# reliefband

## CLINICALLY PROVEN[1] RELIEF FOR THE TREATMENT OF NAUSEA AND VOMITING

## INSTRUCTIONS FOR USE

[1] See cited references at the end of this document

P/N 6990006AW Rev C

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 and vomiting through gentle electrical stimulation of the median nerve.

Reliefband® 50 HOURS offers fifty hours of treatment time. The batteries of Reliefband® 50 Hours are non-replaceable.

RELIEFBAND® CLASSIC and FLEX will last approximately 150 hours of active use at power level 3 or below. The batteries of Reliefband® Flex are user replaceable. Replace batteries in unit when they become drained.

Reliefband® SPORT and PREMIER are rechargeable. A fully charged battery will last for approximately 18-25 hours of continuous use at the mid-power level or below.

**INDICATIONS FOR USE:**
Reliefband® is indicated for use in the treatment of nausea and vomiting associated with physician-diagnosed migraine, hangover, anxiety, motion sickness, chemotherapy and morning sickness from pregnancy, as well as an adjunct to antiemetics in reducing post-operative nausea. For over-the-counter use.

**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 a "tingling" sensation in your palm and/or middle fingers for Reliefband® to work. Replace batteries or charge unit prior to use.

**SAFETY INFORMATION WARNING:**
- No modification of this device is allowed.
- Reliefband® is not intended to be used with HF Surgical equipment or short wave or microwave therapy equipment.

Reliefband® SPORT and PREMIER Charging cord must be unplugged from power source when not in use.
Charging Cord:
Voltage Rating: 5±0.25V
Current Rating: 500mA Max

**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 some models contain batteries that should not be swallowed and/or may pose a choking hazard.
- Nausea and vomiting may be signs of a serious health problem. Contact a doctor if your nausea and vomiting persist.
- 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.
- If you are unable to tolerate any food or liquids or are experiencing weight loss you should contact your doctor.
- Reliefband® is IPX4 splash-resistant. This product is resistant to splashing water (rain, waves, etc). Do not immerse Reliefband® in water or wear while bathing, showering or swimming.
- Reliefband® Sport is IPX7 waterproof and can be submerged in water at a depth of one meter - for 30 minutes.

**SIDE EFFECTS:**
For some people, skin irritation (red or itchy skin, red bumps or small blisters) may occur beneath or around the 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:** Regularly clean your Reliefband® and wrist area, especially if perspiring or reapplying conductivity gel. Gel build-up on the electrodes may decrease stimulation causing a decrease in delivery of therapy. Remove gel-guild up by wiping with a clean, damp wipe using water or a small amount of rubbing alcohol. Do NOT use hand soap, body soap, dish soap, hand sanitizers, cleaning wipes or household cleaners which could get trapped beneath the band and cause irritation. Always dry the band well before putting it back on. Reliefband® must not altered in any way.

Reliefband® 50 Hour, Classic, Flex and Premier: Avoid immersion of the device in liquid.

**OPERATING CONDITIONS:**
Reliefband® should only be used within the environmental ranges of: 0°C to 38°C (32°F to 100°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:** This product contains batteries. The batteries used in this device may explode if not used or handled properly. Do not recharge, disassemble or dispose of them in fire. Consult your local waste agency for proper disposal guidelines.

**TECHNICAL INFORMATION:**
Reliefband® complies with:
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 /EN 60601-1:2006+A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 /EN 60601-1-2:2015+A1:2021 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10:2012+AMD1:2016+AMD2:2023 /EN 60601-2-10:2015+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

**TECHNICAL DATA**

| | 50 Hours | Classic | Flex |
|---|---|---|---|
| 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 LED Setting | | |
| Low Battery | Flashing LED indicator (see figure 1) | | |
| Output Channels | Two electrodes | | |
| Max Output | 40mA | | |
| Battery | Two 3v lithium coin cell batteries Non replaceable, not rechargeable | Two 3v lithium coin cell batteries (CR2025's) User replaceable, not rechargeable | |

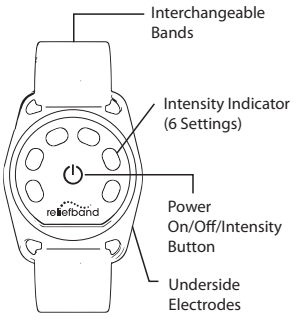
**TECHNICAL DATA**

| | Premier | Sport |
|---|---|---|
| Size | Rectangular shape - max case dimensions: 14.5 mm H x 23.5mm W x 4.1mm L | Round shape 2.05" x 1.57" x 0.47" (5.2 x 3.98 x 1.19 cm) |
| Weight | Approximately 50 grams | Approximately 1.2 oz (34 grams) |
| User Controls | Two Push Buttons: Power On/Off/intensity Down and Intensity Up | Push Button |
| User Displays | Blue LED logo (⁘) pulsing means is providing therapy. Ten diagonal blue LED bars indicate therapy power setting. Four circular blue LED segments indicate battery charge level. | On: Flashing Blue LED at Power Setting |
| Low Battery | When battery level registers 15% or less, a single LED segment will switch from static blue to flashing red. | Flashing LED indicator between yellow and blue indicates low battery. Flashing LED indicator between blue and red indicates critical low battery. |
| Output Channels | Two hypoallergenic surgical grade (316L) stainless steel electrodes | |
| Max Output | 40mA | |
| USB Charging Cable | Cable with custom magnetic connector | |
| Battery | Rechargeable Li-ion Polymer - IEC62133 standard. Battery life is approximately three years or 500 charge cycles. | Rechargeable Li-ion Polymer - IEC62133 standard. Battery life is approximately 800 charge cycles. |
| Waveform Characteristics | @500 ohm load: 40 mA 22.5V, 31Hz, 350us per pulse | @500 ohm load: 40 mA, 20V ±20%V, 31 hz, 350 us/pulse Max @1000 ohm load: 40 mA , 40V ±20%V, 31 hz, 350 us/pulse Max @1500 ohm load: 40 mA , 60V ±20%V, 31 hz, 350 us/pulse Max |
| Atmospheric Pressure | | 700 - 1060 hPa |

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

| **Reliefband 50 Hours, Classic, Flex** | |
|---|---|
| Situation | Recommended Solution |
| Green LED 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 LED is flashing at one of the 5 power settings. |
| No LEDs 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 LED flashing | The flashing LED 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 LED continues to flash, the batteries are running out of power. |
| **Reliefband Premier** | |
| Situation | Recommended Solution |
| Blue intensity LEDS and pulsing blue Therapy On LEDs are illuminated but (no stimulation is felt) | Move the contacts around the underside of the wrist to ensure proper placement. Increase the intensity using the Intensity Up Button. Re-apply a small amount of Reliefband® Conductivity Gel. Ensure gel is rubbed into a sheen. Be sure the strap is secure around the wrist. Be sure blue Intensity LEDs are illuminated at one of the ten intensity settings. |
| No LEDS illuminated | Briefly press the Power On/Off/Intensity Down button once to check if device is powered on. If power is on, the blue Intensity LED bars, the Battery/Charging Indicator segments and the Therapy On Indicator will flash. If nothing flashes, the device may be off. Press and hold the Power On/Off/Intensity Down button for 1.5 seconds to wake up the device. If no LEDs flash, the battery may be drained. To charge the battery - see the "Charging the Device" section. |
| Flashing red low battery LED illuminated | This indicates a low battery and 15% (2.4 hours at level 5) or less of charge remains. Recharge the battery as soon as possible – see "Charging the Device" section |
| **Reliefband Sport** | |
| Situation | Recommended Solution |
| Blue LED Flashing (No Stimulation is felt) | Move Reliefband® around the underside of the wrist to ensure proper placement. Increase the power setting. Re-apply a small amount of Reliefband® Conductivity Gel. Be sure gel is rubbed into a sheen. Be sure the strap is secure around wrist. Be sure Blue LED is flashing at one of the 6 intensity settings. |
| Blue LEDs Flashing between left and right (No Stimulation is felt) | Reliefband® will sense when it has a good connection to your wrist. If the device is removed from the wrist or both electrodes are not touching the wrist, it will enter waiting mode. Increase intensity settings until stimulation is felt. If you continue increasing past setting 6, it will return to "waiting mode" until you press it again to return to setting 1. |
| No LEDs Flashing | If Reliefband® is in "waiting mode" for more than a minute without the user setting it to an intensity, it will turn off on its own for battery saving. Check that device can turn on. Once activated, green LEDs will move from left to right, show battery level and then enter "waiting mode". Once you increase intensity, you should see blue LED at one of the 6 power settings (1-6). If Reliefband® does not turn on, battery may be drained (see Charging the Device section). |
| Blue and Yellow LED Flashing | Blue and Yellow flashing LED indicates a low battery. Set the unit at a lower setting. (See Charging the Device section). |
| Blue and Red LED Flashing | Blue and Red flashing LED indicates a critical low battery. Set the unit at a lower setting. The battery is running out of power and has about 4 hours of runtime use remaining. (See Charging the Device section). |

**SPORT**




**50 HOURS, CLASSIC & FLEX**

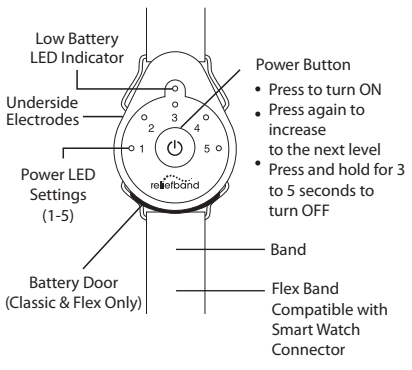
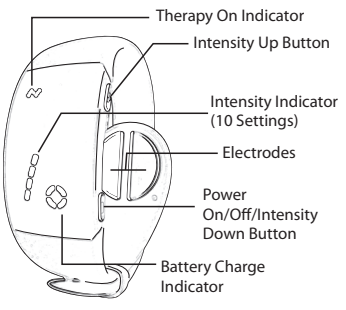



**Figure 1**

**PREMIER**



REPLACING THE BATTERIES - Classic and Flex

1. 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.)
2. 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.

**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

**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 strip (left end of the battery door) is inside the device.
3. Push left side of 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.

**CHARGING THE DEVICE**

1. Ensure Reliefband® is turned off prior to charging. Do not wear while charging.
2. Plug the USB Charging Cable into any standard UL approved 5 Volt USB charging port.
3. Attach the Magnetic Connector end of the USB Charging Cable to the Charging Port on the body of the Reliefband® device.
4. Blue LEDs (Premier) or Green LEDs (Sport) segment(s) will flash when in charging mode:

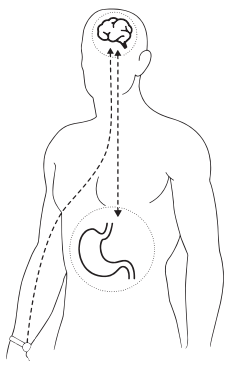
| | Premier (Charge) | Sport (Charge) |
|---|---|---|
| 1 LED segment | 1% - 25% | 16.6% |
| 2 LED segments | 26% - 50% | 16.6 - 33.2% |
| 3 LED segments | 51% - 75% | 33.3% - 49.9% |
| 4 LED segments | 76% - 100% | 50% - 66.6% |
| 5 LED segments | | 66.7% - 83.3% |
| 6 LED segments | | 83.4% - 100% |

5. Full charge is indicated when all LED segments remain constantly illuminated. Typically, it takes about 75 minutes to reach full charge. A 15-minute charge will give about 6 hours of continuous use at the mid-power level or below.
6. When not connected to the Reliefband, unplug the USB Charging Cable from the standard UL approved 5 Volt USB charging port.
7. When turning the Reliefband® Premier device on, the Battery Charge Indicator will indicate how much charge is left in the device. For Reliefband® Sport, green LEDs will go fast from left to right and will indicate how much charge is left on the device.
8. Reliefband® Premier, a single flashing red LED segment indicates 15% or less battery life remaining. Reliefband® Sport, a blue and yellow LED segment indicates 33.3% or less battery life remaining and a blue and red LED segment indicates 16.6% or less battery life remaining.

**USAGE TIPS**

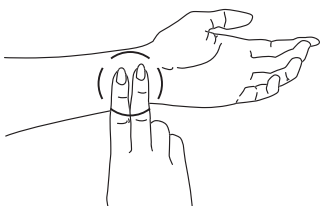
1. Try Reliefband® on each wrist and use it on the wrist where the greatest tingling is felt at the lowest setting.
2. For some people, applying and rubbing in the gel twice assists in nerve stimulation.
3. Reliefband® Conductivity Gel should be re-applied every 2-3 hours, any time after washing, or 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.
8. Avoid an excessive amount of gel; it could decrease the efficacy of the device. 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.

**HOW RELIEFBAND WORKS:**



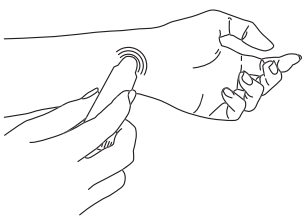
Reliefband stimulates the median nerve at the underside of the wrist with gentle pulses. The resulting impulses from the median nerve then travel through the body's nervous system to the part of the brain which controls nausea and vomiting. The pulses have a rebalancing effect, normalizing nerve messages from the brain to the stomach and reducing symptoms of nausea and vomiting.

**HOW TO USE RELIEFBAND**



**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**

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).

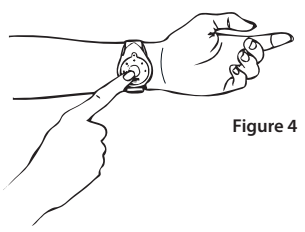


Figure 4

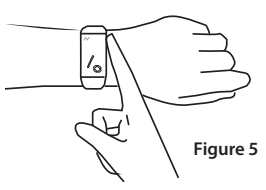


Figure 5

**3 ADJUST & ACTIVATE**

**50 HOURS, CLASSIC, FLEX & SPORT (Figure 4)**
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. Start at power level 1, increase stimulation until tingling is felt through median nerve distribution in palm and middle fingers at a comfortable level. Press " ⏻ " symbol for 3 seconds to turn off.

**PREMIER ((Figure 5)**
Press and hold the Power ON/OFF/Intensity Down Button (-) for 1.5 seconds to turn on or off. Press the intensity Up Button (+) once to set stimulation to level 1. Increase intensity until tingling is felt in palm and middle fingers. Set to the highest comfortable setting for maximum benefit. Press and hold the Power On/OFF/Intensity Down Button for 1.5 seconds to turn the device off.

**SYMBOLS GLOSSARY**

| Symbol | Symbol Title | Standard Reference | Explanatory Text |
|---|---|---|---|
| | Manufacturer | ISO 15223-5.1.1 | Indicates the medical device manufacturer |
| | Refer to Instructions Manual/-Booklet | ISO 7010-M002 | Read these instructions before using Reliefband |
| LOT | Batch Code | ISO 15223-5.1.5 | Indicates the manufacturer's batch code so that the batch or lot can be identified |
| REF | Catalogue Number | ISO 15223-5.1.6 | Indicates the Reliefband device's catalogue number so that the medical device can be identified. |
| | Keep Dry | ISO 7000-0626 | To indicate that the transport package shall be kept dry. |
| | Keep Away From Sunlight | ISO 7000-0624 | To indicate that transport package shall be not be exposed to sunlight. |
| | Temperature Limit | ISO 15223-5.3.7 | Indicates the temperature limits to which the Reliefband can be exposed. |
| | Humidity Limitation | ISO 15223-5.3.8 | Indicates the range of humidity to which the Reliefband can be safely exposed. |
| | This Way Up | ISO 7000-0623 | To indicate the correct upright position of the transport package. |
| | Fragile, Handle with Care | ISO 7000-0621 | |
| | Caution | ISO 7000-0434A | ATTENTION: Reliefband produces physiological effects as described in this guide. |
| LATEX | Contains or Presence of Natural Rubber Latex | ISO 15223-5.4.5 | Reliefband Classic contains natural rubber latex, which may cause allergic reactions. |
| LATEX | No Latex | N/A | Indicates the Reliefband 50 Hours, Flex, Premier and Sport do not contain natural rubber or dry natural rubber latex as a material of construction within the device or their packaging. |
| | Type BF Applied Part | IEC 60417-5333 | Reliefband is classified as a TYPE BF Applied Part |
| IPX4 | IP Rating | IEC 60529 | Reliefband 50 Hours, Classic, Flex and Premier are splash-resistant. |
| IPX7 | IP Rating | IEC 60529 | Reliefband Sport is IPX7 waterproof and can be submerged in water at a depth of one meter, for 30 minutes. |
| | Waste Electrical and Electronic Equipment | IEC 60417-6414 | **For European Union:** Environmental Protection Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your Local Authority or retailer for recycling advice. **California Only:** Perchlorate Material - Special handing may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate |

**LIMITED WARRANTY STATEMENT -**
**Model:** Reliefband®
Reliefband® Technologies warrants each new Reliefband® (exclusive of batteries) to be free from material defect in workmanship and materials for 60 days from the date of purchase, the "Warranty Period." This limited warranty is subject to (a) the customer notifying Reliefband® Technologies within 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 and vomiting associated with physician-diagnosed migraines, hangovers, anxiety, motion sickness, chemotherapy and morning sickness from pregnancy. Reliefband is also indicated as an adjunct to antiemetics in reducing postoperative nausea. 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.

[1]References:
2. White PF et al. Anesth. 2002;97(5): 1075-81
3. Treish I, et al. Support Care Center. 2003;11:516-21
4. Ertas G, et al. Holistic Nursing Practices. 2015;29 (1)

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EC REP

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Reliefband Classic and Flex are not available in Australia

reliefband technologies

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Designed in USA. Made in Malaysia.

In the U.S.A., call 1-877-735-2263
9:00 AM - 5:00 PM Mon. - Fri. CST