



Therabody

TheraFace Depuffing Wand

User Manual

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1. Product Overview

TheraFace Depuffing Wand

Ultra-portable skincare device with science-backed cold and heat treatments to depuff and glow anytime, anywhere.

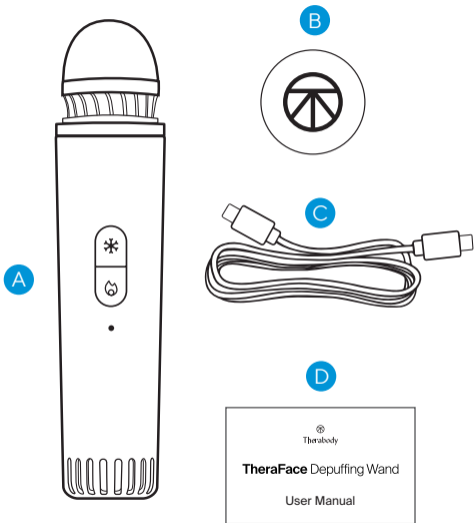
The TheraFace Depuffing Wand delivers science-backed cold and heat facial treatments in one portable device. Powered by our proprietary Cryothermal Technology, the Depuffing Wand delivers a refreshing cold treatment to help decrease puffiness, revitalize tired-looking eyes and reduce the appearance of pores. The rejuvenating heat treatment helps encourage lymphatic drainage, improves product absorption and enhances radiance. And, when combined, heat and cold treatments are clinically proven to enhance radiance, improve elasticity and increase firmness after just one treatment. The TheraFace Depuffing Wand goes where ice rollers can't – the contoured, easy-glide applicator tip is designed to reach every inch of your face, even the curves and corners around the eyes and nose. Unlike ice, which can be too cold and can damage the delicate skin on your face, the wand uses safe, science-backed temperatures - no freezer required.

Intended Use

The TheraFace Depuffing Wand is intended to decrease puffiness, enhance radiance, and reduce dark circles.

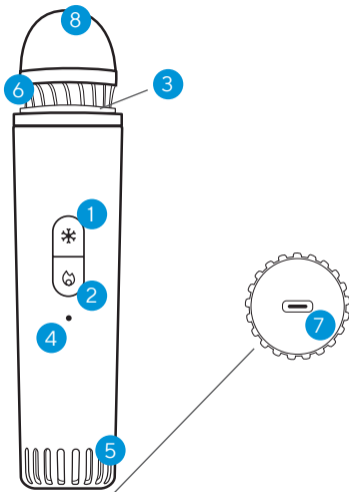
2. What's In the Box

- A. TheraFace Depuffing Wand
- B. Device cap
- C. USB-C to USB-C cable
- D. Instruction manual



3. Getting to Know the Device

1. Cold button
2. Heat button
3. Treatment intensity LED indicator
4. LED battery status indicator
5. Air vent
6. Air intake
7. USB-C charging port
8. Applicator tip



4. Use the TheraFace Depuffing Wand

1. **Charge the device.** Charge the device before use.
2. **Prepare for treatment.** Cleanse and completely dry your face before using the TheraFace Depuffing Wand.
***Avoid using the device over open, broken, or acne covered skin.*
3. **Remove the device cap.** Gently pull off the device cap to remove it from the device. Do not use the device while the cap is attached to either end.
4. **Turn on the device.** Press and hold either the cold or heat button to turn on the device and begin the cold or heat treatment. The blue LED light will turn on during the cold treatment, and the orange LED light will turn on during the heat treatment.
5. **Select your desired temperature setting.** Press the cold or heat button (depending on your selected treatment) to toggle through the three temperature options: cold, colder, and coldest; warm, warmer, and warmest. The LED light will get brighter as the temperature intensity increases. The device will flash once at the lowest intensity, twice at the second intensity, and three times at the third intensity setting. The total treatment time is six minutes. The six-minute timer will reset if you change from cold to hot or hot to cold during treatment. The timer will not reset when the temperature intensity is changed within a treatment.
 - a. **Cold settings:** There are three cold temperature options: 14 °C (57 °F) (default), 12 °C (54 °F), 10 °C (50 °F).
 - b. **Heat settings:** There are three heat temperature options: 35 °C (95 °F) (default), 38 °C (100 °F), 42 °C (108 °F).

6. **Use the TheraFace Depuffing Wand on one side of your face.** Avoid covering the air vents of the device throughout your treatment to achieve target temperatures. Place the device on one side of your face, gently moving underneath your eyes and throughout your face in an upward and outward motion.
7. **Use the TheraFace Depuffing Wand on the other side of your face.** After three minutes, the device's light will flash to signal you to switch to treating the other side of your face.
8. **Continue to use the device (if desired).** The TheraFace Depuffing Wand will automatically shut off after completing the treatment (6 minutes total). If desired, you can use the device for a second treatment cycle (another 6 minutes). Wait 2-3 minutes before turning the device back on and using it on each side of your face.
9. **Turn off the device.** Press and hold the cold or heat button at any point during the treatment to turn off the device. The LED light will turn off when the device is off.
10. **Lock the device.** When not in use or during transport, lock the device to prevent it from turning on accidentally. Quickly press either the cold or heat button three times to initiate the lock function. The LED light will turn purple when successfully locked. Quickly press three times again to unlock. The LED light will turn green when successfully unlocked. If you try to turn the device on while locked, the LED light will turn purple.

5. TheraFace Depuffing Wand Modes Overview

| Treatment mode | Treatment temperatures | Intended treatment benefit | Tips for Use |
|----------------|--|--|--|
| Heat Mode | Low: 35 °C (95 °F) (default) Medium: 38 °C (100 °F) High: 42 °C (108 °F) | Increases circulation and reduces pain and tension | <p>During heat treatment, gently glide the device over your face using massage-like movements to increase circulation.</p> <p>Use the heat treatment prior to or when applying serums and moisturizers to increase product absorption.</p> |
| Cold Mode | Low: 14 °C (57 °F) (default) Medium: 12 °C (54 °F) High: 10 °C (50 °F) | Decrease puffiness and inflammation | <p>During the cold treatment, use the device as you would a cold compress. Gently glide the device in circular motions, moving upward and outward to decrease puffiness.</p> <p>Use the cold treatment in the morning to instantly refresh and revitalize eyes for an awakened look.</p> |

6. TheraFace Depuffing Wand Care & 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 TheraFace Depuffing Wand

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

1. Visually inspect the TheraFace Depuffing Wand for any obvious signs of debris build-up.
2. For everyday use, wipe the base of the device with a damp cloth or alcohol-free cleansing wipe.
3. To thoroughly clean the metal applicator tip, use a <70% alcohol solution or an antibacterial wipe (e.g., Lysol or Clorox) between use and/or users. Do not use an alcohol solution or an antibacterial wipe anywhere else on the device.
4. After cleaning, allow the device to dry thoroughly before storing or beginning another treatment.
5. A properly cleaned device should have no visible signs of debris or moisture.
6. If debris, gel, or lotion gets into the air intake, use a dry cotton swab to gently remove.

Note: This product is not waterproof. Only clean the device with a damp cloth or antibacterial cleansing wipe by wiping it. 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 TheraFace Depuffing Wand

1. The TheraFace Depuffing Wand is USB-C enabled and comes with a charging cable. Before charging the TheraFace Depuffing Wand, ensure that the device is powered off and laying on its side.
2. Connect one end of the charging cable to the USB-C charging port on the device. It is located on the bottom 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: Low battery
 - Flashing Blue: Half battery
 - Flashing Green: High battery
 - Solid Green: Full battery

**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 TheraFace Depuffing Wand

To store and transport the TheraFace Depuffing Wand, keep the cap on the device, keep it on its side, and handle it gently. Store the device in a cool and dry place (Temperature: 0°C/32°F - 35°C/95°F Relative humidity: 10~95% 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 battery won't charge | The battery status LED flashes purple for 10 seconds | The ambient environment temperature is too high or too low. | If the device is in an environment within 5°C/41°F and 35°C/95°F, stop using the device or stop charging it and contact Therabody. |
| Housing feels too hot | The battery status LED flashes purple for 10 seconds | Battery temperature sensor detects overheating | If the device is in an environment colder than 5°C/41°F and warmer than 35°C/95°F, please try again in an environment within 5°C/41°F and 35°C/95°F after the product is off for 60 minutes in that environment. |
| Device powers off during use | The button's LED flashes White for 10 seconds | Temperature sensor detects overheating or the temperature sensor is open or short. | Contact Therabody Visit https://www.therabody.com/us/en-us/support/support.html for the available contact methods. |
| Device won't turn on | The battery status LED flashes White for 10 seconds | Battery temperature sensor is open or short | Contact Therabody Visit https://www.therabody.com/us/en-us/support/support.html for the available contact methods. |

TheraFace Depuffing Wand 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 TheraFace Depuffing Wand in its entirety prior to use.

Important Safety Information

General TheraFace Depuffing Wand Use

Read the full Warnings and Guidance prior to using TheraFace Depuffing Wand Device.

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 TheraFace Depuffing Wand 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.

TheraFace Depuffing Wand 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>.

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 or surgery
- Recent facial treatment, including neurotoxin, dermal filler, microneedling, laser, and chemical

- peel until the skin has fully healed
- Hypertension (controlled)
- Abnormal sensations (e.g., numbness)
- Sensitivity to cold or heat
- Mild peripheral neuropathy
- This device should NOT restrict circulation in any way

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, infections, bruises, or tumors
- Hypertension (uncontrolled)
- Vascular/arterial and circulation diseases, including blood clots, phlebitis, thromboses, and varicose veins
- Acute or severe cardiac, liver, or kidney disease
- Severe peripheral neuropathy or other causes of sensory impairment

- Melasma or hyperpigmentation (especially if exacerbated by mild warmth)
- Direct pressure over recent or healing surgical site or hardware
- Bleeding disorders
- Connective tissue disorders
- Medications that may alter or thin the blood or alter sensations
- Pacemaker or ICD
- History of embolism
- Allergy to device material (Metal, Rubber, Plastic, Silicone)
- Do not use in the presence of unexplained pain

Limited Warranty

For full warranty information, please visit 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-Registered
Limited Warranty Only With Authorized Retailer
Purchase

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Patents at www.therabody.com/patents

Manufactured and Distributed by:
Therabody, Inc.
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Suite 300
Los Angeles, CA 90025
USA

In the Australian market, the TheraFace Depuffing
Wand warranty is 1 year.

For Australian Market Only: The purchase of this
device is accompanied by a limited warranty. For
complete details about the rights afforded to you
under this warranty, visit [https://therabody.com/anz/
en-au/warranty-support/](https://therabody.com/anz/en-au/warranty-support/).

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United Kingdom, EC3N1LJ

UNIT WARNINGS

BEFORE USING OR CHARGING TheraFace Depuffing Wand, READ ALL INSTRUCTIONS AND CAUTIONARY MARKINGS IN THIS MANUAL, ON THE CHARGER, AND ON THE DEVICE.

If your device doesn't turn on or the battery indicator displays a low battery level, please charge before first use. TheraFace Depuffing Wand is intended for commercial or home use.

TheraFace Depuffing Wand are not intended to diagnose, mitigate, or treat diseases. Therabody strives to make TheraFace Depuffing Wand as safe for intended use as possible. TheraFace Depuffing Wand is an advanced mechanical tool with electric components. If TheraFace Depuffing Wand and its accessories are not used or maintained properly, there is a risk of fire, electric shock, or injury. When using TheraFace Depuffing Wand, the following basic precautions should always be adhered to:

1. **USE ONLY AS INSTRUCTED.** Use TheraFace Depuffing Wand as described in the TheraFace Depuffing Wand Instruction Manual only. Use only Therabody recommended accessories and replacement parts. Do not carry out any maintenance other than as advised by Therabody.
2. **NOT FOR CHILDREN.** TheraFace Depuffing Wand and charger are not intended for use by young children or persons with reduced physical, sensory, or reasoning capabilities or lack of experience and knowledge unless a responsible

adult has given them supervision or instruction. TheraFace Depuffing Wand are not to be used as a toy. Advise children not to play with TheraFace Depuffing Wand or charger. Adult supervision should be provided for those under 18 while using this device.

3. **CHARGING.** There is only one correct way to insert the charging cable into the device. Do not force the cable into place. Fully charge the device at least once every six months to prevent device and battery damage.

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 (on the bottom of the device) to charge TheraFace Depuffing Wand. Do not use TheraFace Depuffing Wand 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. Charge TheraFace Depuffing Wand with a USB-C charger. TheraFace Depuffing Wand should be charged indoors in a well-ventilated, dry location. Do not charge TheraFace Depuffing Wand outdoors, in a bathroom, or within 10 feet (3.1 meters) of a bathtub or pool. Do not use TheraFace Depuffing Wand or charger on wet surfaces, and

do not expose the charger to moisture, rain, or snow. Do not use TheraFace Depuffing Wand 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. Obey all signs and instructions.

6. UNPLUGGING THE CHARGER. Do not overcharge TheraFace Depuffing Wand device. 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 use or charge with a damaged cord. Do not stretch the charger cord or place the cord under strain. Keep the cord away from heated surfaces. Do not handle the charger, terminals, or TheraFace Depuffing Wand with wet hands. Always unplug this appliance from the electrical outlet immediately after using and before cleaning.

7. DO NOT CRUSH, DROP, OR DAMAGE THE DEVICE OR CHARGER. Do not use a power adapter or charging cable that has received a sharp blow, been dropped, run over, or damaged in any way. Do not puncture or damage the TheraFace Depuffing Wand. Puncturing the device can lead to incorrect operation.

8. POWER ADAPTER AND CHARGING CABLE CARE. Unplug the power adapter and charging cable when not in use. Pull the plug, not the cable, to reduce the risk of damage to the electrical plug and cable. Store cable to ensure it is not

stepped on, tripped over, or otherwise subjected to damage or stress. Keep the cable away from heated surfaces, oil, and sharp edges. Never operate this device if it has a damaged cable or plug if it is not working properly, if it has been dropped or damaged, or dropped into water. Do not stretch the charger cable or place the cable under strain. Do not handle the cable with wet hands. For long-term storage, store with a fully charged battery. Therabody is not responsible for damages that may occur due to the use of third-party chargers.

9. USAGE. Discontinue the use of TheraFace Depuffing Wand if you are feeling severe pain. Make sure the Battery status LED is OFF when the device is not in use. Use TheraFace Depuffing Wand on make-up free skin. Use the device in a cool, dry environment.

10. DO NOT OPERATE UNDER BLANKET AND PILLOW. Excessive heating can occur and cause fire, electric shock, or injury.

11. SERVICE. If the device is not working properly, has received a sharp blow, or has been dropped, damaged, left outdoors, or dropped into water, then do not use it. Do not attempt to repair or disassemble the device which may result in an electric shock or fire.

12. DEVICE CARE. Handle TheraFace Depuffing Wand with care. TheraFace Depuffing Wand contain electronic components that can be damaged if dropped, burned, punctured, or crushed. Do not disassemble the TheraFace

Depuffing Wand or attempt to repair TheraFace Depuffing Wand yourself. Disassembling TheraFace Depuffing Wand may damage it, result in loss of water resistance, and may cause injury. If TheraFace Depuffing Wand is damaged or if malfunctions occur, contact Therabody Customer service. Do not use damaged TheraFace Depuffing Wand, for example, visible water intrusion, as these may cause injury. Avoid heavy exposure to dust or sand.

13. **CLEANING INSTRUCTIONS.** Visually inspect the TheraFace Depuffing Wand for any obvious signs of debris build-up. Wipe your device with a damp cloth or alcohol-free cleansing wipe. 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. Note: This product is not waterproof. Only clean with a damp cloth or antibacterial wipe by wiping the device. 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.

14. **DO NOT DISASSEMBLE.** Disassembly or incorrect reassembly may result in the risk of electric shock, fire, or exposure to battery chemicals. The warranty will be void if the device, batteries, or charger are disassembled or if any parts have been removed.

15. **STORING THE TheraFace Depuffing Wand AND**

CHARGING CABLE. 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.

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 IEC60601-1-11 requirement(Warning)---For Medical device apply for US , CA

This device is type BF applied equipment . It complies with Medical Electrical Safety Standards (IE(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 atypical 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 this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in proper operation.

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables) 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 TheraFace Depuffing Wand is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraFace Depuffing Wand should assure that it is used in such an environment.

| EMISSIONS TEST | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
|--|----------------|---|
| RF emissions CISPR 11 | Group 1 | The TheraFace Depuffing Wand 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. The TheraFace Depuffing Wand 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. |
| RF emissions CISPR 11 | Class B | |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations flicker emissions IEC 61000-3-3 | Not applicable | |

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS


Guidance and manufacturer's declaration – electromagnetic immunity

| The TheraFace Depuffing Wand is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraFace Depuffing Wand 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 | ± 2 kV for power supply lines ± 1 kV for input/output lines | N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | N/A | Mains 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 | 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 | N/A | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device name requires continued operation during power mains interruptions, it is recommended that the device name 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 hospital environment. |
| NOTE U_T is the a. c. mains voltage prior to application of the test level. | | | |

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

The TheraFace Depuffing Wand is intended for use in the electromagnetic environment specified below. The customer or the user of the TheraFace Depuffing Wand should assure that it is used in such an environment.

| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
|--|--|--|--|
| <p>Conducted RF</p> <p>IEC 61000-4-6</p> | <p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz</p> | <p>N/A</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the device name, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P} \quad d = \left[\frac{12}{V_2} \right] \sqrt{P}$ <p style="text-align: right;"><small>$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.7 GHz</small></p> <p>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).b</p> |
| <p>Radiated RF</p> <p>IEC 61000-4-3</p> | <p>10 V/m</p> <p>80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p> | <p>10 V/m</p> <p>80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p> | <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| NOTE | U _T is the a. c. mains voltage prior to application of the test level. | | |

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 Depuffing Wand is used exceeds the applicable RF compliance level above, the TheraFace Depuffing Wand should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TheraFace Depuffing Wand.

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 Depuffing Wand

The TheraFace Depuffing Wand is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TheraFace Depuffing Wand can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TheraFace Depuffing Wand 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 | 150 KHz to 80 mhz In ism and amateur radio bands | 80 Mhz to 800 mhz | 800 Mhz to 2.7 Ghz |
| | $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ | $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ | $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ | $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ |
| 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 |

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.

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
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
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



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Designed for everybody.



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