

TITAN-IRTM

Instructions for use

Version: 1.1



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1. Company Information

Medify, Inc. is a privately held consumer and medical device company focused on designing, developing, and manufacturing cutting edge Photobiomodulation products that help consumers and patients live happier and healthier lives. Our vision is to become the worldwide leader in the Consumer Wearable and Clinical Photobiomodulation market by creating future forward products for individuals who seek relief around the world. Our future forward technology is safe, efficacious, and meticulously engineered. We pride ourselves on high quality design, production, and manufacturing, for the greatest photobiomodulation experience ever.



TITAN-IR™



2. General Device Information

Indications for Use

TITAN-IR is intended for medical purposes that emits energy at infrared frequencies to provide topical heating.



2.1. Description of the Device

TITAN-IR is the only multi-wavelength, red and near-infrared home wearable device with customizable pulse neuromodulation. The treatment is delivered to the brain via the Pre-Frontal Cortex, which is known to regulate mood and emotions. TITAN-IR is used for the management and maintenance of brain health and wellness, which may improve mental acuity and stress management.

The average TITAN-IR™ session lasts between fifteen and twenty-seven minutes. New users typically start at five days per week, for up to six weeks. Usage past this point, is recommended at a minimum of three days per week, or at a frequency recommended by a clinical provider.

2.2. Device Specifications

LED wavelengths	Multi-Wavelength Infrared Diodes
Max. output optical power density	60 J/cm ²
LEDs	60 Single-Core Therapeutic Infrared Diodes
Operating temperature	0°C to 40°C 32°F to 104 °F

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Storing and transport temperature	-5°C to 55°C 23 °F to 131 °F
Operating humidity	30% to 95% without condensation
Storage and Transport Humidity	20% to 95% without condensation
Charging supply	5V $\overline{\text{---}}$ 2A
Charging port	USB-C
Charging cable	USB-C to USB-A
Charging cable length	1 meter / 3.28 feet
Charging adapter power output	2A
Battery	1*3.7V, 1500 mAh
Battery type	Lithium-ion
Charging time	120-150 minutes / 2-2.5 hours
Recommended use	2 times per day, minimum 3-5 times per week for 6 weeks
Treatment time	15 minutes
Dimensions of the device	185 x 116 x 54 mm
Weight of the device	248 g

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2.3. Device Accessories

Accompanied with the TITAN-IR™ device is a USB-C Charging Cable and Device Storage Pouch.

If the charging cable is missing or one of the products is damaged, contact customer support. We are more than happy to help you.

2.4. Adverse Reaction

If you have any adverse reaction, such as discomfort, skin discoloration, skin irritation or other concerns, from using this Device, stop using it immediately and consult your health professional.

Skin irritation, bruising, contact burns, dizziness, nausea, and headaches are rare but possible side effects. Immediately stop using the device and contact your General Practitioner.

2.5. Contraindications

DO NOT use the device if you have any implants in the brain such as stents, clips on aneurisms, or implantable

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shunts (e.g., Hakim valves) or of rupturing embolized vascular malformations.

DO NOT use the device if you've had a recent hemorrhagic stroke (past 3 months), due to the potential recurrence of bleeding with vasodilation and due to the risk of cerebral warming associated with light absorption by deep hematomas.

DO NOT use the device if you have any active cancer or cancerous lesion.

DO NOT use the device if you are pregnant, planning on becoming pregnant, or breastfeeding.

DO NOT use the device on people under the age of 18.

DO NOT use the device if you have severe acne on the forehead.

DO NOT use the device over areas with phlebitis, thrombophlebitis, and varicose veins.

DO NOT use the device if you have a known allergic reaction to polycarbonate or silicon. The device contains plastics that come into contact with the skin during use. When in doubt of allergies first contact your General Practitioner before using the device.

DO NOT use the device if you suffer from any photosensitive disorder (sensitization to light).

DO NOT use the device if you suffer from any skin condition.

DO NOT use the device if you are taking any medication or drugs that can cause photosensitivity. If you are not sure about your medication contact your health professional.

DO NOT use the device if you suffer from light-induced headaches

DO NOT use the device if you have a medical history of seizures or epilepsy that was triggered by light.

Note: For reasons of hygiene, we do not recommend sharing your device with anyone else.

Note: We highly suggest taking caution when taking any (skin related) damaging medications. If in doubt, consult your General Practitioner.

Note: If you are under the care of a physician, consult your physician before using this device.



2.6. Warnings

STOP using the device and consult your General Practitioner if you experience an adverse reaction from using the device.

STOP using the device if you experience symptoms of hypotension (dizziness or light-headedness) while using the device.

STOP using the device if it is overheating. Turn off the device immediately.

STOP your treatment if it feels hot or your skin feels uncomfortably warm.

DO NOT let children play with the device. Cleaning and charging the device shall not be done by children.

DO NOT use the device to treat rosacea, moles, warts, open sores, cancerous lesions, or any skin condition.

DO NOT use the device on spots without pigmentation or areas on the skin that have vitiligo.

DO NOT shine the light from the LEDs directly into your eyes or someone else's eyes. This may cause temporary loss of sight.

DO NOT place the device on any open wounds

DO NOT use the device outdoors to prevent damage to the product.

DO NOT sit, lay down or step on the device. This will break the device.

DO NOT drop or insert any object into any openings of the device.

DO NOT use the device if it is not working properly, or if it has been dropped or damaged. For warranty and repairs contact customer support.

DO NOT use or store the device near hot surfaces.

DO NOT charge the device when it is close to or might get in contact with water.

DO NOT submerge the device with water.

DO NOT store the device in extreme heat (40°C|104°F) or cold (0°C|32°F).

DO NOT place the device in direct sunlight.



DO NOT attempt to modify the device in any way. Modifying or opening the device will void your warranty. the device contains no serviceable parts. This device contains batteries that are non-replaceable

DO NOT perform maintenance or take apart the product. In case of malfunctioning or damage, contact customer support.

DO NOT use the device if damaged or when the charging cable is damaged.

DO NOT use the device with non-manufacturer-approved accessories.

DO NOT use solvents or abrasive cleaners on the device.

DO NOT use the device in any other way then specified in this manual.

DO NOT use the device if you have had a recent surgery or other surgical procedures.

DO NOT use the device over a bacterial infection as this may result in the worsening of symptoms.

DO NOT use the device on painful areas. Consult your General Practitioner when you experience painful area's during use.

DO NOT use the device on, near, or by children or those with reduced physical and mental abilities. Close supervision is necessary when this device is used, cleaned or stored near children or those with reduced physical or mental abilities.

DO NOT use the device with any other USB-C cable than provided by Titan-IR.

DO NOT use the device with any other topical other than specified by Titan-IR.

DO NOT bend, twist or pull the device.

Note: The device should only be supplied with 5V DC low voltage. If any part of the main adapter or cable is damaged, discontinue use.

2.7. Precautions

- **DO NOT** scratch or damage the light-emitting surface.

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- It will void your warranty if you do not operate the device in accordance with the instruction in the manual.
- Read all instructions carefully before using this device.
- Store the device according to the protocol worked out in this manual.
- This device is intended to be used by one person.
- The device is designed for individuals with good health. Please contact your General Practitioner if you are unsure about your health status.
- The battery of the device is not removable by the user. If the device is to be disposed of, do not put into a fire. Dispose of the device per local regulations.
- Inspect the device and do not use the device if you see any signs of damage such as internal battery leaks. Contact our customer support.
- The device should only be supplied with 5V DC low voltage. If any part of the charging cord is damaged, discontinue use. Contact customer support to arrange a replacement.
- Consult your General Practitioner before using the device if you have a fever, acute inflammation, a severe circulatory disorder, light sensitivity, anaesthetic, or desensitized areas.

2.8. Travel and International Use

TITAN-IR's lightweight design makes it a perfect travel companion. Here are some travel tips:

- If you are travelling to a different region of where you bought the Device, please assure that the device is only supplied with a 5V DC Low Voltage.
- Confirm with the steward that the Device can be carried and/or used on the airplane prior to flight.

2.9. Disclaimer

DO NOT use the Device to treat any other conditions apart from the conditions that are indicated in the Indications for Use statement in Chapter 2; General Device Information.

3. Risks and Benefits

3.1. Potential Risks

- Immediately after treatment skin may appear red. Skin should return to normal within 1-2 hours.
- Temporary headaches are common immediately following light treatment. Headaches can be treated with an appropriate pain killer and rehydration.
- Headache can be minimized by lowering the device power level. Once conditioned to a lower power level, the user can increase the power level to a comfortable setting.

3.2 Potential Benefits

- Improve Relaxation

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- Improve Meditation
- Improve Stress Management
- Improve Cognitive Performance
- Improve Cognitive Focus
- Improve Mental Acuity
- Improve Cerebral Blood Flow

Tip: When connecting your device with the official TITAN-IR app you can choose one of the following treatment settings with their own specialized benefits.



Power 5 Mode



Delta Mode



Theta Mode



Alpha Mode



Beta Mode



Gamma
Mode



Continuous
Wave

4. Light Sensitivity Test

We highly recommend users perform a light sensitivity test before their first use of the device.

1. Place the device on the inner forearm
2. Turn on the device to start a treatment
3. Wait till the treatment is done. The treatment will take 15 minutes to complete.

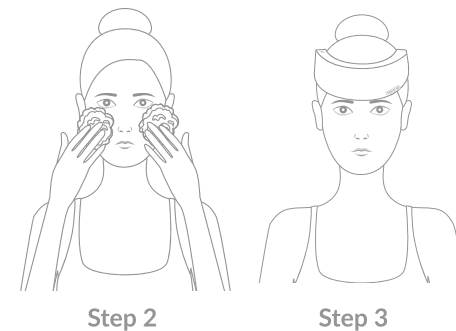
4. If your skin feels hot or uncomfortable during the treatment directly stop! You might be sensitive to light.
5. The device will automatically turn off after the treatment is done. Remove the device and wait for at least 24 hours.

Check your skin regularly over those 24 hours, if your skin appears red and/or itchy the device is unsuitable for you. In the case of light sensitivity please contact customer support.

5. How to use the Device

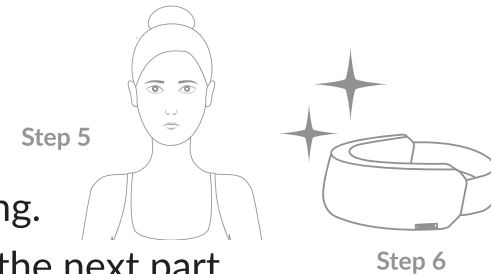
5.1. General Use

1. Prior to using the device, make sure it is fully charged.
2. Clean the skin on the surface area you will place the device.
3. Make sure the device is unplugged and place the device on the forehead, adjust the strap for a comfortable fit.
4. Turn on the device and enjoy the treatment.
 - a. The device can be turned ON by pressing the power button on the device for 3-5 seconds.



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- b. Select a custom treatment by connecting the device to the app or by pressing the power button .
- c. The device switches off automatically after the treatment is finished. You may stop the treatment at any time by pressing the ON/OFF button.
- 5. Take the device off the treatment area.
- 6. Clean the Device using a water-based wipe or a damp clean cloth.
Ensure the Device is NOT connected to the power supply when cleaning.
- 7. Repeat these steps based upon the treatment protocol described in the next part.



5.2. Correct Positioning and Use of the Titan-iR™ Device

Titan-iR™ optimal positioning is higher on the forehead, closer to the targeted treatment area. Place one or two fingers between the users' eyebrow and the bottom of the device for proper placement of the treatment window. Users who place the device too low on the forehead will have a higher chance of side effects.

The Titan-iR™ has a distinct heat profile which is calming for most users. If the device gets too warm, please discontinue for several minutes, and replace the device. Using the device on a lower power level or with a pulsing frequency can minimize the heat profile. The body's temperature-mitigating



mechanism works better when the device is placed correctly on the user's forehead.

5.3. Treatment Protocol

What to expect while using Transcranial Photobiomodulation?

Medify recommends that the first three uses are with the Power 5 Mobile Application Mode on the lowest level. If the mobile application is not available, please use the integrated Alpha Pulse for no longer than 5 to 7 minutes for first three uses. A shorter initial use allows users to acclimate to the Titan-iR™ device, which will minimize transient headaches and other side effects.

The average Titan-iR™ session lasts 15 minutes. Typical brain health and mental wellness management treatment average three times per week. After treatment, most users report increased energy, mental acuity, and stress management levels.

Brain Health and Mental Wellness Optimization

Daily Usage: 1-2 times per day, recommended in the morning and/or early afternoon



Use of device 4 hours before bedtime is not recommended, as the user's sleep may be disrupted

Weekly Duration: Minimum of 3 days per week (Ideally with a break between days)

Initial Treatment Phase: Average of 15 total treatments

Long-Term Usage: Once per week or up to a maximum of five days per week. The average is three days.

Cognitive Performance Optimization

Titan-iR™ may be used for a temporary increase in cognitive performance or mental acuity. Typical use is 15 to 30 minutes before activity or at a specific time in the day when an increase in cognitive performance or mental acuity is needed. Please note: Use of Titan-iR™ at higher power levels, or longer than a single treatment, can increase side effects like transient headaches.