reliefband[®] ... - Model : Reliefband[®] 1.5

INDICATIONS FOR USE: Reliefband® is a digital therapeutic device indicated for use in the treatment of nausea, retching and vomiting due to motion sickness, morning sickness associated with pregnancy, and chemotherapy. Reliefband® is also indicated as an adjunct to antiemetic therapy in reducing post-operative nausea.

IMPORTANT: Positioning Reliefband[®] properly on your wrist is essential for relief of your nausea, retching and vomiting symptoms. Before you start using Reliefband®, please read this Instructions For Use carefully. You must feel stimulation in your palm and/or middle fingers for Reliefband® to work.

CONTENTS: (1) Reliefband®, (2) Preinstalled Batteries (Replaceable), (1) Hypo-allergenic conductivity gel tube and (1) Instructions For Use.



EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague

220 Gibraltar Road, Suite 270, Horsham, PA 19044 Reliefband® is a registered trademark of Reliefband Technologies. Inc. Reliefband® technology is protected by US Patent Nos. 6,076,018; 7,127,288. Japanese Patent Nos. 4,812,810; 4,220,129. Canadian Patent Nos. 2,449,554; 2,342,873. Australian Patent Nos. 766463; 2004200090; 2002305786. European Patent No. 1,109,595-UK, France and Germany (DE 69940405.3) Designed in USA. Manufactured in Malaysia. ©2017 Reliefband Technologies In the U.S.A., call 1-877-735-2263 9:00 AM - 5:00 PM Mon. - Fri. CST

6006820 Rev. D

DESCRIPTION OF RELIEFBAND®: Reliefband® is a digital therapeutic device incorporated into a wristband which has a stimulating electrode that is worn on the underside of the wrist. It provides relief from nausea, retching and vomiting through gentle electrical stimulation of the median nerve. Batteries will last approximately 150 hours of active use at power level 3 or below. The batteries of Reliefband® are user replaceable. Replace batteries in unit when they become drained.

SAFETY INFORMATION

CAUTION:

- Pacemaker users Use this device on the wrist and only as directed to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker. Consult your doctor before using the device.
- · Keep the Reliefband[®] product away from young children as it contains batteries that should not be swallowed and may pose a choking hazard.
- Nausea, retching and vomiting may be signs of a serious health problem. Contact a doctor if your nausea, retching and vomiting persists.
- · Reliefband[®] should only be used on the wrist. Do not use it on any other areas of the body because the device might cause undesirable effects such as tingling, muscle twitching or skin irritation.
- · Reliefband® does not cure the underlying causes of nausea, retching and vomiting. The relief you get may vary depending on your body's individual characteristics and any medications that you may be taking that could cause your body to respond differently.
- If you are unable to tolerate any food or liquids or are experiencing weight loss you should contact your doctor.
- Reliefband[®] is splash-resistant. This product is resistant to splashing water (rain, waves, etc). Do not immerse Reliefband® in water or wear while bathing or showering. Reliefband® is also shock-resistant.
- The elastic strap contains natural rubber latex which may cause allergic reactions.

SIDE EFFECTS:

• For some people, skin irritation (red or itchy skin, red bumps or small blisters) may occur beneath or around the gold plates on the back of the device (electrodes). If skin irritation occurs beneath or around the electrode sites, move the device to the other wrist. If irritation does not disappear within 24 hours, stop using the device and consult your doctor or pharmacist. Continued use of the device on irritated skin may cause skin injury.

FCC INFORMATION: This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

MAINTENANCE: Keep the electrode area clean. A moist cloth may be used to remove gel build-up. Gel build-up may decrease stimulation. Avoid immersion of the device in water.

To purchase additional Reliefband® devices or accessory items, including conductivity gel, go to Reliefband.com

ENVIRONMENTAL USE INFORMATION:

Reliefband® should only be used within the environmental ranges of: 0°C to 45°C (32°F to 113°F) and 20% to 90% relative humidity (non-condensing).



ENVIRONMENTAL STORAGE INFORMATION:

The device can be stored and transported in the environmental ranges of: 0°C to 27°C (32°F to 80°F) and 20% to 80% relative humidity (non-condensing). If the device has been stored or transported in conditions outside this range, keep it within the normal ranges for at least 30 minutes before using.

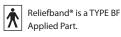


DISPOSAL INFORMATION: The product and batteries do not contain any environmentally hazardous substances and can be disposed of normally. The batteries used in this device may explode if not used or handled properly. Do not recharge, disassemble or dispose of them in fire.

No modification of this device is allowed.

TECHNICAL INFORMATION: Reliefband® complies with IEC 60601-1:2005 +Corr.1 (2006) +Corr. (2007); CAN/CSA-C22.2 No. 60601-1 (2008), EN 60601-1:2006 +CORR:2010, and ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10). Reliefband® has been verified as a class B Digital device per FCC 47 CFR, Part 15 Subpart B and has been found to comply with the following Electromagnetic Compatibility standards: EN55011 (CISPR 11).

Radiated Emission: EN61000-4-2 Electrostatic Discharge Immunity; ENV 50204 and EN 61000-4-3 Radiated Electromagnetic Field Immunity.



Attention, Reliefband® produces physiological effects as described in this auide.

IPX4 Reliefband® is splash-resistant.



California Only: Perchlorate Material – Special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate.



(LATEX) This product contains natural rubber latex, which may cause

TECHNICAL DATA

| Size | Teardrop shape 1.5" x 2" x 0.45" |
|-----------------|---|
| | (3.81 x 5.08 x 1.14 cm) |
| Weight | Approximately 1.2 ounces (34 grams) |
| User Controls | Push Button |
| User Displays | On: Flashing Green LED at Power Level |
| Low Battery | Flashing light indicator (see figure 1) |
| Output Channels | Two electrodes |
| Maximum Output | .40mA |
| Battery | Two 3V lithium coin cell batteries (CR2025's) User replaceable, not rechargeable |

QUESTIONS AND ANSWERS

When to use Reliefband®?

 You can use your Reliefband® either before or after your nausea, retching and vomiting symptoms start, and leave it on for as long as your symptoms last. If you are highly susceptible to motion sickness, apply Reliefband® at least 30 minutes before a motion sickness event (e.g., riding in a car, airplane or boat).

How can I be sure I've found the area for maximum stimulation?

- After the device is turned on, move it slightly up or down, and side to side on the wrist until a "tingling" feeling is felt. You will feel a tingling sensation in your palm and/or middle fingers when Reliefband® is in the proper wrist location. Stimulation will cycle every 4 seconds.
- If little or no tingling is felt after moving the device around, then increase the power level. This device has five levels of stimulation: 1, 2, 3, 4 and 5 (level 5 is the highest setting). If you are at level 5, curl your fingers slightly and bend your wrist up. When stimulation is felt, then secure the band.
- Try the band on the opposite wrist. Use it on the wrist where you feel the most tingling. Increase the power setting to the highest comfortable setting for maximum relief.

On which wrist should I wear Reliefband*?

• Wear it on the wrist that gives you the greatest tingling in the hand at the lowest stimulation level.

Is dry or sensitive skin a problem?

For dry skin, the gel may be lightly applied more often.
If you have especially sensitive skin, switch wrists every 2-3 hours.
Be sure to re-apply gel as directed.

How long will the batteries last?

- The batteries should last for about 150 hours of total use at power level 3, less time at higher power levels. Battery life depends on individual usage of product and brand of batteries.
- There are many different brands of batteries, each giving somewhat different battery life performance. Some batteries last a long time for occasional use, other batteries last longer for more frequent use. Try different brands to determine which brand works best for how you use the device.

How do I know when the batteries are getting low?

• The low battery light (see Figure 1) on the display will flash slowly to let you know when the batteries are low. At this time, about 10 hours use remains depending on the power level used and how long you have used the device.

Green Light Flashing (No stimulation is felt)

 Move Reliefband[®] around the underside of the wrist. Check for proper placement. Increase the power setting. Re-apply a small amount of gel.
Be sure gel is rubbed into a sheen. Be sure the strap is secure around the wrist. Be sure green light is flashing at one of the 5 power settings.

No Lights Flashing

• Check that device is on. You should see a green flashing light at one of the 5 power settings (1-5). Turn device OFF and reactivate. Batteries may be drained.

For additional FAQ, please go to Reliefband.com

TROUBLE SHOOTING

The Troubleshooting Chart below will help to assist you in handling situations that may arise while you use the product.

| Situation | Recommended Solution |
|--|---|
| Green Light Flashing (No Stimulation is felt) | Move Reliefband [®] around the underside of the wrist. Check for proper placement. Increase the power setting. Re-apply a small amount of gel. Be sure gel is rubbed into a sheen. Be sure the strap is secure around wrist. Be sure green light is flashing at one of the 5 power settings. |
| No Lights Flashing | Check that device is on. You should see green flashing light at one of the 5 power settings (1-5). Turn device OFF and reactivate. Batteries may be drained (see disposal Information section). |
| Low battery light flashing | The flashing light indicator (see figure 1) indicates a low battery. Restart unit to see if power remains. Set the unit at a lower setting. If the flashing light continues to flash, the batteries are running out of power. |

LIMITED WARRANTY STATEMENT - Model: Reliefband® 1.5

Reliefband® Technologies warrants each new Reliefband® (exclusive of batteries) to be free from material defect in workmanship and materials for sixty (60) days from the date of purchase, the "Warranty Period." This limited warranty is subject to (a) the customer notifying Reliefband® Technologies within sixty (60) days of the date of purchase of any material defect in the Reliefband® workmanship and materials ("Defective Product") during the Warranty Period, and (b) the customer returning the Defective Product to Reliefband® Technologies. Contact Reliefband® Technologies at 877-735-2263 for return or replacement of Defective Product.

Reliefband[®] is indicated for nonprescription (over-the-counter) use in relief of nausea, retching and vomiting. Reliefband[®] may not be effective for every person because treatment outcomes vary and are dependent upon a myriad of patient profiles and characteristics. Reliefband[®] Technologies' obligation under this Limited Warranty is expressly limited solely and exclusively to the replacement of the Defective Product.

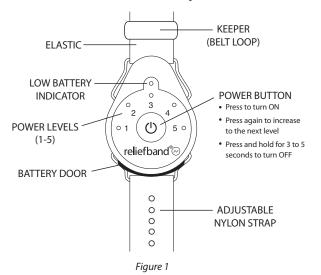
THE LIMITED REPRESENTATIONS AND WARRANTIES SET FORTH HEREIN ARE RELIEFBAND TECHNOLOGIES' SOLE REPRESENTATIONS AND WARRANTIES WITH RESPECT TO RELIEFBAND® OR ANY OTHER SUBJECT MATTER HEREOF AND ARE GIVEN IN LIEU OF ANY AND ALL OTHER REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR SUITABILITY FOR A PARTICULAR PURPOSE. THE REMEDIES AFFORDED TO CUSTOMER FOR ANY BREACH OF WARRANTY WILL BE LIMITED TO THOSE SET FORTH HEREIN TO THE EXCLUSION OF ANY AND ALL OTHER REMEDIES. CUSTOMER WILL NOT BE ENTITLED TO PUNITIVE, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION CUSTOMER'S DENTAL AND MEDICAL COSTS, AS A RESULT OF A DEFECTIVE PRODUCT. NO AGREEMENT VARYING OR EXTENDING THE FOREGOING WARRANTIES, REMEDIES OR THIS LIMITATION WILL BE BINDING ON EITHER PARTY UNLESS MEMORIALIZED IN A WRITING SIGNED BY BOTH PARTIES.

Some jurisdictions do not allow the exclusion or limitation of special, indirect, incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty shall not apply to any Defective Product that has been tampered with or repaired and/or altered by someone other than a duly-authorized Reliefband Technologies' representative. Further, this warranty shall not apply to any Defective Product where the defect has been caused by customer negligence, mishandling or any customer use contrary to the enclosed instructions or customer use inconsistent with the stated purpose.

This warranty is expressly limited solely to the original purchaser and does not extend or confer any rights to any transferee, assignee, or subsequent purchaser or user of a Defective Product. Reliefband[®] Technologies' liability for all claims, (whether based on contract, tort, breach of warranty, or otherwise), which may arise in connection with the purchase and use of any Defective Product is limited to the purchase price paid by the original purchaser.

Features and Components



Replacing the Batteries:

- A low battery indicator (see Figure 1) flashes when the batteries are low. (Approximately 10 hours of use remain depending on the power level used.)
- Peel back the rubberized battery door at the end marked "OPEN HERE" (see Figure 2) and pull out the red colored battery removal tool.
- 3. Remove used batteries and then replace them with two fresh batteries (3V, CR2025 Lithium coin cells only) available at grocery, drug, and other similar stores.
- 4. IMPORTANT: Make sure the new batteries are inserted in the correct direction with the "+" side down (see Figure 3), the battery removal tool is inserted correctly, and the door is closed. Be sure the door is replaced with the "OPEN HERE" facing in original position and there are no gaps in the seal (gaps decrease water resistance). Never insert an empty battery removal tool into the Reliefband[®]. Doing so may damage the device.





Figure 2

Figure 3

Usage Tips:

- Try Reliefband® on each wrist and use it on the wrist where the greatest tingling is felt at the lowest setting.
- 2. For some people, applying and rubbing in the gel twice assists in nerve stimulation.
- 3. Gel should be re-applied every 2-3 hours, any time after washing, or if stimulation decreases.
- 4. While still on the wrist, turn Reliefband® off periodically to determine if you still have nausea, retching and vomiting symptoms. If you still have symptoms, then turn it back on immediately.
- When finished using the Reliefband[®], take it off your wrist and remove the gel from your wrist and the device with a tissue.
- When not using Reliefband[®], be sure to turn the power off to extend battery life.
- Store Reliefband[®] in a safe, dry place. Keep it away from young children.
- If there is excess gel, then the device may not provide enough tingling. If you cannot feel the tingling sensation, then clean both the device and the wrist and re-apply the gel. You can apply extra gel if the tingle feels too strong on level 1.

If you have difficulty closing the battery door, we recommend you consider the following steps:

- 1. Make sure that the red battery removal tool is inserted properly into the device.
- 2. Make sure that the thin blue strip (left end of the battery door) is inside the device.
- 3. Push left side of blue battery door until snuggly inserted into the left lip of the opening.
- 4. Working from left to right, tuck the top part of the door into the device, and lock in right side of the door.
- 5. Working from left to right, tuck bottom lip of the battery door into the device.
- 6. If the battery door still sticks out, roll the battery door (while tucked into the device) on a hard flat surface to flatten battery door into the device about 5 or 6 times to secure the battery door.

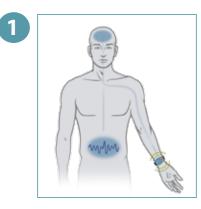
reliefband®

Fast Relief from Nausea, Retching & Vomiting

Associated with Motion Sickness, Morning Sickness, Chemotherapy and Post-Operative*.

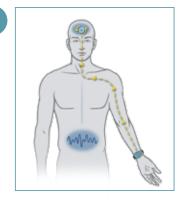


HOW DOES IT WORK?

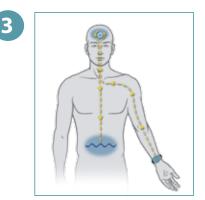


Reliefband[®] generates a proprietary pulse from the underside of the device that stimulates the median nerve, which is located under the skin near the wrist.

HOW TO USE RELIEFBAND®



The resulting impulses from the median nerve then travel through the body's nervous system to the part of the brain which controls nausea, retching and vomiting.



The pulses have a rebalancing effect, normalizing nerve messages from the brain to the stomach and reducing symptoms of nausea, retching and vomiting.

1 AREA



Find the starting area on the wrist.

Using either wrist, the correct area is in between the two tendons on the underside of the wrist – about two finger widths above the distal wrist crease (farthest from the elbow). 2 APPLY

2



Clean the area first.

Apply a small drop of gel and spread in a circle about the size of a large coin with an even sheen (i.e., a thin layer with a shiny appearance).

ADJUST & ACTIVATE



Place the device over the gelled area and attach it to the wrist.

Fasten device snugly. Press " \bigcirc " symbol on center of device to turn on. Start at power level 1, increase stimulation until tingling is felt through median nerve distribution in palm and middle finger at a comfortable level. Press " \bigcirc " symbol for 3 seconds to turn off.