ClearUP™
Sinus Pain Relief

USER'S GUIDE

Gentle microcurrent therapy for temporary relief of sinus pain associated with Allergic Rhinitis

TIVIC HEALTH

Manufactured and distributed by:
Tivic Health Systems Inc., Menlo Park, CA 94025
Patents Pending
This product is for adults only.

TIVIC HEALTH
tivichealth.com

MKT-199A ART-207A

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Introduction

Tivic Health Systems Inc., an innovative health and wellness leader, thanks you for selecting the ClearUP™ Sinus Pain Relief unit. This product can help you stay in better control of ongoing sinus pain associated with Allergic Rhinitis. It allows you to get back to doing your everyday activities without sinus discomfort.

The ClearUP Sinus Pain Relief unit applies microcurrent waves at a very low level electrical current. It is applied to the facial skin over the sinus passages. You may feel a little twinge or a tingle or you may not feel it at all. Rest assured, the device is working away at your unique sinus pain.

Intended Use

ClearUP Sinus Pain Relief is to be used for temporary relief of sinus pain associated with Allergic Rhinitis.

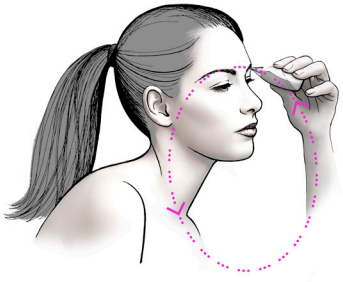
What causes sinus pain conditions?

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

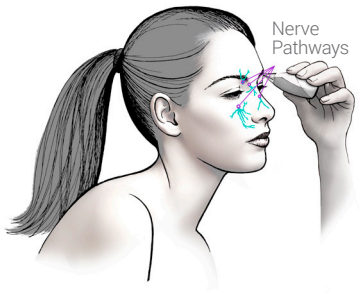
How It Works



The ClearUP Sinus Pain Relief unit uses tiny, gentle microcurrent waves to relieve sinus pain associated with Allergic Rhinitis. The mirocurrent flows from the tip of the unit to the sinus passages under the skin. It then flows back through the hand that is holding the device.

Each treatment is customized

The unit senses your skin's natural electrical properties. It helps you identify and treat the points along the sinus passages (see illustration)



- Proprietary microcurrent waveforms designed for relief of sinus pain associated with Allergic Rhinitis.
- Patent-pending calculations to locate the optimal treatment points
- Simple-to-use system of lights and vibrations to guide your use
- Small, handheld shape so you can glide the device along the sinus passages with ease and comfort.

Clinical study results

A top-tier U.S. science research center conducted a double-blinded, randomized controlled clinical study using the ClearUP Sinus Pain Relief device. Included were 27 sinus pain subjects with Chronic Rhinosinusitis, 49 patients suffering from Allergic Rhinitis, 5 subjects with other sinus conditions. Each subject used the 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. The results from the clinical trial were:

- 74% who used the microcurrent device experienced a reduction in sinus pain
- 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)
- 82% preferred ClearUP Sinus Pain Relief device to their current sinus treatment(s)
- Only one subject experienced minor reddening of the skin which disappeared within minutes.
- The statistically significant results demonstrate that the ClearUp device is a safe and effective treatment for sinus pain associated with Allergic Rhinitis.

Safety Information

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

⚠ Warnings and Cautions

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

Do not use unit if the Treatment Intensity Level light is continually flashing. This indicates a device fault. Contact Customer Service.

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

Do not alter the unit.

Stop 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.

Do not apply stimulation in the presence of electronic monitoring equipment (e.g. cardiac monitors, ECG alarms) because it may disrupt the proper operation of the equipment.

Do not use if you have implanted metallic devices or electrostimulation devices including a pacemaker, a DBS (Deep Brain Stimulation device) or a cochlear implant.

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 while pregnant because the safety of electrical nerve stimulation during pregnancy or delivery has not been established

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

Do not insert unit into the nose or inside any other body part.

Do not put the unit directly on or in your eyes or ears, on your neck, or on any body part not indicated.

Do not use without cleaning before each use with alcohol wipes. Do not immerse in any fluid.

⚠ Warnings and Cautions, continued

Do not use if wearing facial piercings or metal jewelry.

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

Do not use in a moving vehicle.

Do not use unit while charging since unit is disabled during charging.

Do not use if you experience any unusual skin sensitivity such as exaggerated writing on the skin when the skin is stroked.

Keep out of reach of children and store it safely away from children.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas, security systems, cell phones) should be used no closer than 30 cm (12 inches) to any part of the ClearUp unit including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Do not use unit if it shuts down or the performance has degraded in any way.

Do not use unit near active HF surgical equipment or in the RF shielded room of an MRI scanner or near RF emitting equipment such as diathermy and electrocautery & RFID because it could result in improper operation.

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

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

Symbols

Type BF Applied Part

Consult instructions for use

Dispose of battery according to local regulations for a Lithium coin cell battery. Do not put in garbage.

Electromagnetic interference from the device is under limits approved by the Federal Communications Commission

IP22

Protection against vertically falling drops of water, if the unit is tilted at 15 degrees. Protection from a large part of the body such as a hand; from solid objects greater than 50mm in diameter.

An item that is known to pose hazards in all MR environments, including magnetic items such as a pair of ferromagnetic scissors.

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
- AC/DC adapter
- Carrying case
- Instructions for Use
- Quick Start Guide

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

User Controls and Indicators

Power Button

Press to turn ON
Press and hold to turn OFF
Press briefly to change Treatment Intensity Level

Contact Indicator

Green light will light up when unit is in good contact with your skin.

Treatment Intensity Levels

LOW: 1 Light

MEDIUM: 2 Lights

HIGH: 3 Lights

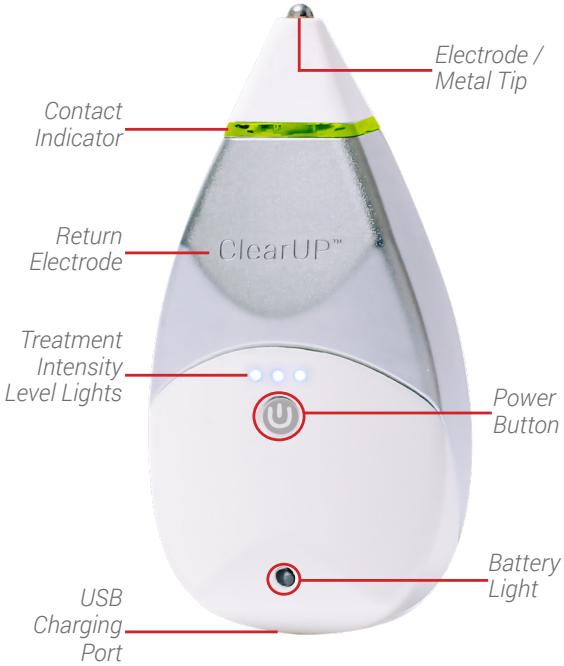
Vibration action of the unit

The unit vibrates and lights up when a treatment point is found. It continues to vibrate during treatment. It stops vibrating after 7 seconds.

Battery Light

When battery is low and needs charging, Low Battery Light will blink.

While charging, Low Battery Light will pulse slowly.



Charging Instructions

Before first use, charge unit fully. Place the USB connector from the adapter into the USB port at the bottom of the unit. Insert the adapter plug into a power outlet.

Unit cannot be used while charging.

Charging is complete when the Low Battery Light turns GREEN.

Caution: Use only the AC/DC charger provided with the ClearUP Sinus Pain Relief unit to avoid damage to unit.

Tip: Before each use, prep the area. Remove glasses and oils, lotions, makeup, metal jewelry and facial piercings.

Basic Operating Instructions

Step 1

Turn Unit on.
Press Power Button for ON. Press and hold for OFF. (Unit will run a self-test. The Contact Indicator Light flashes.The Treatment Intensity Level Lights flash).

Treatment Intensity Levels

LOW: 1 Light **MEDIUM:** 2 Lights **HIGH:** 3 Lights

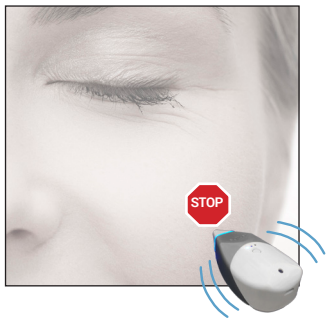
Press Power Button briefly to change levels.
The higher the level the stronger the power. Unit defaults to LOW. Start your first treatment in LOW. Adjust according to your comfort.

Warning! Do not use device if the Treatment Level Lights continually flash. This indicates a fault in the device. Contact Customer Service.

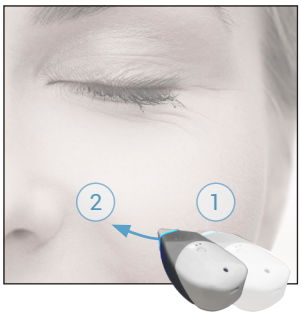
Step 2

Hold device with thumb and forefingers and put metal tip in contact with your skin.

Glide tip VERY SLOWLY to locate the first treatment point. Tip: Do not press button during treatment.



HOLD TIP ON TREATMENT POINT until vibration stops. Unit vibrates when it finds a treatment point. ***If unit doesn't vibrate, see Trouble Shooting tips.***

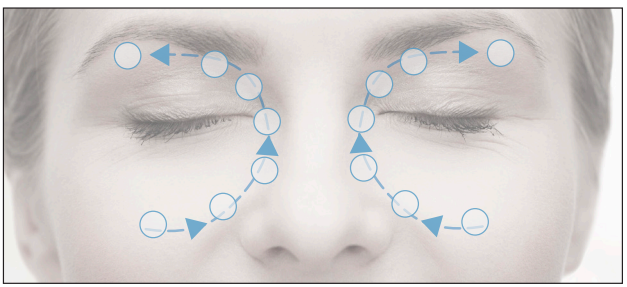


Glide very slowly to locate the next treatment point. Tip: Do not press button during treatment.

Unit VIBRATES when it finds a treatment point. Hold tip on treatment point, until the vibration stops, about 7 seconds.

Step 3

Repeat gliding and holding while unit vibrates.
Treat along the cheek, nose and under brow bone.
(See the "C" shaped path in photo on the right.)
Treat both sides of the face. Complete a cycle and then concentrate on areas of pain.
Treat for 5 minutes total time.
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 the "Treatment Intensity Level" and how do I use it?

Increasing the Treatment Intensity Level will increase the strength of the treatment. There are 3 Treatment Intensity Levels: Low Medium High.

When first turned on, the device defaults to Low.

Try the device on Low. Briefly press the power button to increase the Treatment Intensity Level. The higher the intensity the higher the power. Adjust according to your comfort level.

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 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. Discomfort should stop.

How often should I use the ClearUP™ Sinus Pain Relief unit?

When symptoms are present, up to 4 times a day.

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

For 5 minutes total time. Begin with treating both sides of the face. Next, concentrate on areas of greatest pain.

Sometimes I feel like my eye is vibrating a little during treatment. Is this okay?

The device may detect muscle nerves that control the eye. The eye nerves may vibrate a bit. Although this is harmless, do not continue treating that area.

Maintenance

The ClearUP Sinus Pain Relief unit (tip and body) should be wiped down with alcohol wipes. Allow the device to dry before using.

⚠ ***Caution: Do not immerse in any fluid. In the event of a spill on the unit, wipe the device completely dry before using again.***

⚠ ***Caution: Do not open. Unit contains no user serviceable parts.***

⚠ ***Caution: Unit contains a Lithium-ion coin cell. Dispose of battery according to local regulations for Li-ion battery***

Troubleshooting

Device does not turn on	Connect AC/DC charger to the unit and charge the battery
Device Battery Light does not turn on when charger is attached	Check that AC/DC charger is plugged into a working outlet
Contact Indicator Light does not turn on when unit is in contact with face	Clean skin in treatment area Make sure metal tip is in contact with the skin Lightly moisten skin with water Check that the electrode tip is clean Make sure hand is in contact with metal part of unit, marked as Return Electrode
Unit does not vibrate / detect any treatment spots	Increase Treatment Intensity Level by briefly pressing and holding the power button a second time and/or a third time. There are 3 Treatment Intensity Levels. Clean skin in treatment area Lightly moisten skin with water Check that the electrode tip is clean.
Device is not functional	Device may not operate properly in the presence of microwave ovens or high-power electronics. Move to a location away from emission sources.
Treatment Intensity Level Light continually flashes	Stop use immediately. This indicates a fault in the device. Contact customerservice@tivichealth.com
The device lights up and vibrates properly, but I cannot feel the treatment on the skin.	The microcurrent waves are so low that many users cannot feel the current. It is still working.
In the event of degraded performance of the unit or the device lights and vibrations are wavering or the unit shuts down.	Stop use immediately and walk away from cell phones, security systems, any RF emitting equipment that may be in the near vicinity.

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 / cm²
Waveform	Continuous
Lights	LED illumination of tip to indicate circuit is complete and contact is sufficient for treatment. LED lights to show Treatment Intensity Level setting. LED battery light for charge status
Power Source	Battery: Lithium-Ion coil 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)
Operating/ Storage ATM Pressure	500-1060 hPa
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 19 (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: Used equipment adjacent to or stacked with other equipment	Page 11
5.2.1.1 (d) List of all cables and other accessories	Page 12
5.2.1.1 (e) Warning Statement of using other accessories and cables.	Page 11
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 12-13
5.2.2.1 (a) Compliance to Emissions and Immunity	Page 20-24

Electromagnetic Compatibility (EMC) Information

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 8 -11
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) Statement that exempted from RF immunity at frequency range	150KHz-80MHz, 1Khz, Sine, @ 80% AM (Amplitude Modulation)
5.2.2.5 (b) Warning: Use nearby of emitters at other frequencies could result in improper operation	80Mhz – 2,700MHz, 1Khz, Sine, @ 80% AM
5.2.2.5 (c) List of the frequencies and modulations used to test Immunity	C1) 380 - 390MHz – 18Hz PM (Pulse Modulation) C2) 430 - 470MHz – 1K Sine, @ 80% AM C3) 710, 745 & 780MHz – 217Hz PM C4) 810, 870 & 930MHz – 18Hz PM C5) 1720, 1845 & 1970MHz- 217Hz PM C6) 2450 – 2570MHz – 217Hz PM C7) 5240, 5500 & 5785Mhz – 217Hz PM
5.2.2.6 ME Equipment that claim compatibility with HF Surgical equipment	N/A

Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration- Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	RF emissions are low compared to the FCC Group 1 limits.
RF emissions CISPR 11	Class B	RF emissions are low compared to the FCC Class B limits.
Harmonic emissions IEC 61000-3-2	Compliant	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration- Electromagnetic immunity

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

Immunity test	Compliance level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000 - 4-2	+/- 6 kV contact +/-8 kV air	+/- 6 kV contact +/-8 kV air	Did not show sensitivity to test levels.
Electrical fast transient/ burst IEC 61000-4-4	+/-2 kV for power supply lines +/-1kV for input/ output lines	+/-2 kV for power supply lines +/-1kV for input/ output lines	Did not show sensitivity to test levels.
Surge IEC 61000-4-5	+/-1 kV differential mode +/-2kV common mode	+/-1 kV differential mode +/-2kV common mode	Did not show sensitivity to test levels.
Voltage dips. Short Interruptions and voltage variations on power supply input lines IEC 61000-4-1	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	AC use only in charging mode.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Device did not show sensitivity to the test levels.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80MHz to 2.5GHz	3 Vrms 150kHz to 80 MHz 3 V/m 80MHz to 2.5GHz	Separation distances do not apply, because there is no RF emitter in the device. Device uses haptic technology to generate the vibration.

Electromagnetic Compatibility (EMC) Information

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

The 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 the ClearUP as recommended below, according the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	Separation distance according the frequency of transmitter in meter		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	80 MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 1.2\sqrt{P}$
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 System 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, improper storage, mishandling, abuse, disassembly or alterations, unauthorized service, tampering, neglect, fire, flood, war, or acts of God. 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).

Limited Warranty Coverage

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

In order 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. The item shall be shipped at the original end user's expense to a destination specified by Tivic Health.

OBLIGATIONS AND WARRANTY LIMITS

EXCEPT FOR THE LIMITED WARRANTY SET FORTH ABOVE, TIVIC HEALTH MAKES NO OTHER WARRANTIES AND DISCLAIMS ALL OTHER REPRESENTATIONS, GUARANTIES, 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, 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 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.

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For questions:
tivichealth.com
Call toll free: 1-888-276-6888