

### I. GENERAL

#### How does the ReliefBand® work?

The ReliefBand® device is a non-drug, non-invasive treatment for nausea and vomiting caused by motion sickness. It works by gently stimulating the nerves in the wrist to modulate the nerve impulses that restore the normal signals between the brain and stomach, thus reducing nausea and vomiting. More specifically, the ReliefBand® delivers intermittent electrical pulses ranging from 10-35 mAmps to the median nerve on the underside of the wrist, generating natural nerve impulses that interact with the central nervous system and other stimuli to return the stomach's rhythms back to normal.

The ReliefBand® is a patented, electronic, class II medical device, which has been cleared by the Food and Drug Administration (FDA) to treat nausea and vomiting due to motion sickness. The FDA is responsible for evaluating all drugs and Medical Devices for safety and proper medical claims as to their effectiveness before allowing them to be marketed. Their clearance (acceptance) of the ReliefBand® is an indication that the device is safe and has efficacy in addressing certain ailments and conditions. In randomized clinical trials, the ReliefBand® has proven to be more effective than placebo and other non-electronic 'acupressure' type devices. Please visit [www.reliefband.com](http://www.reliefband.com) for more information.

#### How is the ReliefBand® Medical Device different from the pressure bands that I am familiar with?

To start with, it is a patented electronic medical device supported by clinically proven studies. While the pressure bands apply passive pressure, the ReliefBand® is clinically proven to stimulate the median nerve and generate nerve impulse signals. With pressure bands, the body soon accommodates for this pressure and ignores the stimulation (nerve fatigue). By virtue of the variable, pulsing electronic stimulation, the ReliefBand® does not allow the body to compensate. Therefore, the stimulation continues to have an effect for as long as the medical device is activated and worn. Also, with pressure bands you can never be quite sure that you have positioned it on the right spot for optimum relief. With its mild tingling sensation in the palm and middle fingers, the ReliefBand® provides a form of biofeedback that it is correctly positioned on the right nerve stimulation point. You can actually feel it working.

#### Is the ReliefBand® good for all types of motion sickness or just flying and boating?

All motion sickness is caused by similar conditions in the body. Therefore, the ReliefBand® Medical Device should have similar results with virtually all motion related nausea and vomiting, such as boating, air travel, car sickness, video gaming and amusement park rides.

### II. OPERATION / APPLICATION

#### Which way does the ReliefBand® need to be oriented on my wrist?

The ReliefBand® is placed on the underside of the wrist with the pointed end (end with the L.E.D.) towards the thumb. This is the proper application due to the fact that the ReliefBand® is contoured to stay in place much more effectively in this orientation.

#### How do I activate the ReliefBand®?

Press the On / Off button located in the center of the ReliefBand® face once. There should be a green flashing light on or near the number 1. Pressing the button again, will increase the stimulation level. The flashing light is not synchronized with the buzzing sensation you will feel.

#### How do I turn the unit off?

Press and hold the On / Off button, in the center of the dial for three (3) seconds. This will deactivate the medical device and put the unit into a battery-save (off) mode for future use.

#### About these settings on the dial; what do they mean?

The numbers around the dial represent different stimulation outputs, the higher the number, the higher the stimulation level. It is recommended that you have the ReliefBand® at the setting high enough so that you consistently feel the

pulsing stimulation, but comfortable so that it is not distracting. Required stimulation levels may be different for everyone, and may change on particular individuals on a daily basis. There are five stimulation levels (1,2,3,4,5).

### **How do I know if the ReliefBand® is applied correctly?**

When you have the ReliefBand® placed (on the underside of the wrist) about two finger widths below the crease in your wrist, between the two tendons, you will stimulate the median nerve. You should feel a gentle pulsing or tingling sensation in the palm and/or middle fingers. If you can't feel the tingling in the palm and/or middle fingers, you may not have positioned the ReliefBand® correctly, or you may have it over a different nerve in your wrist causing tingling in the thumb, for example. Be sure and move the ReliefBand® around the underside of the wrist area between the two tendons until stimulation is felt as described.

### **What do I do if I can't feel the "buzzing" in the palm or middle finger?**

Move the ReliefBand® slowly around the underside of the wrist between the two tendons. If tingling is still not felt, increase the touch pad number setting to the next level and repeat the movement. If the tingling is still not felt at the highest setting of 5, you should try the following:

- Follow the Instructions For Use carefully to make sure the ReliefBand® is applied in the correct starting location.
- Slowly move the ReliefBand® slightly around the starting location until stimulation is felt.
- Re-apply the conductivity gel making sure it is rubbed in to a sheen.
- Clean the underside of the medical device off with a tissue as there may be too much gel accumulated on the bottom (globs of gel may prevent conductivity).
- Switch wrists.

### **Why do I only feel the buzz every few seconds?**

The ReliefBand® stimulates the median nerve intermittently. As a result, the stimulation sensation feels like it increases in intensity and then briefly stops in a cycling pattern.

### **What is the proper setting for me?**

The proper setting varies by individual. Some feel very comfortable with the unit turned all the way to 5. Others feel slight discomfort with the unit above 1. The proper 'tingling' you should feel is the highest setting at which the sensation does not feel uncomfortable. You must feel some 'tingling' in order for the Medical Device to work.

### **Will this tingling feeling always be there?**

Technically, yes. However, over a period of time, usually 30 minutes or so, the sensation you consciously feel will fade into the background and should not be disruptive to daily activities.

### **Do I always have to use the conductive gel? How much should I use?**

Yes. The gel helps enhance the conductivity of the electrodes with the skin; allowing the impulses to penetrate and reach the nerves intended to receive stimulation. Without the gel, you will receive little more than localized skin stimulation. You should use a drop, about the size of a pea. The drop should be spread onto the skin, until a sheen remains, covering an area the size of a quarter, in the intended contact location.

### **Can I use any other kinds of gel for contact, for example, K-Y jelly?**

The manufacturer recommends only using the gel specifically indicated for use with the ReliefBand®. The gel tube included with the ReliefBand® should last for approximately 75 applications. Should you need more, you may order it directly from the manufacturer, NeuroWave Medical Technologies, via the web site, at [www.reliefband.com](http://www.reliefband.com), or by calling 1-800-735-BAND or 312-334-2505.

### **Do I need to wear this before I travel, or can I use it after I get sick?**

This is one of the key benefits of the ReliefBand® over any of the other known remedies for motion sickness currently available. While it is suggested that known sufferers can use the Medical Device prior to travel as a preventive measure, many users experience relief of the symptoms of nausea / vomiting after they appear. For obvious reasons, the ReliefBand® should be applied as rapidly as possible after symptoms appear, for optimum results. Motion



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sickness is a progressive disorder. If not alleviated, it can progress beyond the ability of even the ReliefBand® to reverse the symptoms.

### **How long until the ReliefBand® begins to have an effect?**

When applied correctly, many patients begin to feel relief within a few minutes.

### **How long may I wear the ReliefBand®?**

The ReliefBand® may be worn as long as necessary, during the life of the battery. Suggestion: wear the Medical Device in the proper position and turn it on as needed.

### **Do I have to wear it all of the time?**

Only when you want it to be activated. Many users will place it in the proper location, activate the Medical Device, and then turn the ReliefBand® off until it is (if at all) needed. Then, when needed, simply turn the unit on; as it is already in the proper location for use. This minimizes the time lag for application and activation, and also helps extend battery life.

### **Are there any other uses for the product? May I wear it anywhere else?**

No. While there may be other indications that the ReliefBand® can remedy / treat, there is no FDA clearance for those at this time. The ReliefBand® is only intended / indicated for use as specified in the manufacturer's instructions for use.

## **III. BATTERY / PRODUCT LIFE CYCLE / WATERPROOF**

### **How long does the ReliefBand® last?**

The device has a useful battery life of approximately 150 hours when used at power level 3. The battery indicator light will flash a red signal when approximately 10 hours of battery power remains. Many people place the ReliefBand® on their wrist and activate it according to their symptoms. You can turn the ReliefBand® off when it is not in use, allowing you to use it over several days, weeks or months.

### **If not in use, how long will the ReliefBand® last in storage? What is the shelf life of the product?**

The batteries in the unit are of a lithium type. This type of battery does not self-deplete very quickly. The shelf life is specified as two to three years, under optimal storage conditions.

### **Is the ReliefBand® waterproof?**

The ReliefBand® is NOT waterproof; however, it is rated as 'Spray and Splash Resistant.' This means that it should perform in most cases of incidental contact with liquid. It should not be submerged, or subjected to long periods of continual exposure to water.

## **IV. SIDE EFFECTS / CONTRAINDICATIONS FOR USE**

### **Are there any drug interactions?**

There are no known drug interactions observed when using the ReliefBand®.

### **Are there any side effects using the ReliefBand®?**

The only known side effect may be a slight skin irritation under the electrodes for users who are allergic to certain metals, or a similar reaction for those who may be allergic to the latex in the strap. Skin irritation may be avoided by using the ReliefBand® on alternating wrists. If symptoms persist, discontinue use.

### **Are there any contraindications?**

No, however there is a warning, stating that all Cardiac Pacemaker users should use the ReliefBand® only as directed on the wrist to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker.

### **Will it make me drowsy?**

No, because there are no drugs used, there are no drug-like side effects associated with the use of the ReliefBand®.

### **May I still consume alcohol during use of the ReliefBand®?**

There are no side effects associated with alcohol use in conjunction with the use of the ReliefBand®.

### **What about using the ReliefBand® on my kids?**

Children are classified as anyone under 12 years of age. There is no indication, nor contraindication, from the FDA, as to use of the ReliefBand® with children. It is suggested that you consult your physician before using it on children.

## **V. COST**

### **Is the ReliefBand® Medical Device cost effective?**

When considering the cost of the device, the following should be considered:

- The ReliefBand® is expected to last at least 150 hours (based on average setting 3) and may cost less, per hour of use, than many of the leading anti-nausea medications.
- ReliefBand® does not have potential for drug interactions, therefore, you do not have to worry about any drug related side effects or associated costs with treatment for side effects.
- One must take into account the longevity of the device and the benefit derived in order to place a value on the device. Consider the cost/benefit associated with participating in your favorite activities and the cost that an incident with motion sickness may have on travel plans.



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