

FlexBeam®

Red Light Device

Instructions For Use

V2.17

November 2023

MEDICAL

FLEXBEAM

Contents

Indications For Use	5
Contra-Indications	6
Warnings	6
Cautions	8
Symbols and Definitions	12
Overview of Controls and Functions	13
Using your FlexBeam®	14
General Device Care	17
Service and Five-Year Limited Warranty	18
Product Specifications	22
Environmental Protection	23
Technical Description	23
Electromagnetic Compatibility	24
Manufacturer Contact Details	26

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:



Revive
Circulation



Relieve
Pain



Improve
Performance



Rejuvenate
Skin



Reduce
Inflammation

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.

¹ 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 electromagnetic-interference. 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

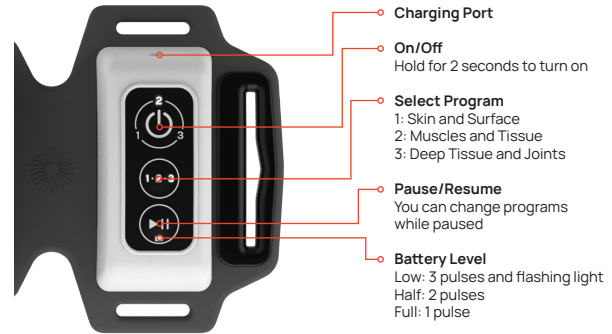


Can Be Used Multiple Times on Different Users

FlexBeam® <small>Headband Light Therapy Unit</small>		<small>SN</small> XXXXXXXXXXXXXXXX <small>GTIN</small> XXXXXXXXXXXXXXXX <small>LOT</small> XXXXXXXXXXXXXXXX <small>UDI</small> XXXXXXXXXXXXXXXX
 NOT USER SERVICEABLE	 IP20	 MULTIPLE USE
 RISK GROUP 1 - CAUTION Do not stare at the light source	 MD	
<small>MANUFACTURED FOR</small> Recharge Co. Ltd. 58/A Moo 7 T. Prachin, A. Muang Chiang Mai 50100, THAILAND Made in Thailand www.recharge.health		 <small>001108203714881111</small> <small>0188441114881111</small> <small>0040910111481211*</small> <small>004492</small>
<small>Rated Input: DC 15.0V 7772.4A 36.0W</small>		



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.

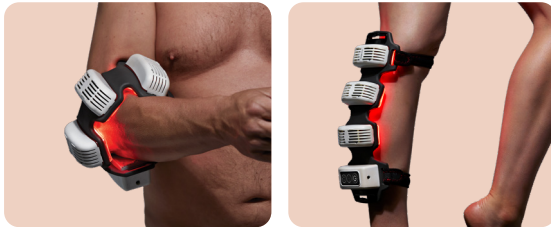
Each program delivers a different degree of light penetration.

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.

① 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.

③ 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.

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 Five-Year Limited Warranty

The five (5) year warranty 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, and the battery.

The battery of FlexBeam® is considered under the regulation of consumer electronics in Norway (and many other jurisdictions) to be limited to a two (2) year warranty. For a battery that is worn out from use, we offer a battery replacement service against a cost after 2 years.

To obtain any warranty 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 60 days after the purchase date, the Company will cover all shipping costs. After 60 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 810-830nm, 3 x 625-635nm
Power Source	90-265V AC input power supply with 15V, 2.5A output
Max. Output Optical Power Density	100mW/cm ² IR, 50mW/cm ² red
Frequency Modulation	Pulsed between 0-100% duty cycle
Application Programs	3 preset programs
Application Time	10 minutes per cycle
Button Interface	3 buttons – on/off, program select, play/pause
Battery	Rechargeable Lithium-ion battery in separate battery pod
Weight	0.775kg (1.6kg including packaging)
Enclosure	ABS-PC plastics and silicon connecting strap
Cooling	Active cooling by fan
Safety	Over-temperature/over-current auto shutdown feature
Accessories	Charging unit, mini band, body band, duo 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, IEC 60529:2020

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: 0-32°C | 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.

Electromagnetic compatibility

Warning

The device has successfully undergone electromagnetic compatibility (EMC) testing and is specifically designed for use in domestic healthcare settings, meeting CISPR 11 class B standards. Exercise caution when using the device near or connected to other devices, as this may result in defective operation. If such usage or installation with other devices becomes necessary, it is essential to verify that all devices involved are functioning normally.

To prevent any adverse effects on the device's functionality, refrain from using portable HF communication devices (e.g., telephones, tablets) within a distance of less than 30 cm from the device and its electrical accessories. Rest assured that the device has been rigorously tested for its electromagnetic immunity and radiation to guarantee basic safety and significant performance characteristics. These test results comply with the limit values outlined in the provided tables, considering the stipulated minimum distance from neighboring devices.

No additional maintenance measures are necessary to ensure the device's basic safety and performance characteristics. Adherence to these guidelines is vital to ensuring the device operates optimally and safely. Failure to follow these instructions may lead to operational disruptions or potential safety risks.

Manufacturer declarations on electromagnetic emissions:

The device is intended for operation in the electromagnetic environment specified below. The user of the device should ensure that it is operated in this type of environment.

EMISSIONS MEASUREMENTS	COMPLIANCE	TEST METHOD	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted Emission	IEC 60601-1-2:2020	CISPR11:2010 (Ed. 5.1)	*The device is suitable for use in all establishments, including domestic establishments and those directly connected to a public power supply network that supplies buildings also used for domestic purposes.*
Radiated Emission	IEC 60601-1-2:2020	CISPR11:2010 (Ed. 5.1)	
Harmonic Emission	IEC 60601-1-2:2020	IEC 61000-3-2:2014	
Voltage Fluctuation	IEC 60601-1-2:2020	IEC 61000-3-3:2013	

Manufacturer declarations on electromagnetic interference

immunity: The device is intended for operation in the electromagnetic environment specified below. The user of the device should ensure that it is operated in this type of environment.

IMMUNITY TESTS	TEST METHOD AND LEVEL	COMPLIANCE
Discharge of static electricity (ESD)	IEC 61000-4-2 2kV, 4kV, 8kV, 15kV air, 8kV contact	IEC 60601-1-2:2020
Radiated Immunity	IEC61000-4-3 3V/m, 80MHz to 2700 MHz	
Electrical Fast Transient	IEC 60601-1-2 2kV 5/50ns 5kHz, Criterion B	
Impulse voltage (surges)	IEC 61000-4-5 ±1 kV differential mode voltage ±1 kV and ±2 kV commonmode voltage	
Immunity in compliance with conducted interference	IEC61000-4-6 Band and the amateur frequency bands between 0.15 MHz and 80 MHz	
Magnetic field with the supply frequency (50/60 Hz)	IEC61000-4-8 30A/m 50Hz and 60Hz	
Voltage dips, brief interruptions and fluctuations in the supply voltage	IEC 61000-4-11 0% UT; 0.5 periods at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% UT; 1 periods and 70% UT 25 periods. Single phase: at 0°	

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

Contact Recharge Health if you need any assistance setting up
or maintaining your FlexBeam®.



For online support,
please scan this QR code

Recharge® and FlexBeam® are registered trademarks of Recharge Company Limited or of
Recharge Health AS. © 2023 Recharge Co. Ltd. and Recharge Health AS. All rights reserved.

