reliefband . Model: RB-EL

INDICATIONS FOR USE: Reliefband^{*} is a digital therapeutic device that is indicated for use in the relief of nausea and vomiting due to travel/motion sickness and pregnancy/morning sickness.

IMPORTANT: Positioning Reliefband^{*} properly on your wrist is essential for relief of your nausea 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^{*} Model RB-EL, (1) Preinstalled Batteries (Replaceable), (1) Hypo-allergenic conductivity gel tube and (1) Instructions for Use.



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220 Gibraltar Road, Suite 270, Horsham, PA 19044 Reliefband® is a registered trademark of Reliefband Technologies. Reliefband®

technology is protected by US Patent No. 6,076,018; 6,567,695; 6,735,480; 7,127,288; 7,171,266. Japan Patent No. 4,168,380; 4,812,810; 4,220,129. UK Patent No. 1,109,595; Canadian Patent No. 2,449,554; 2,429,677. Designed in USA, MFD in Malaysia. Manufactured for Reliefband Technologies. ©2016 Reliefband Technologies In the U.S.A, call 1-877-735-2263 9:00 AM - 5:00 PM Mon. - Fri. CST 6006820 Rev. C

DESCRIPTION OF RELIEFBAND: Reliefband^{*} is a digital therapeutic device incorporated into a wristband worn on the underside of the wrist. It provides relief from nausea and vomiting due to motion sickness and morning sickness through gentle electrical stimulation of the nerves in your wrist. 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

- Pacemaker users Use this 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.
- Nausea and vomiting may be signs of a serious health problem. Contact a doctor if your nausea and vomiting seem to be lasting a long time.
- Do not use Reliefband[®] when the cause of nausea and vomiting symptoms is undiagnosed because those symptoms might be an important indicator of more severe health problems.
- 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 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.
- Reliefband[®] should be kept out of reach of young children.
- If you are unable to tolerate any food or liquids or are having 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. 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, which may decrease stimulation. Avoid immersion of the device in water. To purchase additional Reliefband®'s or accessory items, including conductivity gel, call 1-877-735-2263.

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 mistreated. Do not recharge, disassemble or dispose of them in fire.

No modification of this device is allowed.

TECHNICAL INFORMATION: Reliefband^a 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^a 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 guide.

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 allergic reactions.

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	35mA
Battery	Two 3V lithium coin cell batteries (CR2025's) Toshiba or Panasonic User replaceable, not rechargeable

QUESTIONS AND ANSWERS

When to use Reliefband*?

 You can use your Reliefband[®] either before or after your nausea 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[®] one half hour 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 the maximum "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 four seconds.

- If little or no tingling is felt after moving it around, increase the power level to the next level of stimulation. This device has five levels of stimulation: 1, 2, 3, 4 and 5 (level 5 is the highest setting).
- 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*?

• 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 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 in to sheen. The area should appear shiny. 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 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).

How can I be sure Reliefband® stays in place at night?

 In general, if you are sleeping comfortably, you most likely do not need to wear the device while sleeping. If you do need the device on to control symptoms while sleeping, then it may help to secure Reliefband[®] in place by using strips of medical tape or an ace bandage to secure it in place.

For additional FAQ, please see www.reliefband.com

TROUBLE SHOOTING

Reliefband® has been designed to provide feedback to ensure proper usage to relieve nausea and vomiting symptoms. 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. The area should appear shiny. 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 - Reliefband[®] Model No. RB-EL

Reliefband^{*} Technologies warrants each new Reliefband^{*} to be free from defect in material and workmanship for 30 days from date of purchase, exclusive of batteries. All other warranties, express and implied, are limited to 30 days from the date of purchase.

Reliefband^{*} is indicated for nonprescription (over-the-counter) use in relief of nausea and vomiting due to motion sickness and morning sickness. Reliefband^{*} is not warranted to be effective in every case since relief varies dependent upon user characteristics.

Reliefband[®] Technologies's obligation under this Limited Warranty is expressly limited solely and exclusively to the replacement of the unit to which Reliefband[®] Technologies' satisfaction is defective. Contact Reliefband[®] Technologies at 877-735-2263 for replacement within 30 days after date of purchase as indicated on the sales receipt. Some States do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

This warranty does not extend to any liability for medical or dental expenses or for any other direct, indirect or consequential damages caused by failure, defect or malfunction of any Reliefband[®] except as herein provided, whether such damage claim shall be based on contract, tort, breach of warranty, or otherwise. Some States do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty shall not apply to any Reliefband^{*} which has been repaired, tampered with, or altered by someone other than a duly authorized Reliefband^{*} Technologies representative, nor to any Reliefband^{*} which has been subjected to negligence, accident, mishandling or which has not been used in accordance with the enclosed instructions or for the stated purposes.

This warranty is expressly limited solely to the original purchaser (consumer) and does not extend to any transferee, assignee, or subsequent purchaser or user of any Reliefband^{*}. 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 Reliefband^{*} is limited to the purchase price paid by the original purchaser therefor. This warranty gives you specific legal rights, and you may also have other rights which vary from State to State.

Features and Components



Replacing the Batteries:

- 1. A low battery indicator (see Figure 4 at the top of the page) flashes when the batteries are low. (Approximately 10 hours of use remain depending on the power level used.)
- 2. Peel back the rubberized battery door at the end marked "OPEN HERE" (see Figure 5) and pull out the red colored tray.
- 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 6), the battery tray 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 tray into the ReliefBand. Doing so may damage the device.



Figure 3

Usage Tips:

- 1. 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 and vomiting symptoms. If you still have symptoms, then turn it back on immediately.
- 5. When finished using the ReliefBand, take it off your wrist and remove the gel from your wrist and the device with a tissue.
- 6. When not using Reliefband, be sure to turn the power off to extend battery life.
- 7. Store Reliefband in a safe, dry place. Keep it away from young children.

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

- 1. Make sure that the red battery tray 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 0r 6 times to secure the battery door.

reliefband[®] ···

Associated with General Nausea, Motion Sickness and Morning Sickness



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.



The signals generated by Reliefband[®] which are transmitted through the skin to the median nerve then travel through the body's nervous system to the part of the brain which controls nausea and vomiting.



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

HOW TO USE RELIEFBAND®



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 – two finger widths from the second crease in the wrist (nearest your elbow).

2 APPLY



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).





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

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