pbmFLEX®

Instruction Manual
for
Phototherapeutic Device
LX 1000

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Proprietary Technology
This product is protected by:
China Patent ZL 2016 3 0001002.2
Hong Kong Patent 1601259.7

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Table of Contents

Important

Introduction

Read this instruction manual carefully before you use the Phototherapeutic Device and save it for future reference. This medical device is available without prescription. To achieve optimal treatment success, you have to use the device according to the Treatment Chart and the Instructions in this manual. In case of any further questions, please consult a specialist or your primary physician.
The Phototherapeutic Device uses photobiomodulation technology to maintain health, reduce inflammation, help repair damaged cells and relieve pain, which uses the body's natural processes to heal.

Intended Use

The Phototherapeutic Device is a wearable medical device that intends to relieve back pain, neck discomfort, joint aches and muscle soreness at home and work. The device is intended to be only used and operated by persons 18 and over. It should always be used in accordance with the safety procedures and operating instructions included in this manual and for the purpose of which it is designed.

Contra-indications

Do not use the Phototherapeutic Device:
– If your skin is burnt or sunburnt.
– If you have a fever.
– If you have an active implanted device, such as a cardiac pacemaker, defibrillator, neurostimulator, cochlear implant, or an active drug administration device.
– If you have any known disease or idiopathic dermatosis such as porphyria, polymorphic light eruption, chronic actinic dermatitis, actinic prurigo or solar urticaria that causes photosensitivity.

– If you have active skin cancer, or a history of skin cancer, or any other localized cancer in the areas to be treated, or pre-cancerous lesions or large moles in the areas to be treated.
– If you are taking photosensitising agents or medications, check the package insert of your medicine and never use the appliance if it is stated that it can cause photo-allergic reactions, photo-toxic reactions or if you have to avoid sun when taking this medicine.
– If you have a history of severe osteoporosis, or another severe bone disease.
– If you have had an acute dislocation or fracture within the previous 8 weeks.
– If you have had any failed back surgery or any surgery to torso, head or back within the previous 8 weeks.
– If you are bitten by spider, bee, wasp, any other insect or animal in the areas to be treated.
– If you are pregnant, lactating or at menstruation.
– If you have widespread pain.
– If you are in poor general health.

Warning

– Do not immerse the Pad in water or rinse it under the tap.
– Do not use the Phototherapeutic Device in wet surroundings.
– The Phototherapeutic Device is not intended for use by persons younger than 18 and persons with reduced physical, sensory or mental capabilities.
– Keep the Device out of the reach of children.
– Do not use the Phototherapeutic Device on eyes or directly shine (nonvisible light) into eye when the Pad indicator light is on.

– Only use the Device and accessories supplied by the manufacturer.
– Do not connect any other power supply to the Pad or Controller.
– Do not use the Device if the power supply is damaged.
– Do not modify the Phototherapeutic Device and its accessories.
– Always return the Phototherapeutic Device to a service center authorized by PBMFLEX HEALTH for examination or repair.

Caution

– The Phototherapeutic Device is designed to relieve back pain, neck discomfort, joint aches and muscle soreness at home and work. Do not use it for any other purpose.
– If any irritation or discomfort occurs while or after treatment, discontinue use immediately.
– Consult with your primary healthcare professional before use if you are currently on prescription medication or under medical treatment.
– Handle with dry hands when plugging into or unplugging from an outlet, the Pad or Controller.
– Keep the Device, DC cord and Velcro® strap out of the reach of children.
– Whenever there is the possibility of a lightning storm in your area, disconnect the Power Supply from the outlet.
– Do not open or modify the Pad, Controller or Power Supply.
– Do not stab the Pad with sharp objects.
– Do not place heavy objects on the Pad or Controller.
– Do not expose the Pad, Controller or Power Supply to strong sunlight or any other heat source.

– Do not contact the Pad with oil or other organic dissolvent like acetone, kerosene, etc.
– Do not press the Pad when it is rolled.
– Do not squeeze or twist the Pad by force.

Treatment

It is explicitly emphasized that the Phototherapeutic Device is not a quick fix solution to pain as one or infrequent treatments seldom works. To effectively use the Device it must be performed following a specific protocol, much like a doctor's prescription. As with a prescription, it is specified and must be taken continually or it will be ineffective. Follow the instructions given in the Treatment Chart as specified. In some cases, results will occur in just a few days, whereas for severe conditions may take weeks or even months to resolve.

Rate of Effect

The rate of effects to one's tissue is based on each individual's response. Some respond quickly while others need prolonged treatment. Factors such as the lag time between injury and the start of treatment, the degree of pain or injury and age are also important factors. Usually within three weeks of consistent use positive results are noticed. In some incidents, problem resolution takes place quickly (in a few treatments) but that is not a general rule.

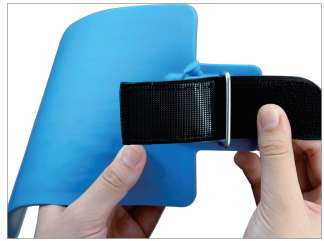
Operating Instructions

Unit Operation and Strap Use

The Pad of Phototherapeutic Device is of a flexible material. The Device is designed to be attached onto the skin and held against the body with a strap, with two metal rings, one at each end of the Pad, powered by an AC-DC power supply.

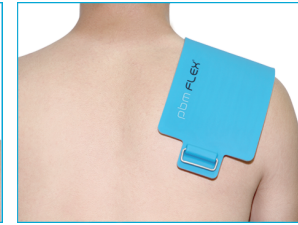
1. Remove the waterproofing plug

2. Use the strap if necessary, by wrapping Velcro® strap through the metal ring at one end and secure.



3. Plug the DC connector from the Controller and securely insert into the DC jack on the Pad.

4. Attach the Pad around the lower back and secure the other end of the Velcro® strap; or wrap the Pad around the elbow or knee or neck or anywhere you are experiencing pain.

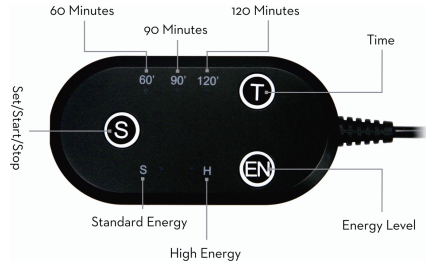


5. Plug the Power Supply into an outlet.

6. Connect the Power Supply to the Controller by inserting the DC plug into the jack.

7. Follow the instructions in Controller Operation to start treatment.

Controller Operation



When the Controller is first time powered up, the indicators for S (Standard energy) and 60′ (60 minutes) flash, which is a default setting. You can simply press S (Start) button to start treatment or find an appropriate setting on Treatment Chart (Energy Density) to get started.

Treatment Chart (Energy Density)

Energy Level	Conditions	T (Time) & Energy Density		
		60′	90′	120′
S (Standard Energy)	Chronic pain - Injuries, Joints, Inflammation, Muscle & Ligament	3 times/day (20 J/cm^2)	2 times/day (20 J/cm^2)	1 time/day (13 J/cm^2)
H (High Energy)	Acute pain - Injuries, Joints, Nerves & Inflammation	3 times/day (29 J/cm^2)	2 times/day (29 J/cm^2)	1 time/day (20 J/cm^2)

1. When the Controller is at setting status, each of the indicators for T (Time) and EN (Energy) flash; press T button to select time, press EN button to select energy level.
2. Press S (Start) button to start treatment, the indicators on the Controller and the Pad light up.
3. To stop the current treatment or change the setting during the treatment, press and hold S (Stop) button until the indicators turned off.
4. When the treatment is about over in 20 seconds, the Controller starts beeping, press S (Stop) button to stop the buzzer or wait for the indicators to turn off. The current setting will be memorized for the next treatment.
5. To start a new treatment, press S (Set) button, the last setting is recalled; press S (Start) button or set new Time and Energy level by doing the step 1 - 2.

Possible Side-effects

– The skin may become a little red during or after treatment. This is normal and caused by increased blood circulation due to the warmth of the Phototherapeutic Device. The skin redness is harmless and will disappear in a few hours after the treatment has ended.
– You may feel a little bit hot during treatment. To avoid overheating, attach the Pad firmly onto the skin and/or use the device in open air.

Device Specifications

Photon Wavelength	880 nm
Photon Energy	1.8 mW/cm^2 (at Standard energy level) 2.7 mW/cm^2 (at High energy level)
Operation Lifespan	2 years (based on 3 hours a day)
LED Emitting Area	22.7 cm x 9.8 cm
Pad Weight	175 g
Pad Material	Silicone
Device Input	10V DC, 1.5 A
Power Supply Class	Medical Class II
Power Supply Input	100 – 240V AC, 50 – 60 Hz
Power Cord Length	2 m
Velcro® Straps	1 for waist size 28" – 42", 1 for waist size 40" – 65", nylon polyester material
Operating Environment	Temperature 10 °C – 35 °C, relative humidity 30% – 90%

Safety and Storage

Safety and Certification

– Passed CE, FCC and Medical Device Class IIa testing and certification
– FDA Listed Device No. D316762
– Classified as Risk Group 1 (according to IEC60601-2-57:2011)

Storage and Transport Condition

– Temperature: -30 °C – 80 °C
– Relative humidity: 30% – 90%
– Atmosphere pressure: 86 kPa to 106 kPa

Symbol Descriptions

	Type BF Applied Part		Date of manufacture	IP22	Protection against fluid ingress: Drip Proof
	Refer to instruction manual/booklet	EC REP	Symbol of European Authorized Representative		Temperature limitation
CE 0598	CE Marking of Conformity	SN	Serial Number		Humidity limitation

	Manufacturer ID, expressly indicate the manufacturer's name after this symbol		The device should be sent to the special agencies according to local regulations for separate collection after its useful life		Atmosphere limitation

EMC Declaration

1) This device needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.
   This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this device can be affected by portable and mobile RF communications equipment.
2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the device. This may result in incorrect operation of the device.
3) This device has been thoroughly tested and inspected to assure proper performance and operation.
4) This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The Phototherapeutic Device is intended for use in the electromagnetic environment specified below. The customer of the user of the Phototherapeutic Device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Phototherapeutic Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Phototherapeutic Device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The Phototherapeutic Device is intended for use in the electromagnetic environment specified below. The customer or the user of Phototherapeutic Device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the Phototherapeutic Device requires continued operation during power main interruptions, it is recommended that the Phototherapeutic Device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The Phototherapeutic Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapeutic Device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Phototherapeutic Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 MHz

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compli-ance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey

should be considered. If the measured field strength in the location in which the Phototherapeutic Device is used exceeds the applicable RF compliance level above, the Phototherapeutic Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Phototherapeutic Device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
portable and mobile RF communications equipment and the Phototherapeutic Device .

The Phototherapeutic Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Phototherapeutic Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Phototherapeutic Device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty and Maintenance

Warranty

PBMFLEX HEALTH offers the following warranty to the originally purchased product.

– The Phototherapeutic Device is warranted against any electronic or mechanical defect in material or workmanship within one year (12 months) from the date of purchase.
– Should a defect occur, PBMFLEX HEALTH will repair or, at its option, replace defective unit/parts with new or rebuilt materials without charge for either parts or labor. Replacement unit/parts will be warranted for the remaining portion of the original warranty period.

For product service, call (852) 2420-2588 or email service@pbmflex.com to arrange for a free repair or replacement.

The warranty does not cover the following:
– Apply to any cosmetic appearance items such as scratches.
– Damage from accident, misuse, abuse, improper wiring, incorrect voltage, operating the unit against the instructions given in this manual or any product which has been opened, altered, or tampered with.
– If the Device is used for commercial purpose, the warranty will only apply for 90 days from the date of purchase.

Repair Information

If service is required on your Device during the 12 month warranty period, call PBMFLEX HEALTH at (852) 2420-2588 or send an email to service@pbmflex.com to obtain a Return Material Authorization (RMA) number. Pack the Device properly with its original packing along with a copy of your purchase receipt and a letter describing the problem. Send the unit under freight prepaid and insured to:

PBMFLEX HEALTH
Unit 1306, Level 13, Landmark North, 39 Lung Sum Avenue
Sheung Shui, Hong Kong
Attn: Customer Service
Tel: (852) 2420-2588

Note: No return will be accepted unless an assigned RMA number appears on the outside of the shipping box.

Device Maintenance

– The Pad can be cleaned with damp cloth, with water and the most popular household cleaners in the market.
  Note: When clean, keep the waterproofing plug inserted into the DC jack on the Pad; getting water or any solution into the DC jack may cause the Pad damage.
– The Pad can also be sterilized with the most popular household disinfectants in the market.
– Do not immerse the Pad in water or rinse it under the tap.
– To prevent damage to other clothes in the washing machine, secure the both ends of Velcro® strap and wash the straps in a washing bag.
  Note: Dry the Velcro® strap in the air, not in a tumble dryer. Do not iron the Velcro® strap.

Troubleshooting

If you are unable to solve the problem with the information below, contact PBMFLEX HEALTH.

Problem	Possible Cause	Solution
The Pad is not warm after treatment starts for 5 minutes.	Lost connections	Check if the indicator on the Pad is lit up and secure the connections.
The Pad becomes hot during treatment.	There is a distance between the Pad and skin.	Attach the Pad firmly onto the skin.
The power supply becomes warm.	This is normal.	No action required.

Owner's Card

Fill in this card and keep for your permanent record, or go to Product Register on www.pbmflex.com to fill in all the necessary information.

Name:_____

Address: _____

City: _____State: _____

Zip Code: _____Date of Purchase: _____

Dealer's Nam: _____

Model No.: _____ SN: _____