



## Frequently Asked Questions - OTC MARKET

### I. GENERAL

#### **Does ReliefBand® Medical Device really work?**

The ReliefBand® Medical Device is a patented, electronic, class II medical device, which has been cleared by the Food and Drug Administration (FDA) to treat nausea and vomiting for multiple clinical indications, both as a prescription (Rx) and OTC (over the counter) sale. 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 for prescription, or over the counter use. Their clearance (acceptance) of the ReliefBand® Medical Device is an indication that the device is safe and has efficacy in addressing certain ailments and conditions. In randomized clinical trials, the ReliefBand® Medical Device 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 does the ReliefBand® Medical Device work?**

The ReliefBand® Medical Device is a non-drug, non-invasive treatment for nausea and vomiting due to chemotherapy, pregnancy, motion sickness and post-operative nausea. It works by gently stimulating the nerves in the wrist, which interferes with the body's nausea and vomiting process. More specifically, the ReliefBand® delivers intermittent electrical pulses ranging from 10-35 mAmps to the P6 meridian acupoint.

#### **What are the medical conditions for which the ReliefBand® Medical Device has FDA clearance?**

The prescription ReliefBand® Medical Device is indicated for the treatment of nausea and vomiting due to chemotherapy, pregnancy, and post-operative nausea. The over the counter (OTC) ReliefBand® Medical Device is indicated for the relief of motion sickness and pregnancy related morning sickness. The ReliefBand® Medical Device was cleared by the FDA in 1999 as an over-the-counter remedy for motion sickness, and for morning sickness associated with pregnancy in 2003. Prior to 1999, the ReliefBand® Medical Device was available only by prescription for the indications of nausea and vomiting due to pregnancy, chemotherapy, and post-operative nausea.

#### **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, not simply an elastic band with a knob on the underside. While the pressure bands apply passive pressure, and; therefore, stimulation to the nerves, the body soon accommodates for this pressure and ignores the stimulation. By virtue of the variable, pulsing electronic stimulation, the ReliefBand® Medical Device 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 buzzing in the palm and middle fingers, the ReliefBand® Medical Device 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® Medical Device 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.

### II. OPERATION / APPLICATION

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

The ReliefBand® Medical Device 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® Medical Device is contoured to stay in place much more effectively in this orientation.

#### **How do I activate the ReliefBand® Medical Device?**

Press the On / Off button located in the center of the ReliefBand® Medical Device face once. There should be a flashing light inside, 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.



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### 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 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® Medical Device at a high enough energy level so that you consistently feel the stimulation. 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® Medical Device is applied correctly?

When you have the ReliefBand® Medical Device 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 buzzing in the palm and/or middle fingers, you may not have positioned the ReliefBand® Medical Device 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® Medical Device 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® Medical Device slowly around the underside of the wrist between the two tendons. If tingling is still not felt, increase the touch pad number setting 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® Medical Device is applied in the correct starting location.
- Slowly move the ReliefBand® Medical Device 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.
- Switch wrists.

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

The ReliefBand® Medical Device 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 'buzzing' you should feel is the highest setting at which the sensation does not feel uncomfortable. You must feel some 'buzzing' 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® Medical Device. The gel tube included with the ReliefBand® Medical Device 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.



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### **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® Medical Device over any of the other known remedies for motion sickness currently available. While it is suggested that known sufferers should use the Medical Device prior to travel, as a preventative, many users experience relief of the symptoms of nausea / vomiting after they appear. For obvious reasons, the ReliefBand® Medical Device should be applied as rapidly as possible after symptoms appear, for optimum results. Motion sickness is a progressive disorder. If not alleviated, it can progress beyond the ability of even the ReliefBand® Medical Device to reverse the symptoms.

### **How long until the ReliefBand® Medical Device 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® Medical Device?**

The ReliefBand® Medical Device 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® Medical Device 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® Medical Device can remedy / treat, there is no FDA clearance for those at this time. The ReliefBand® Medical Device is only intended / indicated for use as specified in the manufacturer's instructions for use.

## **III. BATTERY / MEDICAL DEVICE LIFE CYCLE / WATERPROOF**

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

The reusable medical 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 4-6 hours of battery power remains. Many people place the ReliefBand® Medical Device on their wrist and activate it according to their symptoms. You can turn the ReliefBand® Medical Device 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® Medical Device 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.

### **What types of batteries are used in the reusable ReliefBand® Medical Device and where can I purchase extra batteries?**

The reusable ReliefBand® Medical Device uses 2, 3V lithium batteries (CR2025) and they are available at your local drug store, or where camera batteries are sold.

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

The ReliefBand® Explorer RB-EL Unit 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.



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### IV. SIDE EFFECTS / CONTRAINDICATIONS FOR USE

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

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

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

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 can be accommodated by using the ReliefBand® Medical Device 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® Medical Device 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® Medical Device.

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

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

#### **What about using the ReliefBand® Medical Device 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® Medical Device with children. You may use your own parental discretion as to use on your children or discuss with your physician.

### V. COST

#### **This ReliefBand® Medical Device seems expensive. Why does it cost so much?**

What price is the assurance of a pleasant trip or alleviating morning sickness worth to you? If you consider the actual costs of the ReliefBand® Medical Device, the initial usage of 150 hours will cost less per hour of use than many of the leading anti-nausea medications and still allow for you to enjoy activities you might otherwise have to miss out on, or run the risk of ruining what might have been a very expensive outing for you and others around you. Over the life of the device, the cost for the ReliefBand® Medical Device becomes just pennies per hour to use.