



Therabody

# TheraFace Mask Glo

User Manual & Unit Warnings

Clinically-Proven LED Technology

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# TheraFace Mask Glo

## 1. Product Overview

TheraFace Mask Glo is an LED skincare mask to help you achieve younger looking, healthier skin with anti-aging, restoring and rejuvenating benefits. This mask combines 504 full-face Red, Red + Infrared, and Blue LED lights and is an FDA-Cleared, Class 2 Medical Device.

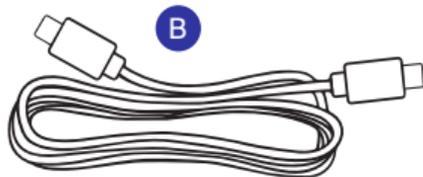
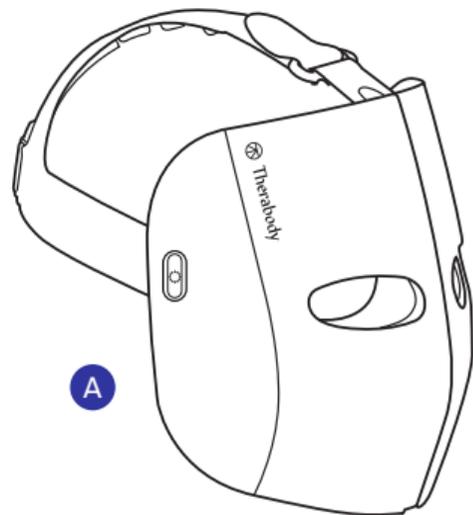
### Indications for Use

- Red Light is intended to treat full face wrinkles
- Blue Light is intended to treat mild to moderate inflammatory acne
- Red + Infrared Light is intended to treat full face wrinkles

The device is safe for use on all skin types (Fitzpatrick Types 1 - 6).

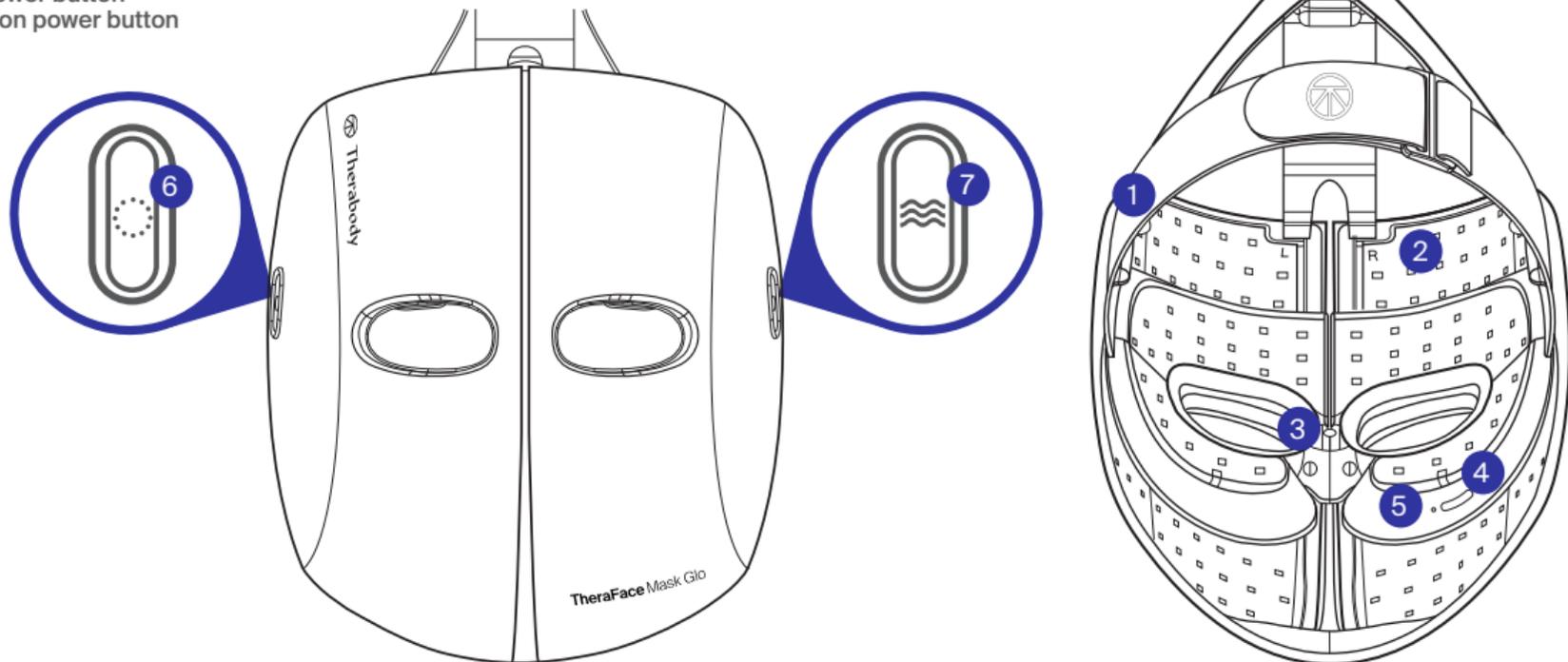
## 2. What's In the Box

- A. TheraFace Mask Glo device
- B. USB-C cable
- C. Instruction manual



### EN 3. Getting to Know Your Device

1. Head massage units
2. Multi-color LEDs
3. Pre-installed eyeshield (assembled)
4. USB-C port
5. LED indicator
6. LED power button
7. Vibration power button



## 4. Using Your Device

- 1. Charge the device.** Charge the device before use.
- 2. Prepare for treatment.** Begin with a clean, dry face. Do not allow the device to come in contact with colored solids or liquids, as it is hard to clean after being dyed. Remove all makeup, wash hands thoroughly, and ensure that cosmetics (such as lipstick) and oils do not come into contact with the device.
- 3. Put on the device.** Place the device on your face, and adjust both of the Velcro straps to your desired fit. The device should feel snug but not too tight on your face.
- 4. Turn on the device.** Press and hold the LED power button to begin a light and vibration treatment. Press and hold the vibration power button to turn on the vibration treatment only. At any point during the light and vibration treatment, press and hold the vibration button to turn off the vibration for light treatment only.
- 5. Select your desired LED light treatment setting.** The device will guide you through a 12-minute science-backed treatment that automatically cycles through three LED light treatment types: red light, red + infrared light, and blue light. Each treatment will be 4 minutes long. Press the LED power button at any point to cycle through light therapy types. You will hear a beep when the light therapy type changes.
- 6. Select your desired vibration treatment setting.** There are two vibrating motors located in the headstrap. Press the vibration button to toggle through the three vibration modes (Relax: low-frequency continuous; Refresh: higher-frequency continuous; and Relieve: wave). Use vibration as a standalone treatment without LED light by pressing and holding the LED button while vibration is on. If vibration is used as a standalone treatment, it will run for 12 minutes.
- 7. Sit back and enjoy.** Relax and enjoy your treatment.
- 8. Turn off the device.** Press and hold the power button at any point during the treatment to turn off the device. The LED light will turn off when the device is off. The device will automatically shut off after the 12-minute treatment is complete.

\*This device has built-in eyeshields. Normal use of the eyeshields may result in redness around your eye area. Some redness is normal and should subside within 5-10 minutes of using the device.

## 5. How Your Device Works

Therapy	Intended Benefit	Settings
Red light therapy	Red Light is intended to treat full-face wrinkles.	12-14 J/cm <sup>2</sup> of energy generated across the entire device in a 4-minute treatment when therapy is on
Red + infrared light therapy	Red + Infrared Light is intended to treat full-face wrinkles.	Red light: 12-14 J/cm <sup>2</sup> of energy generated across the entire device in a 4-minute treatment when therapy is on Infrared light: 9-11 J/cm <sup>2</sup> of energy generated across the entire device in a 4-minute treatment when therapy is on
Blue light therapy	Blue Light is intended to treat mild to moderate inflammatory acne.	10-12 J/cm <sup>2</sup> of energy generated across the entire device in a 4-minute treatment when therapy is on

**Recommended Use: 6 days per week**

To learn more about the science and benefits behind the modalities included in this device, visit [therabody.com/science](http://therabody.com/science)

## 6. Care, Cleaning, & Cleaning

### Device Maintenance

The following maintenance instructions are important to ensure that your device continues to work as it was designed. Failure to follow these instructions may cause your device to stop working.

### Cleaning the Device

Read the following instructions carefully before cleaning the device to ensure longevity of the device and its components.

1. Before cleaning, turn off the device. Ensure that the device is not connected to a charging cable or power source before cleaning.
2. Visually inspect the device for any obvious signs of debris build-up.
3. Wipe off any visible dirt with a disposable cloth moistened with a mild detergent. Be sure to wipe the interior surfaces of the mask. Next, use a soft cloth dampened with 70% isopropyl alcohol to wipe and disinfect the mask for three (3) minutes, especially the inner surface of the mask. Repeat this process three times. Finally, wipe the disinfectant with a clean, dry cloth or towel until there is no visible residue. Do not submerge the device in water or apply excessive cleaning solution or disinfectant when cleaning.
4. After cleaning, allow the device to dry thoroughly before storing or beginning another treatment. A properly cleaned device should have no visible signs of debris or moisture.
5. For best hygiene practice, clean the device after every use.

Note: This device is NOT waterproof. Only clean the device as noted above. Do not submerge the device in water or clean it under running water. Do not allow the device to come into contact with corrosive solutions, which can damage the device's appearance and function.

### Charging the Device

1. The device is USB-C enabled and comes with a charging cable. Before charging the device, ensure that it is powered off.
2. Connect one end of the charging cable to the USB-C charging port on the device. It is located on the side of the device. Connect the other end of the charging cable to a power adapter.
3. The LED light will indicate the battery status when the device is on or charging. Turn the device on to check the battery status.
  - Flashing Orange: Recharge
  - Solid Orange: Low battery
  - Solid Green: High battery

The battery life of the device is up to 60 minutes, depending on the settings used. Use a USB-C power adapter of at least 20W when charging the device. \*\*Note: If using a charger from a third party, ensure that it is from a certified manufacturer and has not suffered any structural damage. Do not try to use the device while charging.

### Store and Transport the Device

To store and transport the device, handle it gently. Store the device in a cool and dry place (Temperature: 0°C/32°F - 35°C/95°F Relative humidity: 10~90% RH). Do not store the device where temperatures may exceed 35°C/95°F, such as in direct sunlight or in a vehicle.

# Troubleshooting Guide

Scenario	Error Code Displayed	Potential Cause	Potential Solutions
The device does not power on	The battery indicator blinks orange, blue, and green for 5 cycles and then turns off	The battery pack may be overheating	Let the device rest for 60 minutes and then try again. If the issue still persists after verifying all of the above, contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods
	The battery indicator blinks white at 4 Hz for 5 seconds	Battery NTC short circuit or open circuit	Contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods
Vibration motor stops running	The battery indicator blinks orange	Low battery level	Charge the device.
	The battery indicator blinks orange, blue, and green for 5 cycles and then turns off	The battery pack may be overheating	Let the device rest for 60 minutes and then try again. If the issue still persists after verifying all of the above, contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods
	—	Motor may be broken	Contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods
The battery won't charge	—	The ambient temperature is too high or too low	Charge the device when the ambient temperature is between 5°C and 35°C
	—	The power adapter cable is not well connected to the adapter socket on the console	Unplug the power adapter cable and plug in again. Make sure they are connected
	—	The power adapter cable is dirty	Clean the power adapter cable
	The battery indicator blinks white at 4 Hz for 5 seconds	Battery NTC short circuit or open circuit	Contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods
	—	Battery may be broken	Contact Therabody for further assistance. Visit <a href="https://www.therabody.com/us/en-us/support/support.html">https://www.therabody.com/us/en-us/support/support.html</a> for the available contact methods

# Warnings and Guidance (Precautions and Contraindications)

## Background

Therabody products are designed to unlock the body's natural ability to achieve health and well-being. Through science and technology, the Therabody portfolio of products allows people to access the therapeutic benefits of different natural phenomena to meet both their needs and preferences. There will be times when it is advisable to modify how devices are used (precautions) or times when it is not appropriate to use certain devices (contraindications). Read the following safety information for the device in its entirety prior to use.

## Important Safety Information

### General Device Use

This device is intended for use by people in good health. This device is contraindicated against and should not be used by or on anyone with a history of epilepsy, seizures or cardiopathy.

The device is not recommended for anyone with an electronic implanted device (such as a pacemaker), cardiac arrhythmia, tumors, or acute episodes of inflammatory diseases. The device is not recommended for those who have arteriosclerosis, thromboses, or implants in the body region being treated. The device should not be used if you have dark brown or black spots, such as large freckles, birthmarks, moles, or warts, on the area being treated. The device is not recommended if you have eczema, psoriasis, lesions, open wounds, or active infections other than mild to moderate acne, such as cold sores, in the area being treated. Wait for the infected area to heal before using the device. The device should not be used if you have abnormal skin conditions caused by diabetes or other systemic or metabolic diseases. If you have a history of herpes outbreaks in the area of treatment, use of the device is not recommended unless you have consulted with your physician and have received preventive treatment.

Please consult your physician prior to using the device if you are pregnant and/or nursing. **Immediately stop using the device at the first sign of discomfort.** If you have any medical considerations please consult your doctor before using the device.

## Safety, Precautions and Contraindications

These recommendations are derived from consultation with medical experts and published research regarding precautions and contraindications as of the printing date. For up-to-date information, please visit us online at <https://www.therabody.com/us/en-us/precautions-and-contraindications.html>.

## LED Light Therapy: Red, Red + Infrared, and Blue Light Therapy

### Precautions:

Due care is required in these circumstances and device use may need to be modified. Consult with a medical professional if you currently have or suspect you may have any of the following conditions or if you have any questions.

- Have face piercings/jewelry that cannot be removed
- Recent injury or surgery to the face or eyes
- Recent facial treatment, including but not limited to neurotoxin, dermal filler, microneedling, laser, and chemical peel until the skin has fully healed.
- Current Herpes Simplex Virus breakout
- Broken skin
- Retinol application before use of red LED light

**Contraindications:**

The following are circumstances where the potential risks may outweigh the benefits. Consult a medical professional before use.

- Eye-related disorders such as e.g. retinitis pigmentosa, ocular albinism, other congenital retinal disorders
- Skin rash, open wounds, blisters, local tissue inflammation, infection, bruises, or tumors
- Pregnancy/nursing
- Abnormal sensations (e.g., numbness)
- Cancer/tumors
- Epilepsy
- Cardiopathy (heart disease)
- Photo allergy or disorder (e.g., Lupus, porphyria)
- Medications that cause light sensitivity
- Medications for severe acne
- Extreme sensitivity to light
- Melasma or hyperpigmentation (especially if exacerbated by mild warmth)
- Suspicious lesions or skin cancer – please consult your physician
- If taking or using any retinol or other sun-sensitive medications, products, or benzoyl peroxide, do not use infrared light
- Allergy to the device material (Lycra fabric and medical grade transparent TPE and silicone)

**Vibration Therapy****Precautions:**

Due care is required in these circumstances and device use may need to be modified. Consult with a medical professional if you currently have or suspect you may have any of the following conditions or if you have any questions.

- Recent injury, surgery, or facial treatment, including neurotoxin, dermal filler, microneedling, laser, and chemical peel until the skin has fully healed.
- Current Herpes Simplex Virus breakout
- Broken skin
- Hypertension (controlled)
- Abnormal sensations (e.g., numbness)
- Sensitivity to pressure
- Medications that may alter sensations

**Contraindications:**

The following are circumstances where the potential risks may outweigh the benefits. Consult a medical professional before use.

- Skin rash, open wounds, blisters, local tissue inflammation, infection, bruises, or tumors
- Active acne breakout
- Bone fracture or myositis ossificans
- Hypertension (uncontrolled)
- Acute or severe cardiac, liver, or kidney disease
- Neurologic conditions resulting in loss or altered sensation
- Bleeding disorders
- Recent surgery or injury
- Connective tissue disorders
- Peripheral vascular insufficiency or disease
- Medications that thin the blood or alter sensations
- Direct placement over surgical site or hardware
- Extreme discomfort or pain
- Pacemaker, ICD, or history of embolism

## Limited Warranty

For full warranty information, please visit [www.therabody.com/warranty](http://www.therabody.com/warranty). Customers who are in need of product support should visit <https://www.therabody.com/us/en-us/support/support.html> for the available contact methods.

FDA-Cleared, Class 2 Medical Device, K230293  
Limited Warranty Only With Authorized Retailer Purchase

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Therabody UK Limited  
Portsoken House 155-157  
The Minorities, London,  
United Kingdom, EC3N1LJ

Device Battery Information - EU  
The weight: 23g  
The capacity: 1200 mAh  
The chemistry: Lithium polymer battery

## UNIT WARNINGS

**READ ALL INSTRUCTIONS AND CAUTIONARY MARKINGS IN THIS MANUAL, ON THE CHARGER, AND ON THE DEVICE BEFORE USING OR CHARGING THE DEVICE AND ITS ACCESSORIES.**

1. **USE ONLY AS INSTRUCTED.** Use only Therabody recommended accessories and replacement parts. This device is not intended to diagnose, mitigate, or treat diseases. The device is an advanced mechanical tool with electric components. If the device and its accessories are not used or maintained properly, there is a risk of fire, electric shock, or injury. Failure to use and maintain the device and corresponding attachments in accordance with the instructions outlined in this manual will void the warranty and may result in product damage or physical injury. The device is intended for commercial and home use.
2. **NOT FOR CHILDREN.** The device is not intended for use by those under 18 years of age or persons with reduced physical, sensory, or reasoning capabilities or lack of experience and knowledge. The device is not a toy. Do not play with, bend, or pull the electrical components.
3. **CHARGING.** If your device doesn't turn on or the battery indicator displays a low battery level, please charge before first use. Charge the battery using the USB-C cable (included). When you use the charging cable (included), make sure its USB-C connector is fully inserted into a compatible power adapter before you plug the adapter into a power outlet. You can also charge the battery with third party cables that are compliant with USB-C and with applicable country regulations and international and regional safety standards. Other adapters may not meet applicable safety standards, and charging with such adapters could pose a risk of death or injury. Do not force the cable into place. Fully charge the device at least once every six months to prevent device and battery damage. Unplug the power adapter and charging cable when not in use.
4. **DO NOT OVERCHARGE.** Do not leave the device connected to the power adapter for more than one hour after the battery has been fully charged. The battery includes a protection system to avoid the risk of overcharging. However, overcharging may reduce its life over time.

5. **CHARGING LOCATIONS.** Ensure that the battery status LED is OFF before charging. Insert the USB-C cable into the port (behind the power button) to charge the device. Do not use the device while charging. Avoid skin contact when the USB-C is plugged into a power source as it may cause discomfort or injury. Do not sleep or sit on the USB-C connector. The device should be charged indoors in a well-ventilated, dry location. Do not charge the device outdoors, in a bathroom, or within 10 feet (3.1 meters) of a bathtub or pool. Do not use the device or charger on wet surfaces, and do not expose the charger to moisture, rain, or snow. Do not use the device or its compatible charger in the presence of explosive atmospheres (gaseous fumes, dust, grain, metal powders, or flammable materials). Sparks may be generated, possibly causing a fire.
6. **UNPLUGGING THE CHARGER.** Pull the plug, not the cord, to reduce the risk of damage to the electrical plug and cord. Never carry the charger by its cord. Keep the cord away from heat, oil, and sharp edges. Do not stretch the charger cord or place the cord under strain. Do not handle the charger, terminals, or the device with wet hands. Always unplug this appliance from the electrical outlet immediately after using and before cleaning. Store cable to ensure it is not stepped on, tripped over, or otherwise subjected to damage or stress. Do not use a power adapter or charging cable that has received a sharp blow, been dropped, run over, or damaged in any way. For long-term storage, store with a fully charged battery.
7. **USAGE AND SKIN SENSITIVITIES.** Adjust the device to fit comfortably on your face. Always adjust the device while the device is OFF. Press and hold the Power Button to turn off the device. Make sure the Battery status LED is OFF. Discontinue the use of the device if you feel any discomfort. Some people may experience reactions to certain materials used in wearable items that are in prolonged contact with their skin. This can be due to allergies, environmental factors, extended exposure to irritants like sweat or other causes. You may be more likely to experience irritation from any wearable device if you have allergies or other sensitivities. If you have known sensitivities, take special care when using the device and accessories. If you experience redness, swelling, itchiness, or any other irritation or discomfort on your skin around, or beneath, your device, remove the device and consult your physician before resuming use. Continued use, even after symptoms subside, may result in renewed or increased irritation.
8. **DO NOT OPERATE UNDER BLANKET AND PILLOW.** Excessive heating can occur and cause fire, electric shock, or injury.
9. **DEVICE CARE AND SERVICE.** Handle the device with care. The device contains electronic components that can be damaged if dropped, burned, punctured, or crushed. Do not disassemble the device or attempt to repair the device yourself. Disassembling the device may damage it, result in loss of water resistance, and may cause injury. If the device is damaged or if malfunctions occur, contact Therabody Customer service. The warranty will be void if the device, batteries, or charger are disassembled or if any parts have been removed. Do not use if damaged as these may cause injury. Avoid heavy exposure to dust or sand. Do not puncture or damage the device. Puncturing the device can lead to incorrect operation.
10. **STORING THE DEVICE AND ACCESSORIES.** Store in a cool, dry place. Only charge the device when the ambient temperature is between 35°C/95°F and 0°C/32°F. Do not store the device or charging cable where temperatures may exceed 35°C/95°F, such as in direct sunlight, in a vehicle, or in a metal building during the summer.
11. **DEVICE DISPOSAL.** This device contains a lithium-ion battery, and care must be taken upon disposal of the device. Before disposal of this device, please review your local laws and requirements surrounding Lithium-Ion Battery disposal. The preferred method of disposal is recycling the whole device.

Label	Description	Location of Label
IP 22	Degree of protection against ingress of water	On rating label
	Read instructions before use	On rating label
	Level of protection type BF applied part	On rating label
	In accordance with Direction 2014/30/EU Electromagnetic Compatibility	On rating label
	UKCA Mark for UK	On rating label (Only in the EU)
	Therabody, Inc. 1640 S. Sepulveda Blvd. Suite 300 Los Angeles, CA 90025	On rating label

## Reporting adverse events to FDA

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help the FDA evaluate your report. However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

## Submitting adverse event reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1. Report Online at: [www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home](http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)
2. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at: [www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf](http://www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf)
3. Call FDA at 1-800-FDA-1088 to report by telephone.
4. Reporting Form FDA 3500 commonly used by health professionals. The form

is available at: [www.fda.gov/ downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf](http://www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf)

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.

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.

#### Medical EMC + Safety

IEC 60601-1 and IEC60601-11 Requirement ( Warning )---For Medical device apply for US, CA.

This device is Class III equipment with type BF applied. It complies with Medical Electrical Safety Standards (IEC 60601-1).

This device also complies with Medical EMC Standard (IEC 60601-1-2).

The has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

**1\* WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

**2\* WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**3\* WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME EQUIPMENT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

### GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION

The <b>TheraFace Mask Glo</b> is intended for use in the electromagnetic environment specified below. The customer or the user of <b>TheraFace Mask Glo</b> should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The <b>TheraFace Mask Glo</b> uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <b>TheraFace Mask Glo</b> suitable for use in all establishments, including domestic establishments 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 function / flicker emissions IEC 61000-3-3	Complies	

## Guidance and manufacturer's declaration – electromagnetic immunity

The <b>TheraFace Mask Glo</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>TheraFace Mask Glo</b> 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or home environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode	Mains power quality should be that of a typical commercial or home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°  0 % UT; 250/300 cycle	45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°  0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or home environment. If the user of the <b>TheraFace Mask Glo</b> requires continued operation during power mains interruptions, it is recommended that the <b>TheraFace Mask Glo</b> be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz magnetic field) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or home environment.
NOTE $U_i$ is the a.c. mains voltage prior to application of the test level.			

The TheraFace Mask Glo is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraFace Mask Glo 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 150kHz to 80MHz  6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 150kHz to 80MHz  6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the TheraFace Mask Glo, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance: $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$ $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz    800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.5GHz  385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80MHz to 2.5GHz  385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	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). <sup>a</sup>  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>a</sup>  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 is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b 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 TheraFace Mask Glo is used exceeds the applicable RF compliance level above, the TheraFace Mask Glo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TheraFace Mask Glo.

c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

#### Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the TheraFace Mask Glo

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.

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

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[ \frac{12}{V_2} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70



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