



Vibrance® Pelvic Trainer

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User Guide & Warranty

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Manufactured by:

**Bioinfinit (M) Sdn. Bhd.**

No. 21, Jalan 4/62A, Bandar Menjalara, Kepong

52200 Kuala Lumpur

Malaysia

Phone: +603-62733068

Fax: +603-62720093

info@mybioinfinit.com

www.mybioinfinit.com

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Thank you for choosing Vibrance Pelvic Trainer, the easiest to use, FDA Cleared, Clinically Proven solution for your pelvic health.

## **INDICATIONS FOR USE**

The Vibrance Pelvic Trainer (VPT) is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence.

## **ABOUT BIOINFINITY**

Bioinfinity is a medical device manufacturer aiming to introduce innovative medical technology that can significantly improve quality of life. It is the manufacturer of the award-winning Vibrance Pelvic Trainer, winner of the 2012 Medical Device Design Excellence Award. The Vibrance Pelvic Trainer helps women all over the world strengthen their pelvic floor muscles.

## **VIBRANCE PELVIC TRAINER INCLUDES:**

1. Vibrance Pelvic Trainer
2. 3 Training Sleeves
3. User Guide and Warranty

## VIBRANCE PELVIC TRAINER DESCRIPTION



The Vibrance Pelvic Trainer (VKD700) is an intra-vaginal exercise device intended to strengthen the pelvic floor musculature by offering resistance to an individual's voluntary contractions of these muscles. The Vibrance Pelvic Trainer incorporates an active vibration biofeedback mechanism for the identification of the pelvic floor muscles, and the training sleeves provide graduated resistance levels for the progressive strengthening of the pelvic floor muscles.

The User Guide provides information and instructions, which must be followed to ensure safe performance of the Vibrance Pelvic Trainer. The User Guide also contains warnings and precautions, which must be observed at all times.

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## CONTRAINDICATIONS

Do not use this device:

1. When using other intra - vaginal products such as diaphragms, tampons, and pessaries.
2. During menstruation if user feels uncomfortable.
3. During six-week postpartum period after childbirth. Pregnant women should check with their doctor.
4. For a minimum of six weeks after genitourinary or pelvic surgical procedures.
5. If user has any urinary tract infections.
6. Do not share your Vibrance Pelvic Trainer with others. It is for your individual use only.
7. Do not use if you have severe pelvic pain.
8. Do not use during sexual intercourse. It is not a contraceptive device and will not protect against pregnancy or Sexually Transmitted Infections (STIs).
9. Do not use during active phase of any STIs.

10. If you use an Intrauterine Device (IUD), discuss using this product with your doctor.
11. Do not use this device for other than its intended purpose, as described in the instruction manual.
12. This device is not intended to be used by children.

## WARNINGS

1. Avoid exposure to heat and do not place device in or near flammable materials.
2. If you are unsure about using this product, consult your doctor.
3. You should only use mild soaps and disinfectant to clean the Vibrance Pelvic Trainer. You should not use bleach, hydrogen peroxide or other harsh disinfectants as this may cause damage to the silicone rubber.
4. Do not short circuit any electrical components of this device.
5. Do not accept product if QC Seal is broken prior to purchase.
6. Use batteries by reputable establishments. It is recommended to use Bioinfinity supplied batteries. The Battery specification is CR1220.



## PRECAUTIONS

1. Read the instructions carefully before use.
2. Product to should be stored at room temperature.

## DIRECTIONS FOR USE

Wash your hands and clean the device before each use.

Once the batteries have been inserted and the bottom cap screwed on tightly, the Vibrance Pelvic Trainer is ready for use. It is recommended to start using the device without any additional training sleeve.

After sanitizing hands, test the device by squeezing the device with your fingers. The device should vibrate, which indicates that the Vibrance Pelvic Trainer is active and ready to be used.

If necessary, apply an appropriate amount of water-based personal lubricant cleared by the FDA. Lie on your back and gently insert the VPT into the vagina.



The wings of the sheath should fit snugly against the vagina. The oval block should cling snugly to the vagina, as shown in the picture below, without any space between. You should clench and contract the pelvic floor muscles like you are holding a stream of urine with force until it vibrates. The vibration means that you have exercised the correct muscles in order to begin the proper exercising of the pelvic muscles.



### **Tips to Trigger the Vibration**

1. When starting out, try doing the exercise with the VPT without using the training sleeves, until you can consistently trigger the vibration on the VPT
2. Make sure you are not using abdominal or buttocks muscles

3. Imagine holding in urine or squeezing your rectum
4. You should imagine lifting up your pelvic floor. The VPT should be gently drawn into the vaginal canal.

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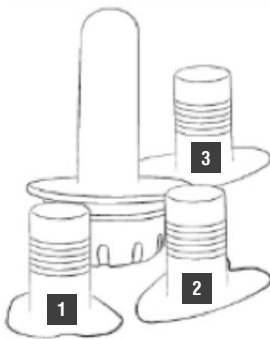
**Note:** It may take you a few days to be able to consistently find and use your pelvic floor. You will know you are using the correct muscle group when you can consistently trigger the vibration on the Vibrance Pelvic Trainer.

Once you are able to consistently trigger the vibration on the Vibrance Pelvic Trainer with your pelvic floor muscles, you may do the following routine:

- Clench your muscles and hold for 5 seconds, then relax for 5 seconds. Repeat 50 times.
- Clench your muscles and hold for 2 seconds, then relax for 3 seconds. Repeat 50 times.
- It is recommended to do one session in the morning and one in the evening daily.

## Using Strength Enhancing Sheaths

The Vibrance Pelvic Trainer has three Strength Enhancing Sheaths, numbered underneath the wings from 1 (Easiest) to 3 (Hardest). Once you are able to exercise with the base sheath very easily, generally after two weeks of twice daily exercise, you can increase the challenge of the exercise with the Strength Enhancing Sheaths. The Strength Enhancing Sheaths provide resistance for the pelvic floor muscles to work against, helping you to build greater strength.



**1** Easiest    **2** Hard    **3** Hardest

To use a training sleeve, pick the level of difficulty desired. The training sleeve have numbers under their wings, 1 is the easiest and 3 is the hardest. If you find it challenging to trigger the vibration at a higher level, try with a lower level for at least 2 weeks.

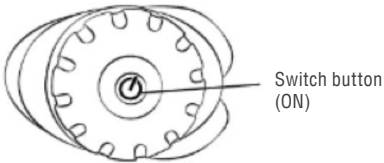
The training sleeve is slipped over the base sheath. When you are ready to move to the next level, remove the training sleeve and slip the next sleeve. Slide the sheath straight down the body of the Vibrance Pelvic Trainer (instead of twisting it) for best results.

**Note:** Do not remove the Base Sheath on the Vibrance Pelvic Trainer Main Unit.

## AUDIO GUIDED TRAINING

The Vibrance Pelvic Trainer has an audio-guided training feature that helps you count the timing and repetitions.

The button at the bottom of the Vibrance Pelvic Trainer enables the audio-guided training.

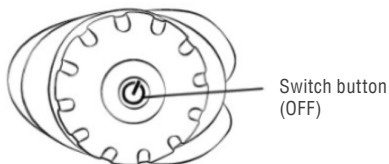


After pressing the button, the device will wait 5 seconds, allowing you to position the Vibrance Pelvic Trainer in your vagina. It will then start to beep; the beep indicates that you should contract the pelvic floor muscle. The audio-guided training helps to count the timing and repetition of the contractions accurately.



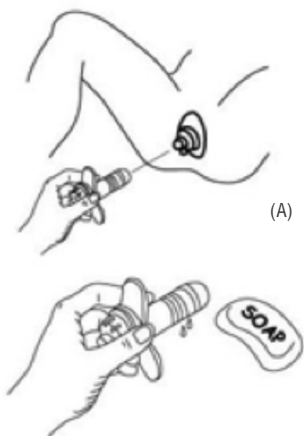


To switch off, simply press the button again.



## WASHING AND STORAGE OF YOUR VIBRANCE PELVIC TRAINER

Please clean the Vibrance Pelvic Trainer before and after each use.





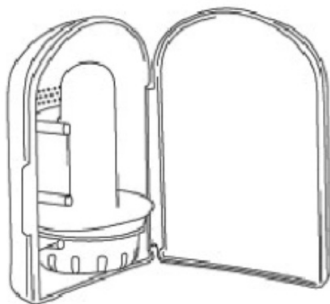
The main body and training sleeves should be cleaned separately. When the bottom cap is screwed on tightly, the main body is waterproof.

Please ensure that the bottom cap of the main body is screwed on tightly.

Apply Vibrance Cleanser (or a mild soap) or disinfectant to the device and resistance sheath, and rinse thoroughly.

Please ensure that all of the soap or disinfectant has been rinsed off, wipe, then air dry the Vibrance Pelvic Trainer in its designated casing.

Store Vibrance Pelvic Trainer in a cool, dry and safe place.



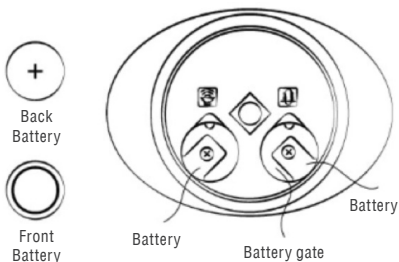
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**Warning:** You should use mild soaps and disinfectant to clean the Vibrance Pelvic Trainer. Do not use bleach, hydrogen peroxide or other harsh disinfectants as this may cause damage to the silicone rubber.

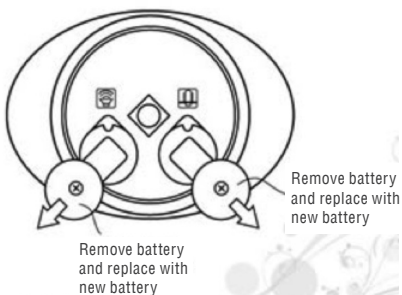
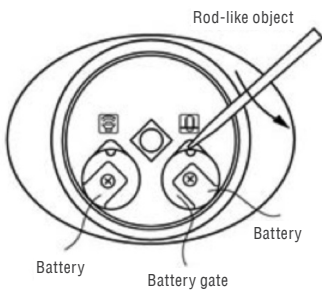
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## BATTERY

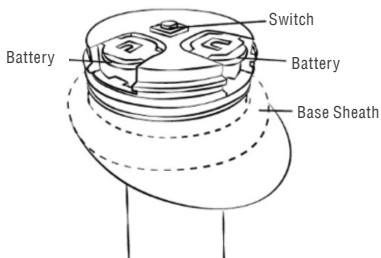
The Vibrance Pelvic Trainer uses CR1220 batteries. To insert the batteries, please ensure that the flat (+) side is facing downwards (away from the direction of the shaft). Slide the batteries into the battery slots, one for the vibration and one for the audio guided training.



The picture below illustrates the correct way to change the batteries. Rotate the lower cover anti-clockwise to open. Remove the batteries with a rod-like object, and insert the new batteries. Then place the cover back onto the base, and rotate clockwise to lock and close the lower cover.



Please ensure that the base sheath completely covers the base skirting and screw the bottom cap tightly to ensure waterproofing.



Take precautions to ensure that the batteries are placed in the correct position.

The batteries should be replaced if vibration is weak and the sound battery if sound is weak. When washing the device or changing batteries, please take care to ensure that the waterproof rubber base sheath is properly adjusted and that the cap is screwed tightly to maintain the waterproofing.



## **Disposal of the battery**

Lithium batteries are best disposed of as a non-hazardous waste when fully or mostly discharged. The Federal Environmental Protection Agency (EPA) (governed by the Resource Conservation and Recovery Act (RCRA)) do not list or exempt Lithium as a hazardous waste. However, if waste lithium batteries are still fully charged or only partially discharged, they can be considered a reactive hazardous waste because of significant amounts of unreacted, or unconsumed lithium remaining in the spent battery. The batteries must be neutralized through an approved secondary treatment facility prior to disposal as a hazardous waste (as required by the U.S. Land Ban Restrictions for the hazardous and Solid Waste Amendments of 1984.) Secondary treatment centers receive these batteries as manifested hazardous waste under code "D003 - reactive." Button cells are exempt because they contain so little lithium and therefore can be disposed of in the normal municipal waste stream. Use a professional disposal firm for disposal of mass quantities of undischarged lithium batteries.

**DO NOT INCINERATE** or subject battery cells to temperatures in excess of 212°F. Such treatment can cause cell rupture.

Dispose in accordance with appropriate regulations. Open cells should be treated as hazardous waste.

*For information about recycling or proper disposal, consult your local solid waste (garbage) collection or disposal organization.*

## **CORRECT DISPOSAL OF THIS PRODUCT (WASTE ELECTRICAL ELECTRONIC EQUIPMENT)**

This product should not be disposed of with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

*For information about recycling or proper disposal, consult your local solid waste (garbage) collection or disposal organization.*

## PRODUCT SPECIFICATIONS

### **Use of this device should take place at:**

Temperatures between 5°C + 40°C

A relative humidity up to max 93%

### **Transport and store this device at:**

Temperatures between -13°F+158°F (-25°C-+70°C)

A relative humidity of 15% to 93%

Atmospheric pressure of 700 hPa to 1060 hPa

## WARRANTY

1. This product is guaranteed by Bioinfinity to be free from manufacturer's defects within 12 months from the date of original purchase.
2. If the main body of the Bioinfinity Vibrance Pelvic Trainer is found to be faulty in manufacture within the warranty period, it will be replaced free of charge on an exchange basis only by Bioinfinity and its authorized agents.
3. Proof of purchase and this warranty card must be presented together with defective device to the authorized dealer for warranty claim.
4. This warranty does not cover damages due to improper use, improper maintenance, unsuitable storage, accidents, battery leakage and normal wear and tear. Warranty is not applicable if physical or heat damage is apparent on the product.
5. Bioinfinity offers no other warranty either express or implied. Any warranty which may be implied by law shall expire within the period of the express warranty. Under no circumstances shall Bioinfinity be held responsible for remote or consequential damages.

## TROUBLESHOOTING & FREQUENTLY ASKED QUESTIONS

- 1. If you are unable to trigger the vibration with your pelvic muscles:**
  - a. Make sure that you are not using your abdominal muscles or buttocks muscles.
  - b. Imagine that you are trying to hold in your urine.
  - c. Try using a lower level of resistance sheath; this will make the exercise easier.
  - d. If the device slips out, try “lifting up” your pelvic floor. If the exercise is done correctly, the device should be drawn into the vaginal canal.

- 2. When should I replace my Vibrance Pelvic Trainer (VPT)?**

With proper care, the VKD is expected to give you lasting service.

Typical lifespan of this device is two years following proper maintenance instructions. Please replace your device if any signs of damage or wear (e.g. cracking) of any components and hardening of silicone rubber sheath are noted.

**Note:** Over time, the medical grade silicone rubber might develop a slightly darker tinge. This is normal and will not affect the comfort or functionality in any way.

## SYMBOL LEGEND



Manufacturer



Catalogue number



Lot number



Consult Instructions for Use



Do Not Use if Package is Damaged



Date of Manufacture



Authorized Representative in the  
European Community



Use By



Non-Sterile



Emergo Europe  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands

**Australian Sponsor:**  
Emergo Australia  
Level 20, Tower II Darling Park  
201 Sussex Street  
Sydney, NSW 2000  
Australia



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