average of 17 treatment sessions, initial repigmentation was noticed in the majority of patients. Marked repigmentation was observed in 60% of patients in successive treatments.
Skin	Wounds/Scars	de Paiva Carvalho	2009	28	830	40	24 hours after undergoing an Inguinal Herniation Surgery, the patients received treatment followed by 3 treatment sessions the very same week – LLLT vs. sham laser.	LLLT applied after inguinal-hernia surgery was effective in preventing the formation of keloids. In addition, LLLT resulted in better scar appearance and quality. These benefits sustained according to 6 month postsurgery measurements.

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Skin	Post pregnancy stretch marks	Trelles	2008	10	800 -1800	8 – 45 J/cm ²	4 sessions with 15 days apart of LLLT treatment	Histology showed positive changes in the epidermis and dermis related to improvement in tissue condition. The satisfaction index from the questionnaires was average
Skin	Acne	Harto	2007	36	585	-	1 treatment session every 4 weeks	At twelve weeks of treatment a decrease of 27 % of non inflammatory lesions and of 57 % of active lesions was observed
Skin	Acne	Jih	2006	20	1450	-	3 sessions, 4 weeks between sessions - Faces were splitted randomly: half face receiving a does of 14 J/cm ² and half receiving 16 J/cm ²	A significant decrease in Acne lesions and amount of facial sebum collected was found in both dosage groups right after the first sessions. This decrease got more profound after the following treatments and sustained in follow up measurements, a year after the last session.

Category	Disease	Author	Year	n	Laser wavelength (nm)	Laser power (mW)	Treatment	Results
Inflammation	Surgically induced wound	Bahat	2009	30	780	not stated	LLLT vs switched off LLLT	Inflammatory markers decreased in treatment group
Ulcers	Acute and chronic wounds	2008	16	904	Not stated	not stated	LLLT applied to wounds	12/21 wounds - significant improvement at nine weeks
Ulcers	Decubitus ulcers	Lucas	2003	86	904	Not stated	Conservative treatment vs. conservative treatment + LLLT	No beneficial effect of LLLT