



ClearUP™

Sinus Pain Relief

USER'S GUIDE



*Gentle microcurrent therapy
for temporary relief of sinus pain
associated with allergic rhinitis*



TIVIC HEALTH

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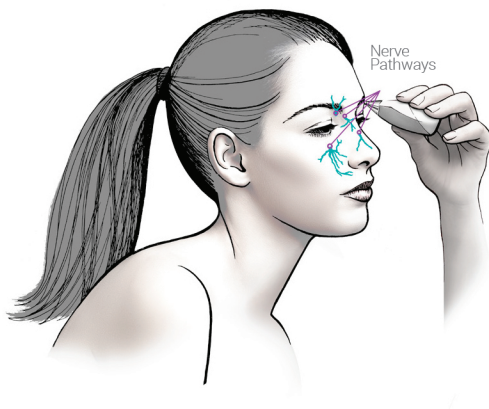
Introduction

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 on-going 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 outer skin of the facial 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 and pressure.

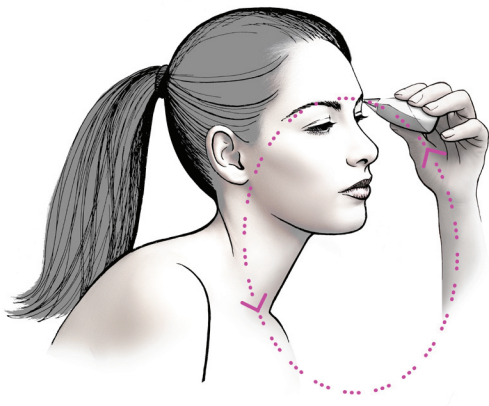
Intended Use

ClearUP™ Sinus Pain Relief is to be used for temporary relief of sinus pain associated with allergic rhinitis.



How It Works

The ClearUP™ Sinus Pain Relief unit uses tiny gentle microcurrent waves. The microcurrent flows from the tip of the unit to the facial 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. The ClearUP™ Sinus Pain Relief unit provides a customized, effective treatment using:

- Proprietary microcurrent waveforms designed for the sinuses
- 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

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 device 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.

Use only the AC/DC charger provided with the ClearUP™ Sinus Pain Relief device to avoid damage to the device.

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.

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

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 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.

Getting Started

Unpacking Instructions

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

- ClearUP™ Sinus Pain Relief unit
- AC/DC adapter
- User Guide
- Quick Start Guide
- 1 Carrying Case

Charging Instructions

Connect the AC/DC charger provided with the ClearUP™ Sinus Pain Relief unit to fully charge before use.

In a low battery condition, Low Battery Light will blink quickly.

While charging, Low Battery Light will blink slowly. Unit cannot be used while charging.

Charging is complete when the Low Battery Light turns off.

User Controls and Indicators

Power Button

Press to activate device.

Press and hold to place in standby mode.

Press briefly to change Treatment Intensity Level.

Contact Indicator

(Blue light) lights up when unit is in good contact with your skin.

Battery Light

(Yellow light) When battery is low and needs charging, Low Battery Light will blink.



Treatment Intensity Level

(Blue lights)



Low
1 Light



Medium
2 Lights



High
3 Lights

Vibration

The unit vibrates when a treatment point is found. It continues to vibrate during treatment. It stops vibrating after 7 seconds to prompt user to treat next point.

Tip: ClearUP™ Sinus Pain Relief unit works best on clean skin. Remove oils, lotions, makeup, glasses, metal jewelry and facial piercings before use.

The microcurrent waves are so small that you may feel a twinge, a tingle, tapping or nothing at all. If the device vibrates, it is working.

Basic Operating Instructions

Step 1

Turn Unit on. Device will run a self-test and momentarily activate the vibration sensor and flash all LEDs.

Tip: Do not press button during treatment.

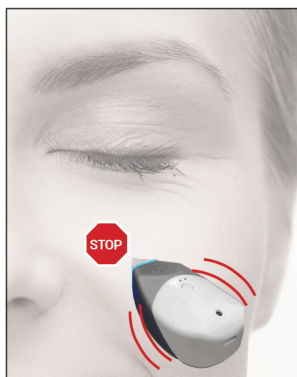
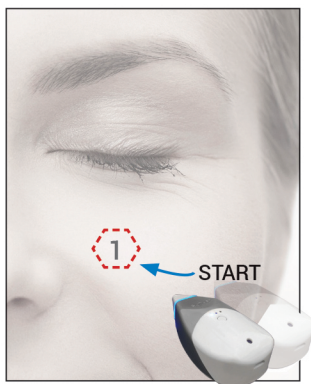
Press Power Button briefly to change levels.

The higher the level the stronger the power.

Unit defaults to LOW.

Start your first treatment in LOW. Adjust according to your comfort.

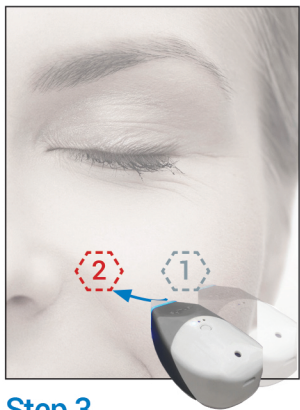
Tip: Discover which level of Treatment Intensity Level is best for you. Choose the setting that provides you the most comfortable experience.



Step 2

Grasp the metallic shell of the Device with thumb and forefinger and place tip in contact with the skin. The Contact Indicator Light (near the tip) should light up indicating good contact.

Slide the tip slowly along the skin and STOP when the unit vibrates. KEEP tip on treatment point until vibration stops (7 sec.).

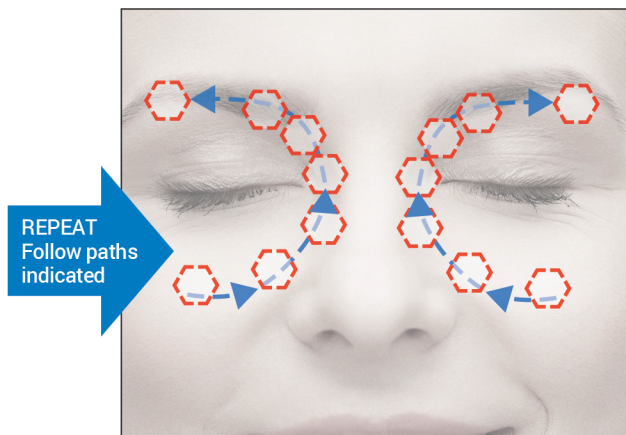


Step 3



Step 4

Glide slowly to locate the next treatment point.
Repeat gliding and holding as unit vibrates.



Tip: Use gentle pressure. Keep metal tip in contact with your skin. If Contact Indicator light is on, it's working.

Treat along the cheek, nose and under brow bone.
Treat both sides of face (minimum 14 points). Exact treatment points may vary. Continue treatment up to 5 minutes.

Frequently Asked Questions

How many treatment points should I expect to find?

Most people will find 14+ 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.

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

Up to 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 in between uses. Allow the device to dry before using. Store in a cool, dry place.



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



Do not open unit. Unit contains no user serviceable parts.

Symbols



Type BF
Applied Part



Consult instructions
for use



Place device in
standby condition



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



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	<p>Clean skin in treatment area</p> <p>Make sure metal tip is in contact with the skin</p> <p>Lightly moisten skin with water</p> <p>Check that the electrode tip is clean</p> <p>Make sure hand is in contact with metal part of unit, marked as Return Electrode</p>
Unit does not vibrate / detect any treatment spots	<p>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.</p> <p>Clean skin in treatment area</p> <p>Lightly moisten skin with water</p> <p>Check that the electrode tip is clean.</p>
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

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

Specifications

Channel	One
Output Current	Max Current Density at 500 ohms (at tip): 3.2mA / cm ²
Waveform	Continuous
Lights	Blue LED illumination of tip to indicate circuit is complete and contact is sufficient for treatment. Blue LED lights to show Treatment Intensity Level setting. Yellow LED battery light for charge status
Power Source	Battery: Lithium-Ion coil cell, +3.7V @ .3AH, with factory safety PCB
Operating Temperature	+10°C to +40°C (50°F to 104°F)
Storage Temperature	-20°C to +60°C (-4°F to 140°F)
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
Protection against Fluid Ingress	IP22
Expected Service Life	3 years or 1000 charge cycles

Manufactured and distributed by:
Tivic Health Systems, Inc., Menlo Park, CA 94025
Tivichealth.com

Made in the USA Patents Pending
This product is for adults only.

ClearUP™ Sinus Pain Relief is an investigational technology.
Claims have not been evaluated by the FDA
and ClearUP™ is not currently for sale in the U.S.
FDA 510K clearance is pending.





Treat both sides of face.
Complete one treatment, then
concentrate on areas of pain.

Treat for  total time.

Exact points may vary

1

TURN unit on

Press button for ON.

Press and hold for OFF.

Do not press button during treatment.



Low Medium High

3 treatment levels

Start on Low.

Adjust according to your comfort level.

Press power button briefly to change level.

3 Easy Steps

Battery Light

BLINKS when low.

PULSES SLOWLY while charging.

URNS GREEN when charging is complete.

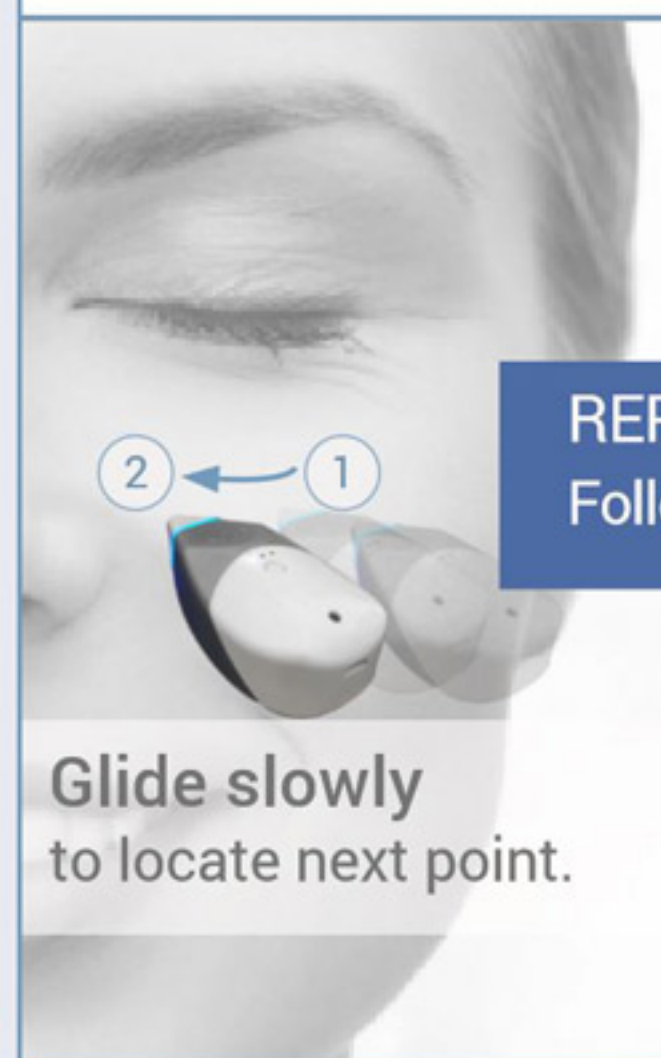
Hints and Tips

Remove make-up, lotions or oils. Remove metal facial jewelry.

Use mild pressure. Ensure metal portion of tip remains in contact with your skin. Green light near tip indicates contact pressure is sufficient.

You may feel nothing, a tingle, or a prickling sensation. If sensation is too sharp, move tip to another point. Avoid hair follicles, as treatment may feel sharper.

2



REPEAT
Follow paths

3

