5.4. Charging

Charge your device fully for 2 hours before your first use. Only use a 5V adapter.

To charge the device insert the USB-C cable into the device. Insert the USB-A side of the cable into a USB power supply. The LED indicator on the device will start to flash slow or blink slow to indicate charging. When the device is fully charged the LED indicator will turn off.

Before charging, make sure that the plug and socket are completely dry. Failure to do so may result in electric shock, short circuit, or fire.

Note: Always unplug the device before use, the device will not work while being charged.

5.5. Care and Storage

- The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
- Store the device at room temperature in dry conditions.

• Avoid storing the device in dusty conditions, in direct sunlight or in damp and humid conditions.
• This device contains no serviceable parts.
• Before each use, with the device switched off, clean the Device following the cleaning instructions below.

Important

The product has a limited lifecycle of two years under nominal use. Following the treatment protocol for two years is considered as nominal use.

The device must be handled with care.

5.6. Cleaning

• Clean the Device with a water-based wipe or damp clean cloth. Stubborn stains can be removed by wiping gently with 70% alcohol.
• **DO NOT** use any other cleansing Devices as these may damage the Device.
• **DO NOT** clean the device while it is turned on.
• **DO NOT** clean the device while charging.

5.7. Connecting the Device

To get the most out of your device you will be able to connect your device to the official Titan-IR app. Download the app in your preferred app store.
Start of by creating an account. After successfully setting up, and login in to your account you will be able to connect your device. Make sure the Bluetooth on your phone is turned on, and connect your device in the app.

5.8. Troubleshooting

If the actions suggested fail to fix the problem, or the problem reoccurs, and your device is within the warranty period please return to Medify PBM.

- **DO NOT** attempt to investigate any further.
- **DO NOT** attempt to modify the device in any way. The device has NO parts you can repair yourself.

Problem	Cause	Solution
The device doesn't switch on.	The device is not fully charged, because the charging cable was not properly inserted into the power outlet.	Insert the charging cable properly into the power outlet.
	The device is not fully charged, because the charging cable was not properly inserted into the device.	Insert the charging cable properly into the device and charge the device.
	The power outlet didn't work during charging.	Try a different power outlet.
	The on/off button has not been pushed one full second. The device is still connected to a charger. The device will not turn on while being charged.	Push the on/off button for 3-5 second straight. Disconnect the charger and press the on/off button.
The device switches off unexpectedly.	The battery level is too low. Device is overheated and shuts down	Charge the device. Let the device cool down and try again.

5.8. Disposal

DO NOT dispose of the device with household waste. The Device should be recycled. The Device contains a Lithium-ion battery. For protection of the environment, please safely dispose of the device following your local guidelines.

6. Warranty

The device is warranted to be free from defects in material and workmanship for 12 months from its original purchase date under normal use. This warranty extends only to the original retail purchaser with original proof of purchase and only when purchased from an authorized retailer or reseller. This warranty only extends if the device is used in conjunction with authorized Device accessories. If the Device should become defective within the warranty period, contact the retailer that you purchased the device. This warranty does not cover Devices damaged by:

- Accident, misuse, abuse, or alteration.
- Use with unauthorized accessories or use other than as instructed.
- Connecting to incorrect current and voltage.

Medify, Inc shall not be responsible for any incidental, special or consequential damages resulting from the use of this Device. All implied warranties, including but not limited to implied warranties of fitness and merchantability are limited in duration to one year from date of original purchase.
This warranty gives you specific legal rights, and you may also have other rights that vary from country to country. Some countries do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so some of the above limitations and exclusions may not apply to you.

This warranty is given in lieu of all other warranties, written or oral, whether expressed by affirmation, promise, description, drawing, model or sample. Any and all warranties other than this one, whether expressed or implied, including implied warranties of merchantability and fitness for a particular purpose are hereby disclaimed.

If the Device is defective within the warranty period, please contact the Medify Customer Support Team.

To register your Device and be kept up to date with new and exciting developments from the Customer Service team, please take a moment to sign up on our website www.medifypbm.com. To

complete your registration online you will need to enter the Device batch number.

7. Safety

The Device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The Device has been tested to or complies with the following standards:

EN 60601-1:2006/A12:2014. Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

IEC 60601-1-6 2010 AMD12013 Medical Electrical Equipment – Part 1General Requirements for

Basic Safety and Essential Performance –Collateral Standard: Usability.
IEC/EN60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC/EN 60601-2-57:2011 Medical electrical equipment. Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

EN 62471:2008 Photobiological Safety of Lamps and Lamp Systems.

EN 62366-1:2015 Application of usability engineering to medical devices.

EN ISO 10993-1:2010-04 Biological evaluation of medical devices Part 1: Evaluation and testing.

EN ISO 10993-5: 2009 Part 5: Tests for in vitro cytotoxicity.

EN ISO 10993-10: 2021 Part 10: Tests for skin sensitization.

EN ISO 15223-1:2017 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 14971:2012 Medical devices - Application of risk management to medical devices.

EC62133:2012 2nd ed. Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable application.

Registration, Evaluation, Authorisation and Restriction of chemicals (REACH) directive (EC 1907/2006).

8. FAQ

How is Transcranial Photobiomodulation different from other device-based treatments for Brain Health and Wellness?

Typical transcranial medical device treatments modulate the electric potential of a neuron membrane. These are electric or magnetic current devices such as Electric Convulsive Therapy (ECT), Transcranial

Direct or Alternating Current Stimulation (tDCS), or Repetitive Transcranial Magnetic Stimulation (rTMS or TMS) use. Transcranial Photobiomodulation works specifically with individuals cells which researchers have associated with simulation of the mitochondria. This stimulation may produce Adenosine Triphosphate (ATP) which creates an increase in bioavailable ATP.

How does Transcranial Photobiomodulation exactly work?

Like many of other brain devices approved by the FDA, the exact mechanism of action of Photobiomodulation is not completely understood. Leading researchers have identified the potential to work by enhancing mitochondrial metabolism. These mechanisms may lead to improved neuronal functioning, improved oxidative stress, inflammation, and neurogenesis.

Can photobiomodulation be combined with other medication and/or antidepressant treatments?

There are many published studies that include patients receiving Photobiomodulation in combination with psychotherapy and antidepressant medications. No serious adverse events were reported for these combinations. There are no reports on the combination of Photobiomodulation with other transcranial treatments such as rTMS, TDCS, or ECT. Researchers have deduced that there

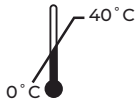
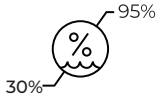
is no rationale for avoiding the simultaneous use of Photobiomodulation with other device-based treatments. Secondary effects of potentiation of the antidepressant effects might occur, and some side effects – such as memory impairment with ECT can potentially be mitigated.

How long should PBM be used for the treatment of brain health symptoms?

Studies have identified that as little as one single session of t-PBM may produce a decrease of symptoms, but this effect seems to be temporary. More consistent improvement was observed in studies that used multiple sessions during 3–8 weeks for the management of brain health symptoms. The safety profile of Photobiomodulation suggests it could be used as maintenance treatment for responders to other therapies. However, the only evidence for long-term use comes from a case report.

9. Symbols

Symbol	Explanation
	Type BF Applied Part, B indicates it is used for the body and F indicates that it is not connected to the mains voltage.
	The Waste of Electrical and Electronic Equipment (WEEE), Indicates the Device may not be discarded as household waste (2012/19/EU).
	Indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.
	This warning symbol on the device label is a warning to read the enclosed documents before use and take all safety precautions required.
	This symbol on the device label means: Read the user manual before you start using the device.
	This symbol means “Manufactured by” and provides the name and address of the legal manufacturer.
	Date of Manufacture.
	This symbol means keep the Device dry.

SN	This symbol indicates the serial number of the device.
	This symbol indicates the USB connector.
Li-ion	This symbol means that the device uses a Lithium-ion Polymer battery.
CN	This symbol means made in China.
	This symbol means keep the device away from direct sunlight.
	This symbol means the upper and lower operating temperatures that the device can be safely used at.
	This symbol means the upper and lower operating humidity that the device can be safely used at.
	This symbol means that the cardboard packaging that the device came in can be recycled.
IP22	This symbol means that the device is protected against a solid object greater than 12.5mm such as a finger and against vertically falling drops of water.

	Class II Medical Electrical Equipment.
	Unique Device Identifier.
	This symbol means: Conforms to certain EC Directives on health, safety, and environmental protection standards. CE stands for"Conformité Européenne'.
	This symbols implies conformity to UK Directives on health, safety and environmental protection standards. UKCA stands for UK Conformity Assessed.
	Handle the packaging with care
	Restriction of hazardous substances.
	This symbol indicates the device can be used whe age above 18.
	Indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.

10. FCC Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions (1)this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The device has been evaluated to meet general RF exposure requirement.The device can be used inportable exposure condition without restriction.

11. Contact Information

Imported and Distributed by:

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TD-01A 说明书
成品尺寸:150*100 MM 公差:-1-0 MM
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装订:骑马钉