

INDICATIONS FOR USE: The ReliefBand® Voyager is indicated for use in the relief of nausea and vomiting due to motion sickness.

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

CONTENTS: (1) ReliefBand® Voyager Model RB-DL(I), Preinstalled Batteries (Not Replaceable), (1) Hypo-allergenic conductivity gel tube, and Instructions for Use.



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ReliefBand® is a registered trademark of Neurowave Medical Technologies. ReliefBand® technology is protected by US Patent No. 6.076.018; 6.567 695: 6 735 480: 7 127 288: 7 171 266 Janar Patent No. 4 168 380: 4 812 810: 4 220 129 LIK Patent No. 1 109 595 Canadian Patent No. 2 449 554 2 429 677 Designed in USA. MFD in Malavsia

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The ReliefBand® Voyager is a Class II medical device for the relief of nausea and vomiting due to motion sickness

DESCRIPTION OF THE RELIEFBAND VOYAGER: The ReliefBand® Voyager is a transdermal neurostimulation medical device incorporated into a wristband worn on the underside of the wrist. It provides relief from nausea and vomiting due to motion sickness by gentle electrical stimulation of the nerves in your wrist. Batteries will last up to 60 days based on approximate usage of device for 2 hours/day of active use at power level 3 or below. The batteries of the ReliefBand® Voyager are not replaceable.

#### SAFETY INFORMATION

#### \land WARNINGS:

- · 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 the ReliefBand<sup>®</sup> Voyager when the cause of nausea and vomiting symptoms is undiagnosed because those symptoms might be an important indicator of more severe health problems.
- The ReliefBand  $^{\odot}$  Voyager 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.
- The ReliefBand® Voyager 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.
- . The ReliefBand® Voyager 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.

#### **CAUTION**:

- . The ReliefBand® Voyager is splash-resistant. This product is resistant to splashing water (rain, waves, etc). Do not immerse ReliefBand® Voyager in water or wear while bathing. The ReliefBand® Voyager 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® Voyager's or accessory items, including conductivity gel. call 1-877-735-2263.

#### **ENVIRONMENTAL USE INFORMATION:** The ReliefBand® Voyager 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: The ReliefBand® Voyager 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). The ReliefBand® Voyager 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.

The ReliefBand® Voyager is classified as TYPE B equipment.

physiological effects as described in this guide.

IPX4 is splash resistant.

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

Attention, the ReliefBand® Voyager produces



This product contains natural rubber latex, which may cause allergic reactions.

#### **TECHNICAL DATA**

- .Teardrop shape 1.5" x 2" x 0.45" (3.81 x 5.08 x 1.14 cm) Size Weight... Approximately 1.2 ounces (34 grams) User Controls. .Push Button User Displays. On: Flashing Green LED at Power Level Flashing light indicator (see figure 7) Low Battery. Output Channels . Two electrodes Maximum Output.. .35mA .Two 3V lithium coin cell batteries Batterv
- Not replaceable, not rechargeable

#### QUESTIONS AND ANSWERS

#### When to use The ReliefBand® Voyager?

 You can use your ReliefBand<sup>®</sup> Voyager either before or after your nausea and yomiting symptoms start, and leave it on for as long as your symptoms last. If you are highly susceptible to motion sickness, apply the ReliefBand® Voyager 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 the ReliefBand® Voyager 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. 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 . If the stimulation increases, tighten the band at that point
- 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 the ReliefBand® Voyager?

. 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 up to 60 days based on approximate usage of device for 2 hours/day of active use at power level 3 or below, less time at higher power levels. Battery life depends on individual usage of product.

#### 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 remain depending on the power level used and how long you have used the device.

#### For additional FAQ, please see www.reliefband.com

#### TROUBLESHOOTING

The ReliefBand® Voyager 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 the ReliefBand <sup>®</sup> Voyager 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 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 7) indicates a low battery. Restart unit to see if power remains. Set the unit at a lower setting. If the flashing light continue: to flash, the batteries are running out of power.

#### LIMITED WARRANTY STATEMENT - ReliefBand® Voyager Model No. RB-DL(I)

Neurowave Medical Technologies warrants each new ReliefBand® Voyager 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.

The ReliefBand® Voyager is indicated for nonprescription (over-the-counter) use in relief of nausea and vomiting due to motion sickness. The ReliefBand® Voyager is not warranted to be effective in every case since relief varies dependent upon user characteristics.

Neurowave Medical Technologies's obligation under this Limited Warranty is expressly limited solely and exclusively to the replacement of the unit to which Neurowave Medical Technologies' satisfaction is defective. Contact Neurowave Medical 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® Voyager 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® Voyager which has been repaired, tampered with, or altered by someone other than a duly authorized Neurowave Medical Technologies representative, nor to any ReliefBand® Voyager 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® Voyager. Neurowave Medical 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® Voyager 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



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- The ReliefBand® Voyager

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# How to use the ReliefBand® Voyager

## $\mathbf{1}$ Find the Starting Location:

1) On the underside of either wrist, measure down two finger widths from the first crease below the hand (see figure 1).



Finding the starting location on your wrist for the device

 Using your index finger, locate the two tendons just under the skin in the center of the wrist. With your finger, find the area between the two tendons. This is where the device should be centered (*see figure 2*).





# 2 Apply The Gel:

1) For best results, clean and dry the area completely (see figure 3).



2) Place a small drop of conductivity gel on the spot on the wrist identified above (*see figure 4*). Spread the gel in a circle about the size of a quarter. Rub in to a sheen. Use of too much gel may reduce the intensity of stimulation.

# (NOTE: The gel should not be rubbed in completely. The area should appear shiny.)

Re-apply gel as needed (*see figure 4*) to maintain the best quality of sensation (about every 2-3 hours).

If there is excess gel, the ReliefBand<sup>®</sup> Voyager may not provide enough tingling. If you cannot feel the tingle, clean your wrist and the back of the ReliefBand<sup>®</sup> Voyager, then re-apply the gel. You can apply extra gel if the tingle feels too strong on level 1.

## How to turn on the ReliefBand Voyager:

Activate the device by pressing the POWER button once (*see figure 7*). This will activate the unit at power level 1. (NOTE: Power level 1 is the lowest setting and 5 is the highest setting.) The green light at level 1 will begin to flash indicating the unit is on. It also lets you know whether you are on setting 1, 2, 3, 4, or 5.

## Finding the Stimulation Point (CRITICAL STEP):

1) With the low battery symbol pointing towards the thumb, place the ReliefBand<sup>®</sup> Voyager on the spot on your wrist where the gel was applied. (Do not fasten the strap yet.) Slowly move the device around the gelled area until a tingling is felt in the palm of the hand and/or into one or both of the two middle fingers (*see figure 5*). This is your signal that you have found the right stimulation point. The tingling will cycle every four seconds.

Figure 5 Activate the device.

- If you do not feel the tingling described above, the ReliefBand<sup>®</sup> Voyager may not be properly located over the nerve, or the power level may be too low.
- 3) To increase the power level, press the POWER button. Each time you press the button, the power level will increase one setting. Adjust accordingly until you feel the highest comfortable level of stimulation. Tingling in the thumb or side of the hand indicates that you are stimulating the wrong nerve. Reposition the device to achieve the feeling in the palm and middle fingers.

If the device is set at level 5 and you press the POWER button once more, the device will return to level 1. To turn off the device, press and hold the power button for 3 seconds.



### Important:

You must feel stimulation in your palm and/or middle fingers for the ReliefBand® Voyager to work. If you do not, move the ReliefBand® Voyager around the underside of the wrist area between the two tendons until stimulation is felt. You will feel a tingling sensation in your palm and/or middle fingers when the ReliefBand® Voyager is in the proper wrist location. Stimulation will cycle every four seconds. If you still do not feel the stimulation, be sure you have it set at an adequate power setting (highest comfortable level) and adjust position.

## Adjusting Strap and Stimulation Level:

 Without moving the device from the stimulation point, tighten strap until it fits snugly but comfortably. (<u>It may be</u> necessary to reposition the device after the strap is tightened.) (see figure 6)

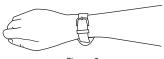


Figure 6

 Adjust the power level for your optimum balance of stimulation and comfort. Set the power level to the highest comfortable setting for maximum relief. The stimulation will cycle every four seconds.

REMEMBER: If you do not feel the tingling in the palm of your hand, you will not be getting the relief the ReliefBand<sup>®</sup> Voyager is capable of providing. Adjust location and power setting to the highest comfortable level to get maximum relief.

## How to turn off The ReliefBand® Voyager:

To turn off the ReliefBand<sup>®</sup> Voyager, press and hold down the POWER button for at least 3 seconds.

## Usage Tips:

- Try the ReliefBand<sup>®</sup> Voyager 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 the ReliefBand<sup>®</sup> Voyager off periodically to determine if you still have nausea and vomiting symptoms. If you still have symptoms, turn it back on immediately.
- When finished using the ReliefBand<sup>®</sup> Voyager, take it off your wrist and remove the gel from your wrist and the device with a tissue.
- 6) When not using the ReliefBand® Voyager, be sure to turn the power off to extend battery life.
- Store the ReliefBand<sup>®</sup> Voyager in a safe, dry place. Keep it away from young children.