# FlexBeam® Red Light Device

#### Instructions For Use

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Congratulations on the purchase of your new FlexBeam® targeted red light device. Read this manual to understand how to use your device properly and safely.

Using safe and clinically proven wavelengths of light, FlexBeam® mimics the natural power of sunrise and sunset, empowering your body to heal itself. Our scientifically developed programs allow the choice of red light, infrared light or a combination of both that may:











#### **Accessories**

- -> Charging Unit
- -> Duo Bands
- -> Mini Band
- -> Body Band
- -> Guide Book -
- > Goggles

#### **Indications For Use**

FlexBeam® is an over the counter electrically-powered medical device designed to emit red light and infrared/near-infrared light for phototherapy primarily to accelerate healing of cutaneous/mucosal tissues and/or to treat musculoskeletal symptoms (e.g., pain, spasm, stiffness) through modification of cellular metabolism and/or improvement of blood flow. It is intended for use in the home and clinical settings.1

The user is the intended operator. FlexBeam® is not designed to be used by infants or young children. Children over 12 years old should use it only under adult supervision. For more information on the correct use of FlexBeam® please contact Recharge Health or consult a healthcare provider.

Red/infrared light phototherapy unit as described by GMDN Code 65723.



**WARNING:** A warning message contains special safety emphasis and must be observed at all times. Failure

to observe a warning message could result in serious personal injury.



**CAUTION:** Failure to observe a caution associated with use could result in minor injury or product damage. Such problems include device malfunction, device failure, damage to the device or damage to other property.



# Recharge Health is an ISO 13485:2016 certified company.

#### **Contra-Indications**

 Do not use over malignant and other tumours.
 Do not use over open bleeding wounds.



# Warnings

- Safe use of FlexBeam® is the primary responsibility of the user. If FlexBeam® appears to be operating incorrectly, stop use immediately and contact Recharge Health customer support. Please follow the instructions outlined in this manual and use FlexBeam® according to its intended use only.
- Burns: FlexBeam® does not cause burns to the skin. This is because the therapeutic effect from FlexBeam® is due to light, not heat. However, in certain cases of extreme skin sensitivity, redness or blistering may occur. Under such occurrences, immediately suspend FlexBeam® use and consult your healthcare practitioner for further advice. Please also contact Recharge Health customer support should you experience this type of reaction.
- FlexBeam® is not designed for use on the eyes, face or head area. Avoid staring directly at the LEDs or using it within 30cm of the eyes. Powerful invisible infrared light emitted.

- Use provided safety goggles in cases when escaped light is directly shining into the eyes.
- Do not use it over breast tissue, thyroid gland and testes. FlexBeam® is not intended to treat endocrine conditions.
- The safety of the use of FlexBeam® has not been established during pregnancy or childbirth.
- To ensure hygiene, do not place directly onto an open wound.
- Refrain from applying FlexBeam® tight over areas with varicose veins, phlebitis, and thrombophlebitis. It can be used over the area when not in skin contact.
- Do not use FlexBeam® on wet skin. Do not immerse FlexBeam® in water or use in an area where contact with water is possible like the bath.
- Avoid spilling fluids on FlexBeam®. Discontinue use if it is immersed in any liquid.
- Extreme heat or cold may affect the operation of FlexBeam®.
- Skin irritation, bruising, contact burns, dizziness, nausea, and headaches are rare but possible side effects.
- Suitable for mains supply voltages 90-265V.
- FlexBeam® contains silicon and plastics that come into contact with the skin during use. Do not use it if you have an allergy or reaction to these materials.
- The charging cable poses a strangulation risk.
  Store appropriately when not in use.

- Do not use your own charger or any accessories not described in the IFU, do not interconnect with any other equipment not described in the IFU or modify the equipment in any way.
- Do not modify FlexBeam® in any way.
- Do not expose any part of FlexBeam® to chemical solvents or harsh cleaning fluids. Follow cleaning instructions in this manual.
- Do not cover or obstruct the air vents on the device, as this may cause FlexBeam® to overheat and automatically shut down.
- FlexBeam® is not user-serviceable. Never attempt to open the housing on this device. Opening the housing will void the manufacturer's warranty.
- Only use the provided Recharge Health power adapter model number YL361-1502400V.



#### Cautions

- FlexBeam® should be used only with manufacturer-approved accessories.
- If the device does not work properly, or seems to be faulty, contact Recharge Health, your FlexBeam® distributor or authorized service representative.
- Consult your healthcare practitioner prior to using your FlexBeam® if you have a fever, acute inflammation, a circulatory disorder, light sensitivity, anesthetised or

#### desensitised areas.

- Use caution if you are taking any medications. If in doubt, consult your healthcare practitioner. Allow 3-5 days after taking photosensitive drugs/supplements, or large doses of corticosteroids. If unsure, consult a healthcare provider.
- If you are a light sensitive individual, reduce exposure time.
- Use caution in applying FlexBeam® over areas which are swollen, infected, or inflamed as this may result in the worsening of symptoms. Consult your physician for further advice.
- Use caution in applying FlexBeam® if you have or may have heart disease.
- Use caution in applying FlexBeam® if you have epilepsy.
- Use caution when applying the device on dark pigmented skin: reduce the exposure time to no longer than 10 minutes in one place.
- Use caution when applying the device over tattoos. Reduce exposure time (until you feel heat) or use Program 2 instead of Program 3 over the tattooed area. If possible, avoid placing FlexBeam® over recently tattooed skin or over tattoos with extensive areas of dark ink.
- Use caution when using FlexBeam® over undiagnosed skin conditions. If unsure, consult your healthcare practitioner.
- Use caution when using FlexBeam® over prostheses or implants. If unsure, consult your healthcare practitioner.

- If you observe unusual device behavior, particularly if such behavior is intermittent and associated with nearby use of radio or TV transmitters, cell phones, or electro-surgical equipment, this could be an indication of electromagneticinterference. If such behavior occurs, you should try to move the interfering equipment further from this device.
- The Flexbeam is designed with your safety in mind and will automatically shut down well below temperature safety limits. We ask that you stop using FlexBeam® if you notice a higher than usual device temperature after each cycle. Let it cool down for 10-20 minutes before the next use.
- · Don't overcharge your FlexBeam®.

## Symbols and Definitions



This device is internally powered only. The symbol indicates the device was manufactured according to the degree of protection against electrical shock for this Type B protection class equipment.



DO NOT use FlexBeam® before reading this manual.



Keep FlexBeam® dry. DO NOT immerse in water.



Not for general waste.



Rated input 15V 2A. Battery Li Ion, 36.48Wh rating. Made in Thailand. IP20: Protected against a solid object greater than 12.5mm such as a finger. Not protected against liquids.



Medical Device



Consult Instructions for Use Before Use



Can Be Used Multiple Times on Different Users









# Overview of Controls and Functions: Programs



#### **Definitions**

**Application:** Placement of FlexBeam® on specific areas of the body.

**Cycle:** A sufficient dose of light stimulation for one 10-minute application of FlexBeam®.

**Program:** Automated pre-set delivery of wavelengths, frequencies, and power modulations of light within a cycle. Each program delivers a different degree of light penetration.

## **Using Your FlexBeam®**

Before you apply FlexBeam® for the first time make sure it's fully charged. Insert the power cord provided into the power port located on the interface module of your FlexBeam®. It will take approximately 2 hours to charge.

#### **∤**-Position FlexBeam®

Place FlexBeam® on the desired location, securing with the supplied bands if needed. Always use your FlexBeam® directly on the skin, removing any clothing. Light does not penetrate clothing and treatment will be ineffective. You can attach FlexBeam® to the body using the supplied bands. The instructions of how to use these bands can be found on-line and in your quick start guide.





**Important:** Never stare at the LEDs or use FlexBeam® within 30cm of the eyes. Powerful invisible infrared light emitted.

### 2-Select the Program

Turn FlexBeam® on and select the program:



1. Skin and Surface Mostly red light.



2. Muscles and Tissue Combined Red/Infrared light to reach depths below the skin.



**3. Deep Tissue and Joints** Powerful infrared light to penetrate deeper inside the body.

Each program is timed as a 10-minute cycle. After completion, your FlexBeam® will make a sound and pause to allow for another program selection. If not in use, it will automatically switch OFF.

#### **∂**•When to Use FlexBeam®

For best results, use once daily, or up to 4 times a day on different areas of the body. FlexBeam® is designed to deliver an optimal dose of light for each program cycle to trigger your body's self-healing response.

When applying FlexBeam® in one part of the body: apply only one cycle (usually this is enough to deliver the optimal dose of stimulation). Do not overuse.

When applying FlexBeam® in multiple parts of the body: apply two to three or up to four 10-minute cycles on different areas of the body in one day. Light has a cumulative effect in the body. When used daily, make sure to take occasional breaks. Do not overuse. Do not apply in the same place twice.

For more guidance, look in your Personal Guide Book, or our support website or contact our support team online at:

Disclaimer: Suggested application protocols are examples of suggested use only and not medical advice. You will at all times, look to any medical practitioner that you have selected for medical services and health conditions in relation to any medical claims for such services and conditions.

## **Indicator Lights**

- When the battery is very low, the yellow light will flash for 1 minute then FlexBeam® will automatically turn off.
- If there is an error the indicator lights around the ON/OFF button will flash in sequence. Turn the device off, wait a few minutes, then turn it on again. If the problem persists, contact Recharge Health or your FlexBeam® distributor.

#### **General Device Care**

#### **Battery**

- FlexBeam® is rated for continuous operation. The device can be used while charging. Charge time from empty to full is 2 hours.
- FlexBeam® can be taken on a plane, either in carry-on or checked luggage.
- Do not attempt to change the Li-ion Rechargeable batteries.
  Doing this may result in a hazard. Battery is replaceable but shall only be changed by authorised service personnel.
  Battery pack replacements are available. Typical Li-ion battery life = 600+ charging cycles = 9000 applications.

#### Lifetime

• FlexBeam® lifetime is 5 years. Battery replacement may be required after 2.5 years; accordingly, the shelf life of FlexBeam® is approximately 2 years. Please contact Recharge Health for battery replacement.

#### Storage and Cleaning

• FlexBeam® should be stored in the provided case when not in use to prevent dust and debris getting inside the device.

- Clean/disinfect your FlexBeam® when the main power is off.
   It is recommended to clean/disinfect the contact surface of
   your FlexBeam® with wipes containing isopropyl 70% alcohol
   after each treatment or before applying it to a different user/
   patient. The rest of the device can be cleaned with a damp
   cloth when it becomes soiled.
- Use of other cleaning/disinfecting solutions (i.e caustic, ethyl alcohol and/or ammonium chloride) may damage or crack the plastic housing. Never spray cleaners directly on the device.
- Using unapproved cleaning agents will void the manufacturer's warranty.

## Service and Two-Year Limited

Wearranty covers any defects in workmanship or in materials under normal use during the warranty period. Recharge Health (the Company) will repair or replace, at no charge, the product or parts of the product that prove defective because of improper material or workmanship, under normal use and maintenance. Accessories or consumables are excluded from this warranty. Excluded items are listed as follows: carrying cases, travel bags, body straps, goggles, etc.

To obtain this service, you must first contact us by email at support@recharge.health or through the support portal on our website, to determine the problem and the most appropriate solution. Please note that in order to proceed with a warranty

service request, you will be instructed to perform a certain number of troubleshooting tasks by our service team.

We will either repair or replace the product at no charge. Once troubleshooting tasks have been performed and our service team has determined that the failure is covered by the warranty, we will arrange for our courier to pick up the product or we may decide to send you a replacement unit instead.

During the first 30 days after the purchase date, the Company will cover all shipping costs. After 30 days from the purchase date, the customer will be responsible for all shipping costs.

The warranty period for all Recharge Health products starts from the date of purchase. Any replacement product or product part assumes the remaining warranty of the original product. The limited warranty cannot be transferred.

Only the persons registered in our store as buyers or as shipment recipients will be entitled to warranty coverage. The company reserves the right to request proof of purchase prior to offering warranty services.

Our products are not user-serviceable. Do not open them or tamper with the finished goods in any way as this will void the manufacturer's warranty. All warnings, cautions, and instructions contained in the instructions for use (IFU) must be followed to ensure full warranty coverage.

The limited warranty does not cover product damages or malfunctions resulting from negligence (like scratches, cracks, falls, water immersion, etc.), improper maintenance or product modification; damage by natural causes like lightning, floods, rain, or other natural disasters; theft or loss of the product.

Any implied warranties including, without limitation, warranties of merchantability and fitness for a particular purpose, shall be limited to the duration of the applicable warranty period. Some jurisdictions do not allow limitations on the duration of an implied warranty, so the above limitation may not apply to you.

#### Returns

If you have purchased your FlexBeam® from a third party Reseller (anywhere except our official website: www.recharge.health),

all product returns, repairs or refurbishments will be handled exclusively by the Reseller.

THE COMPANY SHALL BE UNDER NO LIABILITY FOR ANY DEFECTS IN THE PRODUCTS ARISING FROM REGULAR WEAR AND TEAR, OR ANY WILFUL DAMAGE, NEGLIGENCE, SUBJECTION TO ABNORMAL WORKING CONDITIONS, FAILURE TO FOLLOW THE PRODUCT'S WRITTEN INSTRUCTIONS (QUICK START INSTRUCTIONS, YOUR PERSONAL GUIDE AND INSTRUCTIONS FOR USE), MISUSE OR ALTERATION OR REPAIR OF THE PRODUCTS WITHOUT THE COMPANY'S APPROVAL, OR ANY OTHER ACT OR OMISSION ON YOUR PART OR ANY THIRD PARTY.

IN THE EVENT OF ANY BREACH OF THE WARRANTY, OUR LIABILITY SHALL BE LIMITED TO REPAIR OR, IF THAT IS NOT PRACTICAL, TO REPLACEMENT OF THE PRODUCT(S) IN QUESTION. IN NO CASE WE WILL BE LIABLE FOR ANY SUMS ABOVE WHAT YOU HAVE PAID FOR THE PRODUCT(S).

EXCEPT AS PROVIDED IN THIS WARRANTY AND TO THE MAXIMUM EXTENT PERMITTED BY LAW, THE COMPANY IS NOT RESPONSIBLE TO YOU (THE CUSTOMER) OR ANY THIRD PARTY FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF EXPRESS OR IMPLIED WARRANTY OR CONDITION, OR UNDER ANY OTHER LEGAL THEORY, INCLUDING BUT NOT LIMITED TO LOSS OF USE, REVENUE, ANTICIPATED PROFITS, BUSINESS OPPORTUNITY, GOODWILL AND REPUTATION.

THE COMPANY'S LIABILITY SHALL UNDER NO CIRCUMSTANCES EXCEED THE ACTUAL AMOUNT PAID BY YOU FOR THE DEFECTIVE PRODUCT. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU. THE ABOVE LIMITATIONS SHALL NOT APPLY TO DEATH OR PERSONAL INJURY CLAIMS, OR ANY STATUTORY LIABILITY FOR INTENTIONAL AND GROSS NEGLIGENT ACTS AND/OR OMISSIONS.

This Warranty is updated from time to time by Recharge Health. Please visit the website for the latest version of the Warranty.

## **Product Specifications**

Configuration	3 light pods, 2 infrared and one red LED in each
Wavelength	6 x 810-820nm, 3 x 625-635nm
Power Source	90-265V AC input power supply with 15V, 2.5A output
Max. Output Optical	
Power Density	100mW/cm2 IR, 50mW/cm2 red
Frequency	Pulsad hatanan 0 4000/ duta and
Modulation	Pulsed between 0-100% duty cycle
Woddiacion	3 preset programs
Application Programs	10 minutes per cycle
Application Time	10 minutes per cycle
	3 buttons - on/off, program select, play/pause
Button Interface	Rechargeable Lithium-ion battery in separate
Battery	battery pod
	0.775kg (1.6kg including packaging)
Weight	ABS-PC plastics and silicon connecting strap
Enclosure	Active cooling by fan
Cooling	Over-temperature/over-current auto shutdown
Safety	feature Charging unit, mini band, body band, duo
Accessories	bands, safety goggles
Medical Device Class	FlexBeam® is a class II FDA Exempt Medical Device
Compliance	IEC: 60601-1 (Ed 3.1); IEC: 60601-1-2:2020 , IEC: 60601-1-11:2015, IEC:62366-1:2015, ISO:10993:2018, IEC 60601-2-57:2011, IEC 62304:2006

#### **Environmental Protection**

This device is RoHS3 compliant and there are no toxic chemicals inside the product. This device contains lithium, in the case of fire, use an ABC or BC type fire extinguisher. When FlexBeam® has reached the end of life, do not dispose of in general waste, take it to an e-waste recycler.

## **Technical Description**

The technical description can be obtained by contacting Recharge Health or your authorised distributor. Permissible environmental conditions of use including storage and transport:

Temperature: 0-32oC | Humidity: 10-90%

**WARNING:** No modifications of this equipment are allowed except by qualified service personnel. Instructions of how to replace rechargeable batteries (for qualified service personnel only) may be obtained by contacting Recharge Health.

Recharge Health will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions, or other information required by authorised service personnel to repair parts. Isolation from the supply mains is by removable flexible power cord.

#### **Manufacturer Contact Details**

Recharge Co. Ltd 58/4 Moo 7, T. Padaet, A. Mueang, Chiangmai 50100, Thailand

Phone: +66 649 989 836 Web: www.recharge.health Email: support@recharge.health

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