reletex®
reliefband

INTENDED USES: Reletex® from Reliefband® is a prescription device indicated for use as: (1) An adjunct to antiemetics in reducing post-operative nausea; (2) Treatment of nausea and vomiting due to pregnancy (NVP) or morning sickness; and (3) Treatment of nausea and vomiting (NV) due to chemotherapy (intended for up to 150-hour therapy). In all such instances, Reletex® is for single-patient use.

IMPORTANT: Correct positioning of the Reletex® is important to achieve results. The position of Reletex® on the wrist area should be adjusted until stimulation is felt. A tingling sensation in the palm and/or middle fingers indicates that the device is correctly positioned on the underside of the wrist. Beginning at the lowest power level (1), increase the power level until stimulation is felt consistently and comfortably. Stimulation MUST be felt in the palm and/or middle fingers for Reletex® to provide relief.

⚠ **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of, a physician or other health care professional licensed in the state in which they practice.

CONTENTS: (1) Reletex®, (1) Hypo-allergenic conductivity gel tube, and Instructions for Use.

reliefband® technologies

For Customer Service: In the U.S.A call: (877) 735-2263
9:00 AM - 5:00 PM Mon - Fri CST

Reliefband Technologies, LLC, 220 Gibraltar Road, Horsham, PA 19044, USAReletex® is a trademark of Reliefband Technologies, LLC. US Patent No. 6,735,480, Canadian Patent No. 1,319,174, European Patent No. 05000552. Designed in USA, Manufactured in Malaysia

CE 0086 EC REP
EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

6003410 Rev. G

DESCRIPTION: Reletex® is a prescription transdermal neuromodulation device that is applied to the underside of the wrist. Reletex® emits electrical pulses that stimulate the underlying median nerve. The nerve signals generated on the wrist flow to the central nervous system where they work – via the vagus nerve – to normalize stomach rhythms that cause nausea. It is intended for use as (1) an adjunct to antiemetics in reducing post-operative nausea; (2) a treatment of nausea and vomiting due to pregnancy (NVP) or morning sickness; and (3) a treatment of nausea and vomiting (NV) due to chemotherapy (intended for delivery of up to 150-hour therapy). Reletex® can function with its included set of non-replaceable/non-rechargeable batteries for approximately 150 hours when used on setting 3.

⚠ WARNINGS

- Reletex® should only be used on the designated area.
- Do not use Reletex® when the cause of nausea and vomiting symptoms is undiagnosed.
- Nausea and vomiting are serious medical conditions; seek medical attention if symptoms continue.
- Reletex® is not a curative and should always be used under medical supervision. Treatment outcome may vary depending on patient characteristics and use of concomitant medications.
- Reletex® should be kept out of reach of children.
- 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. Consult with your physician if you have any other implanted devices.
- Reletex® should not be used above an IV line attached to a patient's arm. If a patient is using an IV line, Reletex® should be placed on the opposite arm.

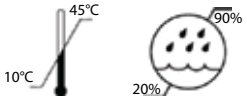
⚠ SIDE EFFECTS

- Isolated cases of skin irritation may occur where the electrodes touch the skin following long term application. Continued use of the device on irritated skin may cause injury.
- If local skin irritation (redness, swelling, blotches, blisters or itching on the wrist under the device) occurs, then discontinue use. If irritation does not resolve within 24 hours, then consult your doctor or other healthcare professional.

MAINTENANCE: Keep the electrode area on Reletex® clean. A damp cloth or alcohol wipe may be used. Do not put the device in water.

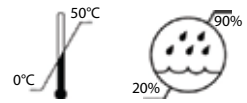
LOW BATTERY WARNING: Low battery indicator flashes when the batteries are low. Dispose device according to your local state/country laws

ENVIRONMENTAL USE INFORMATION:



Reletex® should only be used within the environmental ranges of: 10°C to 45°C (50°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 50°C (32°F to 122°F) and 20% to 90% 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.

⚠ **CAUTION:** The batteries used in this device may explode if mistreated. Do not recharge, disassemble, or dispose in fire.

The device and batteries do not contain any environmentally hazardous substances and can be disposed of normally following your local/countries laws.

Device is not recommended for use in conjunction with electrocautery or MRI equipment.

No modification of this device is allowed.

FCC INFORMATION: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two 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.

SAFETY INFORMATION: Reletex® complies with IEC-60601-1 (1988) Medical Electrical equipment, Part 1: General Requirements for Safety, including Am.No.1 (1991) and Am.No.2 (1995) and EN 60601-1. Reletex™ 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: EM55011 (CISPR 11). Radiated Emissions: EN 61000-4-2 Electrostatic Discharge Immunity; ENV 50204 and EN 61000-4-3 Radiated Electromagnetic Field Immunity.

Reletex® is classified as TYPE B equipment. **IPX4** Reletex® is splash-resistant.

⚠ **Attention: Reletex® produces physiological effects as described in this guide.**

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

NON STERILE

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
On/Power Level	Flashing light indicator
Low Battery	Flashing Red light indicator (See Figure 5)
Output Channels	Two electrodes
Maximum output	40mA (nominal)
Battery	Two 3V lithium coin cells Not replaceable, not rechargeable

QUESTIONS & ANSWERS

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

- After the device is turned on, adjust the positioning of the device on the wrist by moving it slightly up or down, and side-to-side until the maximum "tingling" feeling is felt. You will feel this tingling sensation in your palm and/or middle fingers when Reletex® is in the proper position. Stimulation will cycle every four seconds.
- If little or no tingling is felt, then read just the position of the device on the wrist and/or 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 and do not feel stimulation, curl your fingers slightly and turn the hand inward (thumb towards your body). If the stimulation increases, tighten the band at that point.
- If you are unable to feel the tingling on one wrist, then try the band on the opposite wrist. Use it on the wrist where you feel the most tingling.
- Re-apply gel as directed.

On which wrist should I wear the Reletex®?

- On the wrist that gives you the greatest tingling feeling at the lowest stimulation level.

How do I turn off the Reletex®?

- Press and hold down the Power Button (in the center of the device) for three (3) seconds.

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 desired.

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

- It may help to secure Reletex® in place by using strips of medical tape or a bandage to secure it over the wrist area while you sleep.

How long will the device remain active?

- Reletex® is designed to function for approximately 150 hours when used on setting 3. Actual battery life will vary depending on patient usage. The low battery indicator will signal that the batteries are low. Dispose of the device when batteries are depleted.

What if I find a decrease in stimulation after a couple of days use?

- Check the electrode area for gel and clean as needed. Only apply enough gel to achieve a sheen on the skin. Wipe gel from skin and device after each use.

LIMITED WARRANTY STATEMENT Reletex® PCN-3

Reliefband Technologies warrants each new Reletex® (excluding the batteries) to be free from defect in material and workmanship for 60 days. All other warranties, express and implied, are limited to 60 days from the date of purchase. Reletex® is intended for use as (1) An adjunct to antiemetics in reducing post-operative nausea (PON), (2) Treatment of nausea and vomiting due to pregnancy (NVP) or morning sickness; and (3) Treatment of nausea and vomiting (NV) due to chemotherapy. Reletex® is not warranted to be effective in every case since treatment outcome varies dependent upon patient characteristics. The obligation of Reliefband Technologies LLC 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. 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 Reletex® except as herein provided, whether such damage claim shall be based on contract, tort, breach or 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 Reletex® which has been repaired, tampered with or altered by someone other than a duty authorized Reliefband Technologies representative, nor to any Reletex® 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 Reletex®. 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 Reletex® 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.

DEVICE INSTRUCTIONS
READ ALL INSTRUCTIONS FIRST

1 Find the Correct Area on the Wrist for Stimulation:

Use either wrist. Looking at your palm, bend your wrist slightly toward you. Your fingers should be pointing toward your face. The correct area is in between the two tendons on the underside of your wrist, about 2 finger widths from the hand-wrist crease (See Figure 1). The device should be applied to clean and healthy skin.

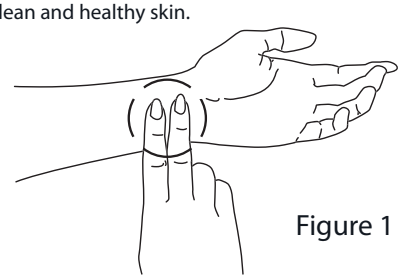


Figure 1

2 Apply Gel:

After finding the correct area on the wrist identified above, clean the skin as needed. Apply the gel and spread to a thin sheen about the size of a quarter or half-dollar (See Figure 2). Do not use too much or too little gel. Too much gel may reduce intensity of stimulation.

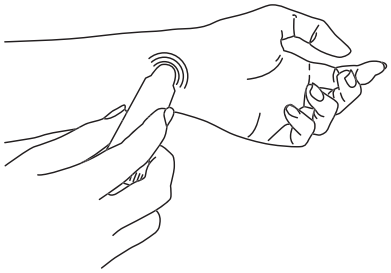


Figure 2

3 Attach to wrist, then activate:

Place the device over the gelled area and attach to wrist. Turn the device on by pressing the "on/off" symbol (See Figure 3 & 5). The blinking green light shows the current power level. Increase the power level to the highest comfortable setting by pressing the power button (on/off Symbol).

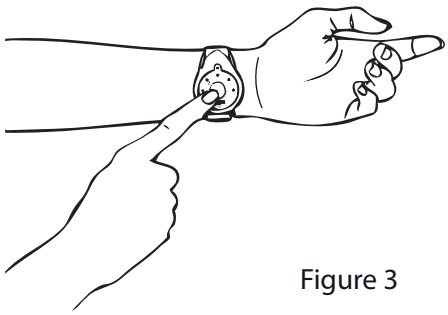


Figure 3

4 Re-apply Gel:

Re-apply gel as needed (See Figure 2) to maintain the best quality of sensation (about every 1 – 6 hrs).

NOTE: If there is excess of 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.

Cut off excess strap:

After placing device on wrist and adjusting the power setting, adjust strap to a comfortable position on wrist. Cut off the extra strap to fit your wrist size. (See Figure 4)

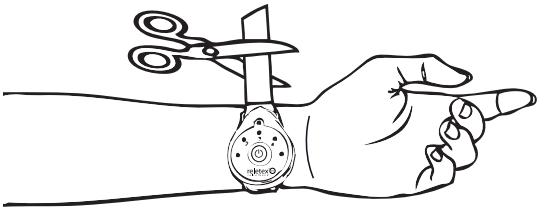


Figure 4

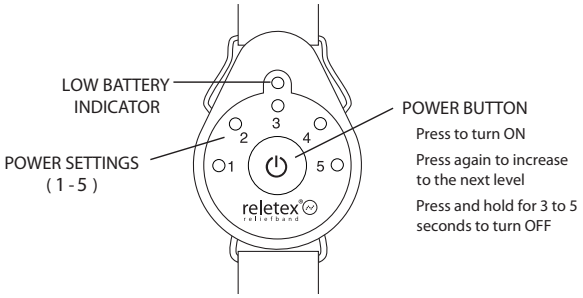


Figure 5