



Rx Only

INTENDED USES: PrimaBella™ is an FDA cleared device that is indicated for use in the treatment of nausea and vomiting due to pregnancy (NVP) or morning sickness. PrimaBella™ is for single patient use.

IMPORTANT: Adjust PrimaBella™ and position on the wrist area until stimulation is felt. You will feel a tingling sensation on the palm and/or middle fingers when PrimaBella™ is in the proper wrist location. Beginning at the lowest setting (I), increase power level until stimulation is consistently felt. Stimulation must be felt in the palm and/or middle fingers for PrimaBella™ to provide relief.

CAUTION: This product contains natural rubber latex, which may cause allergic reactions. Federal Law (USA) restricts this device to sale by, or by the order of, a licensed health care provider with prescribing authority in the state in which they practice.

CONTENTS: (1) PrimaBella™ Neuromodulation Medical Device Model WB-DL(D), (1) Hypo-allergenic conductivity gel tube, and Instructions for Use.

Manufactured for
NEUROWAVE
MEDICAL TECHNOLOGIES
200 East Randolph Street
Chicago, IL 60601 USA
PrimaBella™ is a trademark of Neurowave Medical Technologies.
US Patent No. 6,735,480
Canadian Patent No. 1,319,174
European Patent No. 05000552

Manufactured in Malaysia
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In the U.S.A., call 1-877-735-2263
6003840 Rev. X3



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SAFETY INFORMATION: PrimaBella™ complies with IEC-601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, including Am. No. 1 (1991) and Am. No. 2 (1995) and EN 60601-1. PrimaBella™ 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 Emission: EN61000-4-2 Electrostatic Discharge Immunity; ENV 50204 and EN 61000-4-3 Radiated Electromagnetic Field Immunity.

IPX4 PrimaBella™ is classified as TYPE B equipment.
PrimaBella™ is splash resistant.

Attention, PrimaBella™ produces physiological effects as described in this guide.
California Only: Perchlorate Material – Special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate.

TECHNICAL DATA

SizeTeardrop 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 green light indicator
Low Battery.....Flashing red light indicator
Output ChannelsTwo electrodes
Maximum Output40mA (nominal)
BatteryOne 3V lithium coin cell (CR2025) and One 3V lithium coin cell (CR2016) pre-installed
Not replaceable, not rechargeable

HOW TO USE:

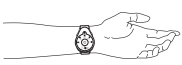
1. Find the correct area



2. Apply gel



3. Attach to wrist



4. Activate



DESCRIPTION: PrimaBella™ is a transdermal neuromodulation device that generates uniquely programmed pulses to stimulate the median nerve on the underside of the wrist. These pulses (specific in waveform, frequency and intensity) create electrical signals that travel to the central nervous system and the higher emetic center in the brain. These signals act to positively modulate neural pathways—via the vagus nerve—thus restoring normal gastric rhythm. PrimaBella™ is indicated for the treatment of nausea and vomiting due to pregnancy (NVP) or morning sickness. PrimaBella™ will last approximately 100 hours when used on setting III.

WARNINGS:

- PrimaBella™ should only be used on the designated area.
- Do not use PrimaBella™ when the cause of nausea and vomiting symptoms are undiagnosed.
- Nausea and vomiting are serious medical conditions; seek medical attention if symptoms continue.
- PrimaBella™ is not a curative and should always be used under medical supervision. Treatment outcome may vary depending on patient characteristics and use of medications.
- 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.
- PrimaBella™ should not be used above an IV line attached to a patient's arm. If a patient is using an IV line, PrimaBella™ 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, swollen, blotchy or itching on the wrist under the device) occurs, discontinue use. If irritation does not disappear within 24 hours, consult your doctor or pharmacist.

MAINTENANCE: Keep the electrode area 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. (Approximately 10 hours of use remain depending on the power level used.)

ENVIRONMENTAL USE INFORMATION: PrimaBella™ 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 of in fire.

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

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

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.

QUESTIONS AND ANSWERS

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 PrimaBella™ is in the proper wrist location. Stimulation will cycle every four seconds.
- If little or no tingling is felt, increase the power level. This device has five levels of stimulation: I, II, III, IV and V (level V is the highest setting). If you are at level V 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.
- Try the band on the opposite wrist. Use it on the wrist where you feel the most consistent tingling. Increase or decrease power setting until stimulation is consistently felt.
- Re-apply gel as directed.

On which wrist should I wear PrimaBella™?

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

How do I turn off PrimaBella™?

- Press and hold down the power button (⏻) 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 directed.

How can I be sure PrimaBella™ stays in place at night?

- It may help to secure PrimaBella™ in place by using strips of medical tape or an ace bandage to secure it over the area while you sleep.

How long will the batteries last?

- The batteries should last approximately 100 hours when used on power level III. Low battery indicator flashes when the batteries are low. Actual consumption depends on individual usage of the product. Dispose of the device when batteries are depleted.

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

- Check 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 - PrimaBella™ Medical Device Model No. WB-DL(D)

Neurowave Medical Technologies warrants each new PrimaBella™ Neuromodulation Medical Device Model No. WB-DL(D) to be free from defect in material and workmanship for approximately 100 hours of continuous or intermittent use exclusive of batteries. All other warranties, express and implied, are limited to 60 days from the date of purchase.

PrimaBella™ is intended for use in the treatment of nausea and vomiting (NV) due to pregnancy. PrimaBella™ is not warranted to be effective in every case since treatment outcome varies dependent upon patient characteristics.

The obligation of Neurowave Medical Technologies 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 1-877-735-2263 for repair or replacement within the warranty period. 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 PrimaBella™ 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 PrimaBella™ which has been repaired, tampered with or altered by someone other than a duly authorized Neurowave Medical Technologies representative, nor to any PrimaBella™ 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 PrimaBella™. 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 PrimaBella™ is limited to the purchase price paid by the original purchaser therefore.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.



PrimaBella™ Instructions

Read All Instructions First

1 Find the Correct Area:

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).

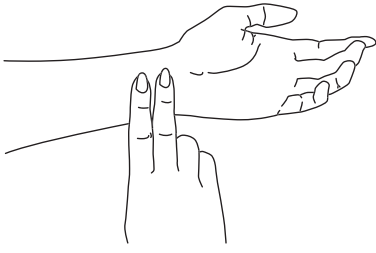


Figure 1

2 Apply Gel:

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

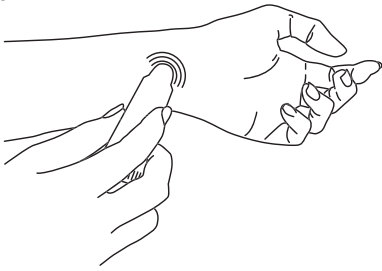


Figure 2

3 Attach to Wrist:

The wristband comes already laced through the metal clasp. Just loosen enough to slip over your hand onto your wrist. Place PrimaBella™ over the gelled area and then adjust the wristband by pulling the elastic end until an appropriately tight fit is reached. The fit should be snug enough not to move around on your wrist but not so tight that it could affect blood flow to your hand.

4 Activate:

Turn PrimaBella™ on by pressing the power button (⏻). The blinking green light shows the power setting. Beginning at the lowest setting (I), increase the power setting by pressing the power button until stimulation is consistently felt (see Figure 3 below and Figure 4 at the top of the page).

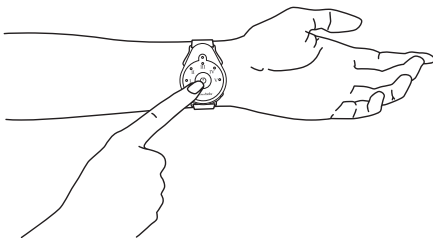


Figure 3

5 Re-apply Gel:

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

Note: If there are blobs of gel, PrimaBella™ may not provide enough tingling. If you cannot feel the tingle, clean your wrist and the back of PrimaBella™, then re-apply the gel. You can apply extra gel if the tingle feels too strong on level I.

PrimaBella™

Features and Components

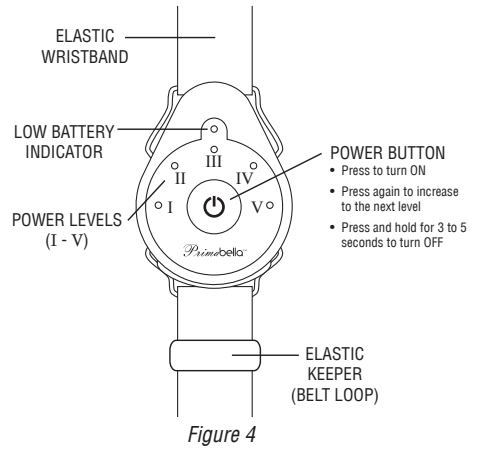


Figure 4

Lacing the Elastic Band Through the Clasp:

If you pull the wristband all the way out of the metal clasp, follow these steps to re-lace it.

1. First insert the end of the wristband through the middle slot of the metal clasp (see Figure 5 and 7).
2. Then, feed it back through the open end slot of the clasp (see Figure 6 and 7).
3. Any additional wristband can be tucked under the keeper (belt loop).

The elastic wristband is designed to fit most wrist sizes. Simply adjust the wristband by pulling the end through the metal clasp until an appropriately tight fit is reached. The fit should be snug enough to not move around on your wrist but not so tight that it could affect blood flow to your hand.

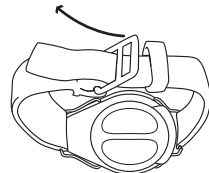


Figure 5

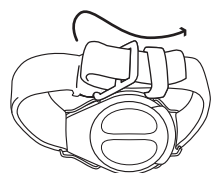


Figure 6

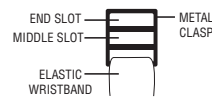


Figure 7