

PHOTIZO

LIGHT THERAPY



INSTRUCTIONS FOR USE 

CE 0123



Thank you

Thank you and congratulations on your purchase! You are now the proud owner of a Photizo Home Care LED Light Therapy unit. You can expect years of smooth and trouble-free operation of the Photizo Home Care.

Great effort, thought, dedication and research has been put into bringing you this amazing, high quality device. We believe that this device will assist you in your healing, pain relief and general health, as many others have experienced. We are proud to be your new partner on the road to wellness.

Please visit our website for more information:
www.photizo.net.

INDEX:

| | |
|---|----|
| INTRODUCTION | 4 |
|  PRECAUTIONS | 5 |
| CONDITIONS & TREATMENT | 8 |
| PAIN RELIEF | 8 |
| SPORT | 8 |
| SKINCARE | 8 |
| FREQUENTLY USED FUNCTIONS | 10 |
|  PREPARING FOR TREATMENT | 14 |
|  HOW DO I ADMINISTER TREATMENT? | 14 |
|  OPERATING PHOTIZO HOME CARE | 15 |
|  TROUBLESHOOTING | 16 |
| SPECIFICATIONS | 17 |
| STANDARD ACCESSORIES | 17 |
| SYMBOLS | 19 |
| CONTACT DETAILS | 20 |

INTRODUCTION

Throughout the ages, sunlight (as the earliest form of phototherapy) has been known to have both healing and wellness properties. Light is energy, and energy sustains life - it cannot be destroyed, but it can be transformed into other forms.

Light Emitting Diodes (LEDs) do not deliver enough power to damage the tissue, but they do deliver enough energy to promote natural self-healing and pain relief. With its power output optimized to be most effective, the LEDs provide a much gentler delivery of the same healing wavelengths of light as laser, but without the risk of accidental eye damage that lasers have.

The Photizo Home Care is an LED device that emits red and infrared light that penetrates the skin to stimulate energy production and other metabolic processes in targeted areas. Infrared light is one of the only physical therapies that act to create a healing effect. Cells that are injured can actually be rejuvenated by light.

LEDs are merely convenient devices for producing light at specific wavelengths, and several studies established that it is the light itself at specific wavelengths that is therapeutic in nature. All biological systems have a unique absorption spectrum that determines which wavelengths of radiation will be absorbed to produce a given therapeutic effect. The visible red and invisible infrared portions of the spectrum have been shown to have highly absorbent and unique therapeutic effects on living tissue.

LEDs also allow the light beam to spread out instead of being a pinpoint light beam. The wide-angle diffusion of the LED confers upon it a greater ease of application, since light emissions are thereby able to penetrate a broader surface area, and this results in a faster treatment time for a given area than laser.

The Photizo Home Care provides one-touch, pre-programmed, effective dosages of near infrared LED light for the treatment of many painful conditions. Photizo Home Care is intended for home use by the end user/public.

PRECAUTIONS

The following residual risks that the user needs to take notice of exist on this device

- If the cleaning procedure between treatments or patients is not followed you may compromise your health by cross contamination.
- Do not touch broken skin or open wounds as it will not assist with the treatment and will only pose a potential cross contamination risk.
- If you over-treat, thus do not follow the proposed treatment times and frequencies, you might compromise the efficacy of the treatment.

Please note that the Photizo Home Care must be seen as an ancillary treatment modality, used in conjunction with medical treatment, and that the manufacturers and distributors of the Photizo Home Care always advocate the use of the device under supervision of a clinician. The Photizo Home Care is not intended as a replacement for standard medical procedures, medication and/or treatment.

The manufacturers and distributors of the Photizo Home Care can in no way be held responsible for any damages, losses or injuries incurred using the device outside the advocated guidelines and protocol treatments. Please also note that not all conditions will benefit in a similar fashion from light therapy.

Do not rely solely on the Photizo Home Care and do not discontinue the use of other medications, antibiotics or antifungal treatments.

Although there are no known side effects to Photizo Light Therapy treatments, we do want to bring your attention to the following precautions:

- **Cancer:** Light therapy does not cure or cause cancer. Do not use light therapy on any cancer or suspected cancerous mass. Light therapy cannot cause cancer – no mutational effects have been demonstrated for LED-based light therapy devices in any medical or scientific literature to date. The light produced by Photizo Home Care is infrared and near infrared, non-ionizing light and is at the opposite end of the light spectrum to harmful ultraviolet (UV) light. The Home Care is, however, useful in treating many of the side effects of cancer treatment, such as mucositis, a painful side effect of chemo- and radiation therapy.
- **Pregnancy:** Photon therapy treatment is a safe and effective treatment during pregnancy. The effects of red or infrared light therapy have not been tested in pregnancy. While the fetus cannot be negatively influenced by light, we would not recommend using the Photizo Home Care on areas directly over the developing fetus.

- Epilepsy: Some studies suggest that pulsed visible light at frequencies in the 3-30 Hz ranges may induce seizures. The Photizo Home Care does not pulse in the 3-30 Hz range, however anyone with seizure disorders should avoid looking directly at the light beam emitted from the probe as a preventative measure.
- Do not over-treat; it will not result in faster healing or pain relief. Excessive daily use may result in over-stimulation and delayed healing (inhibitory effect).
- In some patients with chronic conditions, initial treatment with light therapy might cause some slight discomfort. This is due to the body's response to start the healing process. This is not a cause of concern, and treatment should be continued.
- No eye protection is needed, but as the light is very bright, do not look directly into the emitted light.
- Please do not discontinue your medications and health-care practitioners' prescriptions. Photizo Home Care treatment is a complimentary treatment, assisting and stimulating the cells to speed up the healing processes, relieve pain and muscle spasms.
- Please take into account that after treatment, you may have a false picture of health. Do not overuse the area treated.

It is safe to use Photizo Home Care on:

- Growth plates in children.
- Patients with pacemakers, and other metal implants.
- Patients using anti-clotting medications.
- Diabetics. Light therapy will greatly assist in treating complications of diabetes.

CONDITIONS AND TREATMENT

PAIN RELIEF

Chronic pain:

Usually associated with an underlying condition. Always treat with the probe against the skin, and if possible, press lightly in order to mechanically block the superficial blood flow, as blood absorbs most of the light. This will ensure deeper penetration of the light.

Start with treating the painful areas once (1) daily, for 5 days, thereafter, treat two (2) to three (3) times a week.

SPORT

Non-chronic pain:

A sudden onset of pain usually due to an injury. Always treat with the probe against the skin, and if possible, press lightly in order to mechanically block the superficial blood flow, as blood absorbs most of the light. This will ensure deeper penetration of the light.

In cases of acute pain, you may treat twice daily for two (2) to three (3) days but revert back to two (2) to three (3) times a week.

SKINCARE

Wounds:

Photizo treatment is not a replacement for wound care or wound care products but serves as a complimentary treatment. Prescribed wound care products are crucial for the healing process. **Please follow your health care practitioner's prescriptions.**

Photizo treatment should be given when changing bandaging and after the wound has been cleaned, and before wound care products and bandaging is re-applied. Debris and bandaging will block the light penetration. Treat the whole wound area as well as the surrounding tissues. In the ideal situation, treatment should be applied two (2) to three (3) times a week, but it will depend on the wound care regime.

You may treat the areas surrounding the bandaging when the wound needs to be covered for more than three (3) days. Do not exceed daily treatment for more than seven (7) days, to prevent the possibility of inhibiting the cell growth. Revert back to two (2) to three (3) times a week. **Keep the probe as close as possible to the open wound without letting the probe touch it.**

THE FOLLOWING FREQUENTLY USED FUNCTIONS MIGHT INFLUENCE TREATMENT AS STATED BELOW:

| NO | FREQUENTLY USED FUNCTION | HAZARD | SCENARIO DESCRIPTION | HARM | USER INTERFACE CONTROL MEASURE |
|----|--|---|--|-----------------|--|
| 1 | Pressing button to start. | Keep finger on start button. | The patient or healthcare worker keeps the start button in during treatment and does not release it. | None | Nothing will happen if kept in. |
| 2 | Plugging in to charge. | Plug into wrong power supply – too high. | The patient or healthcare worker plugs the unit into an electrical plug point. | None. | Power supply can handle 110V to 240V. |
| 3 | Wrong unit is chosen for the chosen application. | Not effective enough for the ailment. | The patient or healthcare worker uses the wrong unit for the chosen application. | Less effective. | Users are warned in the IFU to use the Photizo as indicated. |
| 4 | Plugging charger into device to charge battery. | Battery will charge and charge LED in front of power button will flash. | Using charger lower than 12V won't charge battery. Using charger higher than 12V will charge battery but too high voltage charger will blow a fuse on the driver board and the unit will stop functioning. | None. | User cannot control this but the device will indicate that it needs to be charged. |

| NO | FREQUENTLY USED FUNCTION | HAZARD | SCENARIO DESCRIPTION | HARM | USER INTERFACE CONTROL MEASURE |
|----|---|--|---|-------|---|
| 5 | Pressing power button while device is plugged into mains power. | Treatment LEDs will go on during cycle/dose and after the cycle/ dose has completed, the battery will continue charging. | On charger less than 12V the unit will function as normal during the cycle/dose. | None. | User cannot control this but the device will indicate that it needs to be charged. |
| 6 | While on battery power, pressing the power button. | Treatment LEDs will go on during the cycle/dose. | Battery is flat and the treatment LEDs won't switch on. | None | User cannot control this but the device will not operate until it is fully charged. |
| 7 | During a cycle/dose on battery power, plugging the charger into the device. | Cycle/dose will continue uninterrupted, and after the cycle/dose has finished the battery will continue charging. | If charger less than 12V is plugged in, the battery won't charge after the cycle/dose is completed. | None. | User cannot control this but the device will indicate that it needs to be charged. |
| 8 | Administering treatment through bandage or clothing. | Treatment LEDs will go on and run through a cycle/dose as per normal | Ineffective as the light is blocked by bandage or clothing. | None. | IFU indicates the method of application. |

| NO | FREQUENTLY USED FUNCTION | HAZARD | SCENARIO DESCRIPTION | HARM | USER INTERFACE CONTROL MEASURE |
|----|--|--|--|----------------------|--|
| 9 | Administering treatment through see-through plaster. | Treatment LEDs will go on and run through a cycle/dose as per normal | The light may be slightly blocked by the plaster depending on thickness and may cause the treatment to be slightly less effective than without the plaster | None. | IFU indicates the method of application. |
| 10 | Lens touches open wound during treatment. | The treatment will be administered normally and the area will receive the correct dosage | Lens may be covered with blood or other substances from the wound and can be a risk for cross contamination. | Cross contamination. | IFU indicates the method of cleaning. |
| 11 | Treatment administered anywhere on the skin. | Light energy is absorbed through the skin. | Either too little energy received in the skin leading to ineffective treatment or too much leading to inhibition effect. | None. | IFU indicates the method of application |
| 12 | Treatment administered on the face. | Light energy is absorbed through the skin. | Effectiveness could be influenced by a beard that blocks some of the light. | None. | IFU indicates the method of application |

| NO | FREQUENTLY USED FUNCTION | HAZARD | SCENARIO DESCRIPTION | HARM | USER INTERFACE CONTROL MEASURE |
|----|---|--|---|----------------------|--|
| 13 | Treatment administered on the head. | Light energy is absorbed through the skin. | Effectiveness could be influenced by hair that blocks some of the light. | None. | IFU indicates the method of application. |
| 14 | Treatment administered around the eyes. | Light energy is absorbed through the skin. | Shining into eyes causing blurry vision for a short period. | None, Class 1 | IFU indicates the method of application. |
| 15 | During a cycle, pressing and holding in the power button. | The cycle will be stopped. | The user presses the power button after the cycle has started and holds it in for a second or longer. | Less effective dose. | The unit will switch off. |

PREPARING FOR TREATMENT

Cleaning, maintenance and storage

The Photizo Home Care should be cleaned before and after use with the aid of a clean dry cloth and non-abrasive cleaner if required. Clean the skin before application of treatment, as make-up, cosmetics or debris may block the light.

The Photizo Home Care should always be stored in a safe, dry area, preferably within the carry bag provided. Care should be taken when working with the device and it should not be operated or immersed in water.

The Photizo LED diodes can perform for up to 75,000 working hours without a significant loss of output.

HOW DO I ADMINISTER TREATMENT?

Please remember to clean the Photizo Home Care before and after use with the aid of a clean dry cloth and surgical spirits or surgical alcohol if required.

- Place the probe in direct contact with the skin, on the area to be treated, and press the power button. The unit will beep twice. When treating open wounds, the probe should not touch the skin.
- Keep the probe in position until the unit beeps twice again. It switches off automatically.
- Shift the probe to the next spot. Press the power button again.
- Repeat until the entire area has been covered.

OPERATING PHOTIZO HOME CARE

- The Photizo Home Care works on battery or mains power.
- To switch on, press the power button. The power button LED will come on and the unit will beep twice.
- Once the treatment cycle is finished, it will beep twice and switch off automatically.
- To switch the unit off during the treatment cycle, press and hold the power button in for 1 second. The power button LED may stay on green for a while after the cycle has stopped.
- When using on battery power, the power button LED will be on solid green during the cycle and off when not in use.
- When plugging in the mains power, it will beep once and after a 3 second delay the power button LED will start flashing green. Once the battery is fully charged, the power button LED will stop flashing, and be on permanent green.
- When unplugging the mains power, the unit will beep once and the power button LED will switch off.
- Photizo Home Care will provide approximately 1 hr 30 minutes of continuous treatment from each full charge. If you are using the Photizo Home Care in cold temperatures, please note this can reduce the number of doses provided from each full charge.
- Photizo Home Care utilizes high capacity NiMH rechargeable batteries. As with all rechargeable batteries, the capacity will deplete over time and the number of doses between charges will reduce. When the battery capacity reaches a level which is not satisfactory, the internal rechargeable battery

can be replaced. Please contact your local distributor who can provide a quote for installing a new battery.

- Storing an unused Photizo Home Care for more than 3 months should be done with a battery fully charged as it may result in a damaged battery.

TROUBLESHOOTING

| PROBLEM | SOLUTION |
|--|---|
| Unit beeps twice and does not switch on | Battery needs to be charged |
| Unit does not charge | Is the charger connected to the unit/plugged in at the mains supply and switched on? All connections secure? Are you using the correct Photizo charger? |
| The 2 large LEDs don't seem to be on/to be functioning | These LEDs' wave-length lies within the invisible range and thus will not be seen with the naked eye. To confirm if these LEDs are functioning, view it through your cell phone's camera. |

SPECIFICATIONS

The device features a light-emitting array with high-power red & infrared light emitting diodes.

| Product Specification and application time and outputs | | | |
|--|--|-------|----------|
| Protocols | Pain Relief | Sport | Skincare |
| Duration of programs in seconds | 41 | 31 | 16 |
| Risk Classification in accordance with EN 62471 | 1 (Low-Risk) although treatment is less than 100 seconds | | |
| Power Output | Varies with a peak output of 330mW/cm ² | | |
| Coverage Area | 4.7cm ² | | |
| Wavelengths | 633nm red, 850nm infrared | | |
| Mains Power | 100 ~ 240 VAC | | |
| Battery Type | Ni-MH | | |
| Battery Voltage | 7.2 V DC | | |
| Battery Charger | 12V, 1A | | |
| Charging Time | Max 4 hours | | |
| Battery Operating Time | 90 minutes continuous use | | |
| Unit Weight | 280 grams | | |

STANDARD ACCESSORIES

- Power supply
- Instructions for use
- Drawstring bag

Photizo Home Care was developed by a team of physiotherapists, biologists, veterinarians, and engineers to provide a simplified, user-friendly system. We are proud that this product is made to the highest standards and uses only the highest quality components.

WARNING!

ONLY USE THE PHOTIZO BATTERY CHARGER SUPPLIED WITH THE UNIT TO CHARGE THE BATTERIES. ANY OTHER CHARGER MAY DAMAGE THE BATTERIES OR THE PHOTIZO HOME CARE

WARRANTY

This product comes with a 1-year carry-in warranty from the date of purchase, provided original proof of purchase is presented. NO warranty claims stemming from malicious damage, battery leakage, accidental dropping, water damage, or organic solvent damage will be entertained. Please note that specifications may differ from those presented in this manual.

Should you need any assistance or experience product failure, please contact your nearest distributor or e-mail Photon Therapy Systems at: info@photizo.net.

SYMBOLS USED

| | |
|---|---|
|  | <p>Attention! Please follow the instructions in the user manual.</p> |
|  | <p>This symbol on the unit means "Refer to user manual".</p> |
|  | <p>Serial number: indicates the manufacturer's serial number so that a specific medical device can be identified.</p> |
|  | <p>WEEE symbol. (Waste of electrical and electronic equipment). Recycling symbol. THE WEEE symbol used for this product indicates that the device may not be disposed of as a household product. Properly dispose of the product to help protect the environment. For more information on recycling this product, contact the local competent department, the household waste management company or the store in which the product was purchased.</p> |
|  | <p>This medical device is not water resistant and should be protected from liquids.</p> |
|  | <p>Attention! Infrared emission not visible.</p> |
|  | <p>This symbol on your device indicates that it complies with the directive on medical devices (93/42/EEC). The number of the Notified Body is 0123.</p> |
|  | <p>It refers to the manufacturer.</p> |
|  | <p>It refers to the European representative.</p> |
|  | <p>Equipment providing a particular degree of protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protective earth connection (if present).</p> |



PLEASE NOTE THAT PHOTIZO HOME CARE IS NOT A SUBSTITUTE FOR SOUND MEDICAL ADVICE OR TREATMENT, BUT IS AN ANCILLARY, COMPLEMENTARY TREATMENT DEVICE. DO NOT ASSUME THAT ALL CONDITIONS ARE SUITABLE FOR TREATMENT WITH LIGHT THERAPY. PHOTIZO HOME CARE IS NOT A DIAGNOSTIC TOOL AND IS NOT INTENDED TO REPLACE MEDICAL TREATMENT.

CONTACT DETAILS



Photon Therapy Systems (Pty) Ltd
28 Lebombo Road, Ashlea Gardens
Pretoria, Gauteng
South Africa, 0181
www.photizo.net



TNMC Devices Limited
Krežmina 1
10000
Zagreb
Croatia
Tel:+385916229658
tnmchr@tnmc.biz