User's Guide

TIVIC


RISK FREE
60
DAY
TRIAL
ClearUP®
Triple action drug-free relief from
allergy sinus pain, sinus headaches, and congestion.
Questions?
tivichealth.com
1-888-276-6888
customerservice@tivichealth.com
1 year warranty

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Introduction

Sinus pain and congestion can make you miserable. Traditional medication, sprays, and flushes may have side effects and may not provide effective sinus pain and congestion relief.

ClearUP® is different. It's at the forefront of technology and works even when nothing else does. ClearUP applies gentle pulses to reduce symptoms of inflammation such as sinus pain and congestion. Safe and subtle microcurrents are emitted from the tip of the unit to the sinus nerve fibers below the skin. ClearUP works with your body's natural electricity to directly target pain at the source without drugs or chemical side effects.

ClearUP is:

- ✓ FDA approved
- ✓ Clinically safe and effective as demonstrated through clinical trials
- ✓ 100% drug-free
- ✓ Compact, convenient, and perfect for on-the-go treatments

Intended Use

ClearUP Sinus Pain Relief is to be used for the temporary relief of sinus pain associated with allergic rhinitis and moderate to severe congestion. ClearUP is for adults 18+ years old only.

What causes sinus pain conditions?

Sinus pain can be caused by allergic rhinitis. Sinus pain is also associated with migraines, dental infections or muscle tension, which may require medical attention.

What is allergic rhinitis?

Allergic rhinitis is caused by exposure to airborne allergens. It is often called hay-fever. There are two types of allergic rhinitis, seasonal and year-round. Seasonal allergic rhinitis can be triggered by various pollens and mold while year-round allergies can be triggered by pet dander, mold, dust, cleaning products, and perfumes.

Symptoms include sneezing, congestion, runny nose, watery eyes, itching of the nose or roof of the mouth, coughing, and sinus pain.

What causes congestion?

Congestion can be caused by anything that irritates or inflames the nasal tissues which could be caused by the common cold, the flu, sinusitis, and respiratory allergies.

How bad is your congestion?

Before first use, make a note of your congestion symptoms severity using the scale below. If you are at levels 3, 4, or 5 (moderate to severe), ClearUP can help. After two weeks, evaluate your level of congestion relief. If you have not experienced at least 1 point of reduction in congestion, this device may not be effective for your congestion symptoms. This device is not effective for 100% of users.

How much of a problem are the following conditions for you?

Congestion and stuffiness

Device Description

ClearUP Sinus Pain Relief (ClearUP) is a handheld microcurrent stimulation reusable device intended to be used at home for the temporary relief of sinus pain and moderate to severe congestion. The unit applies very low levels of microcurrent to the skin overlying the paranasal sinuses, and continuously measures skin impedance as the user glides the electrode along the skin. When the skin impedance measurement drops below a threshold, ClearUP identifies this as a treatment point in the facial skin which allows current to pass most easily across the skin. The device emits a brief haptic feedback through vibration (haptic vibration) at each treatment point. These low-impedance points correlate with subcutaneous nerve fibers and foramina (holes) through which major nerve fibers pass from the sinus passages, through the skull, to areas near the skin.

The device is held in the hand, with the rounded tip of the device applied to the facial skin in the region of the sinus passages.

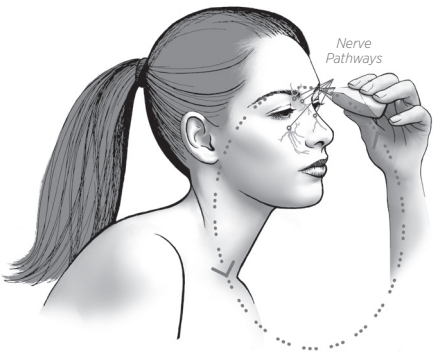
Once the haptic vibration ends at a treatment point, the user is instructed to glide the device along the visually indicated path until reaching the next treatment point at which the haptic vibration will commence again.

How It Works

ClearUP works in several ways

- Safe microcurrent is emitted from the tip of the unit to sinus nerve fibers under the skin.
- Electrical stimulation of nerves reduces feelings of sinus pain for up to 6 hours according to our clinical study.
- Published research has shown that electrical stimulation can also shrink swollen tissue; swelling is often a key cause of nasal and sinus symptoms.[1-4]

Note: *ClearUP must be self-administered and cannot be applied to another person. This is due to the electrical circuit design. The hand holding the device completes the electrical path*



1. Goldsobel, Alan B., Niveditha Prabhakar, and Blake T. Gurfein. "Prospective trial examining safety and efficacy of microcurrent stimulation for the treatment of sinus pain and congestion." Bioelectronic Medicine 5.1 (2019): 1-9.
2. Mandel, Yossi, et al. "Vasoconstriction by electrical stimulation: new approach to control of non-compressible hemorrhage." Scientific reports 3 (2013).
3. Franco, O. S., et al. "Effects of different frequencies of transcutaneous electrical nerve stimulation on venous vascular reactivity." Brazilian Journal of Medical and Biological Research 47.5 (2014): 411-418.
4. Malm, L. "Stimulation of sympathetic nerve fibres to the nose in cats." Acta oto-laryngologica 75.2-6 (1973): 519-526.

Clinical Study Results

Study 1

The Sinus Center at Stanford University conducted a double-blind, randomized controlled clinical study using the ClearUP Sinus Pain Relief device. A total of 71 subjects suffering from sinus pain (27 subjects with chronic rhinosinusitis, 49 subjects suffering from allergic rhinitis, and 5 subjects with other sinus conditions) enrolled in the study. 38 subjects were randomly selected to use the ClearUP Sinus Pain Relief "active" device and 33 subjects were randomly selected to use the "sham" device (a device with haptic vibration but no microcurrent stimulation). Each subject used the active or sham device on the outside of their sinus passages without any assistance for a single five-minute treatment. Each subject rated their level of pain before and ten minutes after treatment.

3 out of 4 felt relief

preferred ClearUP

Note: *24% who used the microcurrent device experienced sinus pain reduction of 3 points or more on the visual analog pain scale (0 no pain to 10 severe pain). Only one subject experienced minor reddening of the skin which disappeared within minutes.*

At the end of the study, subjects were asked to compare their level of congestion before treatment and ten minutes after treatment by completing the modified nasal obstruction symptom evaluation (NOSE) questionnaire. 59 study subjects reported moderate to severe

levels of congestion before treatment. For these subjects, post hoc analysis results were:

- 70% of users (21 subjects out of 30 subjects treated with the active device) experienced a clinically important reduction in congestion symptoms within 10 minutes of treatment.
- The average magnitude of congestion symptom reduction was 35%. For example, subjects were better able to breathe through their noses and reported less nasal stuffiness and blockage.
- 82% (31 subjects out of 38 subjects treated with the active device) preferred ClearUP Sinus Pain Relief device to their current sinus pain treatment method(s). 91% (29 subjects out of 32 subjects treated with the sham device) preferred the sham device to their current sinus pain treatment method(s), which may be attributable to the therapeutic effect of the haptic feedback emitted by the sham device, preference for non-drug treatment options, or placebo response.

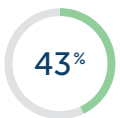
Although other published studies have concluded that subjects can accurately recall symptom severity from previous days, the above Clinical trial involved collecting data on symptom severity from 10 minutes prior. In conclusion, the subgroup of ClearUP-treated subjects with moderate to severe congestion reported significantly greater congestion symptom relief and effectiveness can be noticed within 10 minutes of treatment cycle.

Study 2 (Post-Market Clinical Study)

A single arm (N=30) open-label clinical study using the ClearUP Sinus Pain Relief device was conducted at the Allergy and Asthma Associates of Santa Clara Valley Research Center. Included were 11 subjects with allergic rhinitis, 1 subject with a nasal cyst, 1 subject with nasal polyps, and 17 subjects with undiagnosed causes of sinus symptoms. Subjects used the ClearUP device for five minutes during the study visit and then took the device home with them with instructions to use the device once daily and up to four times daily as needed for 4 weeks, with each treatment lasting five minutes. Subjects rated their level of congestion before treatment and weekly for four weeks during treatment using the congestion quantifier seven (CQ7) instrument. 24 subjects enrolled with moderate to severe levels of congestion. For these patients, the results of the clinical trial were as follows:

of subjects felt congestion relief

reduction in congestion after 4 weeks



reduction in sinus pain after 4 weeks

Up to 6 hours of pain relief

- The average magnitude of congestion symptom reduction was 44% after four weeks

of use. For example, subjects experienced nasal stuffiness, blockage, and congestion less frequently and were better able to breathe through their noses.

- 73% preferred ClearUP Sinus Pain Relief device to their current sinus pain treatment(s).

Note: *Only two subjects experienced minor reddening of the skin and one subject experienced an eyelid muscle twitch, both of which resolved without treatment.*

Study 2 was an open-label 4-week study and did not have a control group or a placebo. To address the uncertainty created by this design, we conducted a literature review to identify the magnitude of the placebo effect in subjects with congestion that completed the Congestion Quantifier 7 (CQ7) questionnaires. The literature search identified two peer-reviewed papers.[1,2] Placebo-treated subjects reported an average reduction in CQ7 score of -27% and -20% in the two studies. This range of CQ7 score reductions was smaller than the average CQ7 score reduction reported in Study 2 (-44%), indicating that ClearUP effectiveness is above and beyond a placebo effect.

Two key clinical studies and FDA approval demonstrated that ClearUP is a safe and effective treatment for sinus pain associated with allergic rhinitis and moderate to severe congestion.

1. Schenkel, E. J., Ciesla, R., & Shanga, G. M. (2018). Effects of nasal dilator strips on subjective measures of sleep in subjects with chronic nocturnal nasal congestion: a randomized, placebo-controlled trial. Allergy, Asthma & Clinical Immunology, 14(1), 34
2. Katotomichelakis, M., Van Crombruggen, K., Holtappels, G., Kuhn, F. A., Fichandler, C. E., Kuhn-Glendye, C. A., ... & Kastanioudakis, I. (2017). A herbal composition of Scutellaria baicalensis and Eleutherococcus senticosus shows vasocontrictive effects in an ex-vivo mucosal tissue model and in allergic rhinitis patients. Clinical Phytoscience, 3(1), 21.

Safety Information

The ClearUP Sinus Pain Relief unit is a rechargeable, battery-operated device for adults 18 years of age and older. Please read the warnings and cautions before use as they are intended to keep you safe, free of injury, and avoid a situation where the device would be damaged.

ClearUP Sinus Pain Relief is an over-the-counter treatment to be used at home by adults suffering from pain as a result of allergic rhinitis or with moderate to severe congestion.

⚠ Warnings

Consult your physician for safety of use if you have implanted electrostimulation devices including a pacemaker, a DBS (Deep Brain Stimulation) device, hearing or visual implant devices (e.g., cochlear implant, auditory brainstem implant, retinal prostheses).

Consult your physician if you have active (powered) implanted metallic devices in the treatment path (i.e. cheek, nose, and brow bone).

Do not use if you currently have abnormal cranial nerve or other neurological findings or symptoms that would require prompt medical attention.

Do not use if the device enclosure or tip is damaged.

Do not use if metal components are hot to the touch.

Do not alter the device.

Stop device use and consult your physician if you experience any discomfort, increased pain, or any adverse reaction.

If you have had medical or physical treatment for your pain, consult with your physician before using this device.

If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.

Care should be taken to apply simulation in the presence of electronic monitoring equipment including cardiac monitors and ECG alarms due to potential

electromagnetic interference.

Actively monitor your treatment and remove probe tip from the treatment location if there is discomfort or muscle twitching of the eye.

Do not use device if the Comfort Level Lights continually flash. This indicates a fault in the device. Contact us at customerservice@tivichealth.com or call 1-888-276-6888.

⚠ Cautions

Use as Directed.

Do not use if the skin is broken or on a wound of any kind.

As appropriate, wipe off the tip of device with wet wipes before each use. Do not immerse in any fluid.

Avoid contact with facial piercings or metal jewelry.

Do not use in a bathtub, shower or steam room.

Do not use the device while charging.

Do not use if you experience any unusual skin sensitivity.

Keep out of reach of children.

Follow manufacturers' recommendations for using portable RF communications equipment (including peripherals such as antenna cables and external antennas) for any limitations of use due to potential degraded equipment performance.

Do not use device near active high frequency (HF) surgical equipment or in the radio frequency (RF) shielded room of a Magnetic Resonance Imaging (MRI) scanner or near RF emitting equipment.

Use of cables other than those specified or provided by the manufacturer of the device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.

Only use the manufacturer charger provided to avoid damage to the unit.

The safety of electrical nerve stimulation during pregnancy or delivery has not been established.

The unit contains a Lithium-ion battery. Dispose of the unit according to local regulations for products containing Lithium-ion batteries. Do not incinerate.

Symbols and Definitions

A type BF applied part complying with IEC 60601-1

Consult instructions for use

Product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005

The electronic device is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission.

IP22

Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical

Medical Device.

Product complies with applicable European Union regulations.

The temperature limits to which the medical device can be safely exposed.

Recyclable

Getting Started

Unpacking Instructions

Remove the ClearUP® Sinus Pain Relief unit from its packaging and inspect for damage. The package should include the following:

- ClearUP Sinus Pain Relief unit
- Charger
- User Guide
- Quick Start Guide

Charging Instructions

Don't forget to charge unit before first time use.

Place the connector from the charger into the charging port at the bottom of the unit. Insert the wall charger plug into a power outlet. The unit is disabled for safety while charging. The unit is fully charged when the battery light turns solid green.

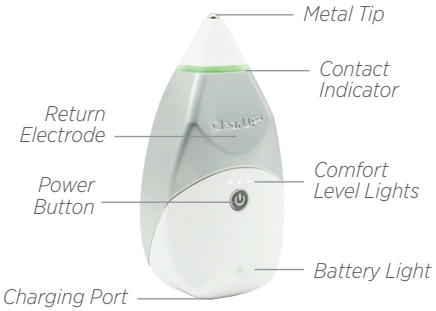
User Controls and Indicators

Power Button

Press to turn ON. Press and hold to turn OFF. Press briefly to change Comfort Level.

Contact Indicator

When the unit is on and the contact pressure is sufficient the contact indicator light will turn green.



Comfort Levels

Press power button briefly to change levels.

Vibration Action of the Unit

The unit guides you to your unique facial treatment points. The unit starts to vibrate when it has detected a treatment point. When it stops vibrating, continue to glide until the unit detects the next treatment point.

Battery Light

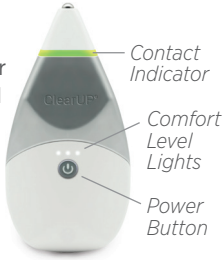
When the battery level is low and needs charging, the Battery Light turns on and will blink orange. While charging, Battery Light turns green and will pulse slowly, and the unit will be disabled. When fully charged, Battery Light will stay solid green until the unit is unplugged from the charger.

Basic Operating Instructions

Step 1

Turn unit on. Press Power Button for ON. Press and hold for OFF.

Unit will run a self-test and the Contact Indicator and Comfort Level Lights flash. At the end of the self-test, only the Comfort Level Light(s) stay on.



Hold unit with thumb and forefingers and put metal tip in contact with your skin (about a 90 degree angle.)

Comfort Levels


Level 1


Level 2


Level 3

Press Power Button briefly to change levels.

Unit defaults to Level 1. Adjust according to your comfort.

The difference in levels does not impact effectiveness.

Step 2

Start on the outside of your cheekbone.
Place the metal tip on your face using mild pressure.

Glide the tip VERY SLOWLY inward along the cheek toward the nose.

STOP gliding when unit vibrates.

If device does not vibrate, see troubleshooting tips.

HOLD TIP ON TREATMENT POINT until vibration stops.

Unit vibrates when it finds a treatment point.

Once vibration stops GLIDE SLOWLY along the cheek moving towards the nose, up and under the brow to locate additional treatment points.

Step 3

Repeat.

Treat both sides of the face and then concentrate on areas of pain.

5 min

The total treatment time is 5 minutes.

Exact treatment points may vary.

Frequently Asked Questions

How many treatment points should I expect to find?

Most people will find 7-10 treatment points on each side of the face. The number of treatment points may vary from person to person and from day to day.

What is a "Comfort Level"?

There are 3 levels. When first turned on, the unit defaults to Level 1. Try the unit on Level 1. Adjust according to your comfort level. The difference in levels does not impact effectiveness.

What does it feel like?

Some users feel no sensation other than the vibration that indicates a treatment point has been detected. Some feel a slight pricking, tapping, or tingling sensation.

The device vibrates but I don't feel any current. Is it working?

Yes. It's okay if you don't feel anything. Microcurrent waves are working if the device lights are on and the unit is vibrating.

Sometimes the sensation is stronger than others. What should I do?

If you find a point is uncomfortable, move the device tip slightly away or change the Comfort Level.

How long does relief last after treatment?

Relief can last up to 6 hours.

How often should I use ClearUP?

Use the device consistently 2-4 times a day for 2-4 weeks for maximum effectiveness. Users report a reduction in severity of symptoms with regular use.

I used the device as directed for 2-4 weeks and did not experience a reduction in symptoms. What should I do?

Consult with your physician regarding your congestion symptoms to determine what other treatments may be appropriate. If you're unsatisfied with your purchase, there is a 60-day risk-free trial period.

How long should I use ClearUP® Sinus Pain Relief in a single treatment?

For 5 minutes total time, treating both sides of the face and then concentrating on areas of pain.

Are there any side effects?

Unlike medications, there are no chemical side effects. A small percentage of users (less than 5%) may experience mild, brief skin irritation.

What are the warranty, refunds, and returns policies?

The unit comes with a 1-year limited warranty. You can read our full Shipping & Returns Policy at tivichealth.com or contact us by email at customerservice@tivichealth.com.

Maintenance

Clean the tip and body of the unit with a wet wipe. Allow the unit to dry before using. Store in a cool, dry place.

⚠ **CAUTION**

Do not dismantle the unit. The unit contains no user-serviceable parts.

How to Reboot Device

1. Plug the device with the factory provided charger into a standard power outlet.
2. Press and hold down the Power Button for 15 seconds continuously and then let go. This will initiate a reset of the device.
3. The device should now initiate a restart and will begin charging. Charging is indicated by the blinking green light.
4. Allow the device to charge for 2-3 hours or until charging is complete. Charging completion is indicated by the solid green light.
5. Once the green light is solid and not blinking, disconnect the device from the charger.

If the device still does not turn on, please repeat steps 1-5 above to reset the device charging system.

NOTE: *Use only the charger that came with the device packaging. Other chargers are not authorized and may damage the device.*

Troubleshooting

	Event	Guidance
1	Device does not turn on	Connect charger to the unit and charge the battery. If unit appears to be fully charged and still does not turn on, follow the "How to Reboot Device" instructions from Pg. 22.
2	Device Battery Light does not turn on when charger is attached	Ensure the factory provided charger is plugged into a working outlet and the charger is fully attached to the unit.
3	Contact Indicator Light does not turn on when unit is in contact with face	Check the unit is turned on. Ensure the power button is not pressed during treatment. Try after removing makeup and/or lotions. Clean the tip of the unit with wet wipes. Be sure treatments are self-administered.
4	Unit does not vibrate/ detect any treatment points	Follow instructions from "Contact Indicator Light" event from Troubleshooting Section. Ensure metal portion of tip remains in contact with your skin during the treatment. Change Comfort Level and try again.

5	Comfort Level Light continually flashes	Follow the "How to Reboot Device" instructions from Pg. 22. If the event persists, contact customerservice@tivichealth.com or call 1-888-276-6888
6	The device lights up and vibrates properly, but I cannot feel the treatment on the skin.	Microcurrent waves are working if the device lights are on and the unit is vibrating.

Specifications

Attribute	Specifications
Channel	One
Output Current	Waveform: AC-coupled square wave Max Voltage at 500 ohms: +/-3V Max Current Density at 500 ohms (at tip): 3.2mA / cm^2
Waveform Frequency Max Phase Charge	Continuous 15Hz 1.5 µC at 500Ω
Lights	LED illumination of the tip to indicate circuit is complete and contact is sufficient for treatment. LED lights to show Comfort Level setting. LED battery light for battery and charging status.
Power Source	Battery: Lithium-ion cell, +3.7V @ .3AH, safety PCB
Operating Temperature	+10ºC to +40ºC (50ºF to 104ºF)
Storage Temperature	-20ºC to +60ºC (-4ºF to 140ºF)
Operating/Storage Relative Humidity	15% to 90% (non-condensing)
Dimensions	Approximately L85xW45xH25 (mm) or L3.3xW1.8xH1 (inch)
Weight	Approximately 55 grams

Specifications are nominal and subject to variation from the listed values due to normal production tolerances.

Electromagnetic Compatibility (EMC) Information

IEC 60601-1-2 Clause 5	Location in Instruction for Use (User Guide)
5.1 Specified Type of Shielded Location	N/A
5.2 Accompanying Documents	
5.2.1 Instruction for Use	Included
5.2.1.1 General	
5.2.1.1 (a) Statement of Environments	Page 23 (Specifications table)
5.2.1.1 (b) Essential Performance	ClearUP Sinus Pain Relief will deliver microcurrent of a specific value.
5.2.1.1 (c) Warning Statement: Use of device adjacent to or stacked with other equipment	Page 13
5.2.1.1 (d) Adapter Cable with non-shielded cable	N/A
5.2.1.1 (e) Warning Statement of using other accessories and cables.	Page 13-14
5.2.1.1 (f) Warning Statement of using portable RF communication equipment	N/A
5.2.1.2 Classified Class B according to CISPR 11	Device meets CISPR 11 Class B limits
5.2.2 Technical Description	Page 7
5.2.2.1 (a) Compliance to Emissions and Immunity	Page 24-28

IEC 60601-1-2 Clause 5	Location in Instruction for Use (User Guide)
5.2.2.1 (b) Deviation from collateral standard and allowances used	N/A
5.2.2.1 (c) All Necessary Instruction for maintaining Basic Safety and Essential Performance	Page 13-17
5.2.2.2 (a) Warning Failure to use equipment in the specified type of shielded location	N/A
5.2.2.2 (b) Specifications for the shielding location	N/A
5.2.2.2 (c) Recommended test methods for measurement of RF shielding	N/A
5.2.2.2 (d) Recommendation of equipment allowed inside shielded location	N/A
5.2.2.3 ME equipment intentionally receives RF electromagnetic energy for the purpose of its operation	N/A
5.2.2.4 ME equipment that includes RF transmitters	N/A
5.2.2.5 (a) List of the frequencies and modulations used to test Immunity	A1) 380 - 390MHz –18Hz PM (Pulse Modulation) A2) 430 - 470MHz –1KHz Sine, @ 80% AM A3) 710, 745 & 780MHz – 217Hz PM A4) 810, 870 & 930MHz – 18Hz PM A5) 1720, 1845, 1970 & 2450 MHz - 217Hz PM A6) 5240, 5500 & 5785MHz - 217Hz PM
5.2.2.6 ME Equipment that claim compatibility with HF Surgical equipment	N/A

Guidance and manufacturer's declaration-Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Compliant	Group 1, Class B
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration-Electromagnetic immunity

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

Immunity test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000 - 4-2	Compliant	+/- 8kV Contact, +/ 2kV, +/- 4kV, +/- 8kV, +/- 15kV Air
Electrical fast transient/ burst IEC 61000-4-4	Compliant	+/-2 kV for power supply lines +/-1kV for input/ output lines
Surge IEC 61000-4-5	Compliant	+/-1 kV differential mode +/-2kV common mode
Voltage dips. Short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliant	<5% Ut (>95% dip in Ut) for 0.5 cycle, 40% Ut (60% dipinUt) for 5 cycles , 70% Ut (30% dip in Ut) for 25 cycles, <5% Ut (>95% dip in Ut) for 5 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Compliant	30 A/m
Conducted RF IEC 61000-4-6	Compliant	3 Vrms 150kHz to 80 MHz, 6 Vrms at ISM band
Radiated RF IEC 61000-4-3	Compliant	3 V/m 80MHz to 2.7GHz

Recommended separation distance between portable and mobile RF communications equipment and ClearUP

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

	Separation distance according the frequency of transmitter in meter		
Output Power of Transmitter in Watt	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800MHz d= 1.2√P	800MHz to 2.5GHz d= 1.2√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.78
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters (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.*

Limited Warranty Coverage

Tivic Health Systems Inc. (“Tivic Health”) hereby warrants that the ClearUP Sinus Pain Relief device (“Device”) shall be substantially free from defects in material and workmanship under normal use in accordance with the User’s Guide supplied with the Device, for a period of one (1) year from the date of purchase. Tivic Health’s limited warranty shall only extend to the original end user, where the original end user purchased a new Device in sealed packaging from Tivic Health or an authorized Tivic Health seller. This limited warranty may not be assigned or transferred. The terms of the Limited Warranty in effect as of the date of original purchase shall apply to any warranty claims.

Limited Warranty Limitations

This limited warranty does not cover defects or damage of any sort resulting from accidents, improper storage, wear, improper operation, mishandling, abuse, disassembly or alterations, unauthorized service, tampering, neglect, fire, flood, war, or acts of nature. Additionally, this limited warranty does not cover damage of any sort resulting from the use of the Device with any charger other than the original charger which was packaged with the Device (or any replacement provided by Tivic Health).

Exclusive Remedy

If any Device fails to meet the foregoing warranty within the applicable warranty period, Tivic Health shall have the option, as selected at Tivic Health’s sole discretion, to repair, replace, or provide a credit to the original end-user. In the event of replacement, Tivic Health shall have the right at its sole discretion to replace the Device with a new, or refurbished, Device. In no event, shall the limited

warranty period of a replacement Device extend past the limited warranty period of the Device it is replacing.

Warranty Service

To obtain warranty service, contact Tivic Health customer service for instructions. In the event an item must be returned, a Return Material Authorization (RMA) number is required. Items returned without an RMA number will not be accepted.

Obligations and Warranty Limits

Except for the limited warranty set forth above, Tivic Health makes no other warranties and disclaims all other representations, guarantees, conditions, and warranties concerning the device, whether direct or indirect, express, or implied, or arising under any statute, ordinance, commercial usage or otherwise, including without limitation any warranty or representation as to fitness for purpose, durability, design, merchantability, or condition of the device (or any part thereof), or relating to the infringement of any patent, copyright, or other proprietary right used or included therein.

Although the device is approved for sale by the FDA for the temporary relief of sinus pain associated with allergic rhinitis and for relief of moderate to severe congestion, the response and efficacy will vary based on the user's physiology and other variable factors and Tivic Health makes no warranty that any specific results will be achieved through the use of the device or that any relief from sinus pain and congestion will be achieved and all such warranties are hereby expressly disclaimed. If any implied warranties apply as a matter of law, they are limited in duration to the length of this limited warranty. Some states

may not recognize a disclaimer or limitation of warranties and/or limitation of liability so the above disclaimer and exclusions may not apply. The original end-user may also have different and/or additional rights and remedies that vary from state to state.

The original end-user acknowledges and agrees that Tivic Health shall not be responsible for any damages that the original end-user may incur from delayed shipment, device failures, or from any other cause, whether liability is asserted in contract, tort (including negligence and strict product liability) or otherwise. In no event shall Tivic Health be liable for any indirect, incidental, consequential, or special damages of any kind (including without limitation loss of profits or loss of use), whether or not Tivic Health shall be or should be aware of the possibility of such potential loss or damage.

Representations and warranties made by any person, including but not limited to distributors, representatives, salespersons, or agents of Tivic Health, which are inconsistent or in conflict with or in addition to the terms of this limited warranty, shall not be binding upon Tivic Health under any circumstance. This limited warranty is the complete and exclusive statement of warranty which Tivic Health agrees to provide with respect to the device and it shall supersede all prior and contemporaneous oral or written agreements, understandings, proposals, and communications pertaining to the subject matter hereof.

Questions?

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