

1. ABOUT THIS PRODUCT

"Women's Guardian" Pelvic Muscle Exercise Machine (SKU: PMEM-16)

PMEM-16 is a brand new product, consulting with domestic and foreign physicians specialized in obstetrics/ gynecology and urology, developed by Women's Guardian Biotechnology, Inc. It grants patterns in many countries and wins the Gold Medal of Grand Prix of the Geneva International Exhibition of Inventions. PEME-16 has optimal functionality and waterproof design; it is easy to use and clean. The proprietary and patented design allows women to set up appropriate pressure series and strengthen their pelvic floor muscles based on the degree of vaginal relaxation. PEME-16 provides the best solution to train the pelvic floor muscle accurately.

2. INDICATION FOR USE

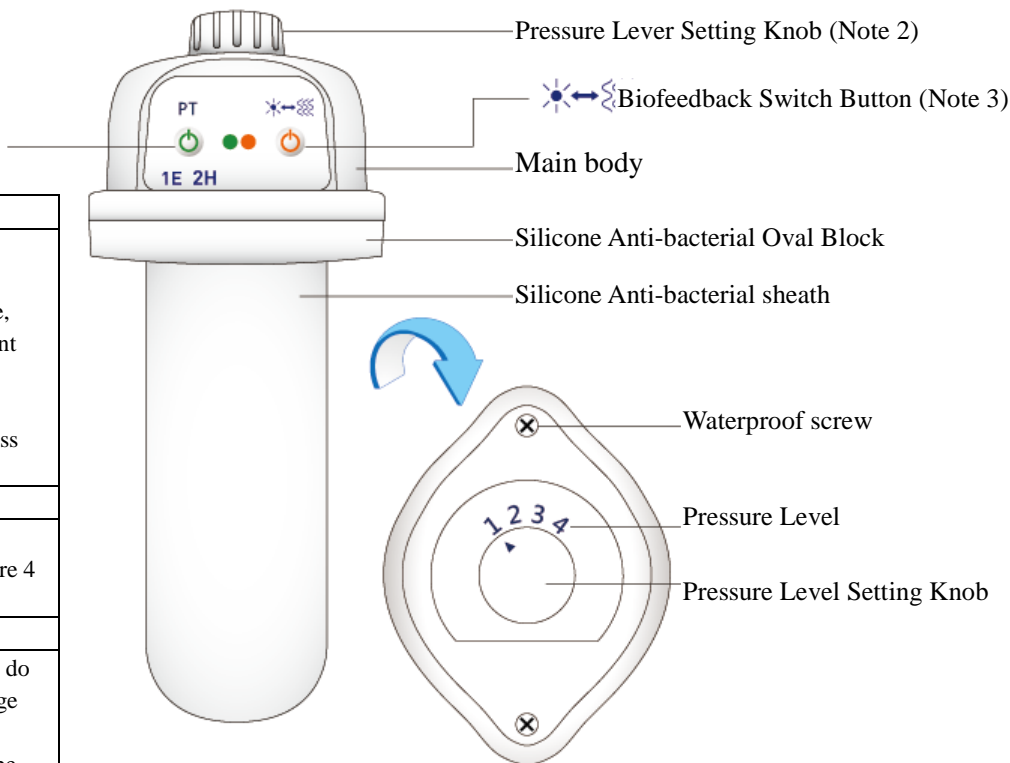
PMEM-16 has to programmed exercise modes to train the pelvic floor muscle (strength of vaginal muscle) leading by LED and improve the condition of urge to urinate, stress urinary incontinence, and vaginal relaxation. It incorporates with biofeedback functions(LED or Vibration) to guide users to train right group muscles.

3. PRODUCT DRAWING

Functions of PT Button:

1. Stand-by
2. Mode Switch Key (Note 1)

| |
|--|
| <p>PT Button (Note 1)</p> <p>EASY Mode: Press PT button 1 time. HARD Mode: Press PT button 2 times. Switch mode: When the device is in use, press PT button 1 time to stop the current mode and press again to enter EASY or Hard mode. Turn off: When the device is in use, press PT button 1 time to stop.</p> |
| <p>Pressure Level Knob(Note 2)</p> <p>Adjust the pressure level based on the condition of vaginal relaxation. There are 4 levels for setting.</p> |
| <p>Biofeedback Switch Button(Note 3)</p> <p>Biofeedback function is to guide you to do pelvic floor exercise correct by an orange LED or vibration. The default setting is vibration. The biofeedback setting can be switched by pressing this button at any time when the device is in use. It is inactive when the power is off</p> |



4. PRODUCT SPECIFICATIONS

Dimensions (L x W x H): 120 mm x 69 mm x 51 mm

Weight: 60 g

Temperature to use the device: 5°~40°C

Maximum Humidity of operation: 93%

Temperature to transport and store this device: -25°~70°C

Humidity to transport and store this device: 15%~93%

Maximum altitude to use this device: 2000 m

Battery specification: CR-1220 3V*2

Maximum operation and atmospheric pressure range: 700hPa~1060hPa

5. WARNING

- Do not use this device for any other than its intended purpose.
- Do not share your PEME-16 with others. It is for your individual use only.
- This is not intended to be used by children.

6. CONTRAINDICATIONS

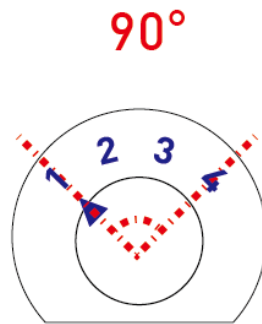
Do not use this device

- If you have any urinary tract infection
- If you have severe pelvic pain
- If your vagina has bleeding or injury
- During sexual intercourse
- At the final stage of pregnancy
- During active phase of any Sexual Transmitted Infections(STIs)
- When the other intra-vaginal products are using such as pessaries, diaphragms, and tampons.
- If you use an Intrauterine Device (IUD), discuss with your doctor for instruction.
- During menstruation if you feel uncomfortable.
- During six-week postpartum period after childbirth. Pregnant women should discuss with their doctor for instruction

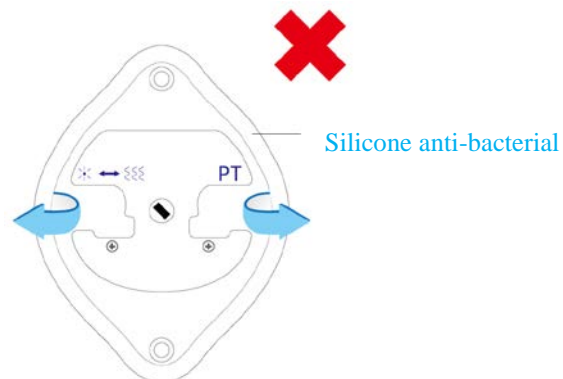
- A minimum of six weeks after genitourinary or pelvic surgical procedures.
- Women have no sex experience.
- Avoid training when there is an urge of urination.

7. NOTES

- While having the problem to trigger PMEM-16 as contracting your pelvic floor muscle, set the pressure level at 1 to maximize device's sensitivity(Fig.1)
- For pressure level setting, rotate the knob clockwise/ counterclockwise within approximately 90 degree from 1 (lowest) to 4 (highest). Do not over rotate the knob exceed 90 degree as this may cause damage to the axis.(Fig2)



- Do not remove the silicone oval block and sheath form main body as this may affect the waterproof function and sensitivity of detection.



- IV. Do not hold the silicone sheath with your hand as this may affect the waterproof function and sensitivity of detection.
- V. Do not rotate the pressure level setting knob to alter pressure when you are changing batteries. This may cause damage to the waterproof function of device.
- VI. Suggest not using PMEM-16 in water. Clean and rinse the device gently to keep mechanical and electronic parts of main body in good condition.
- VII. Lie on your back and relax your legs, abdominal and buttock muscle before inserting into the vagina. Tighten these muscles will increase pressure inside of abdominal cavity as may cause severe problem to your body. If necessary, discuss with your healthcare providers for the instruction to train pelvic floor muscles correctly.

8. Pressure Level Chart

| | | | | |
|--|----------------------------|---|---|---|
| Pressure Level (Enhance Muscle Strength) | 1 | 2 | 3 | 4 |
| PMEM-16 Sensitivity | High \longrightarrow Low | | | |
| Pelvic Floor Muscle Clench | Low \longleftarrow High | | | |

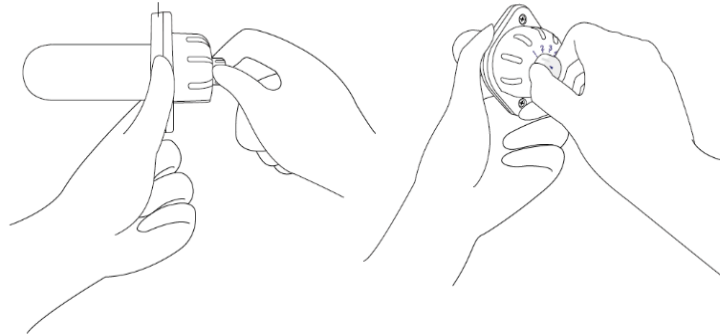
Set the appropriate pressure level that you can trigger PEME-16 consistently prior to use this device. Hold on to the silicone sheath when you rotating the knob.(Fig.A)

Modes of Exercise

| Mode of Exercise (Enhance Muscle Endurance) | EASY | HARD Mode |
|--|--|---|
| Pelvic Floor Muscle Clench | Clench the pelvic floor muscle when green LED is on for 3 seconds, then relax for 3 seconds when the light is off. | Clench the pelvic floor muscle when green LED is for 5 seconds, then relax for 5 seconds when the light is off. |
| Duration for Each Training Session | 300 seconds | 300 seconds |

Beginners should start with lower pressure level and EASY mode, and the next level when you are ready. It is recommended to do two sessions in the morning(10 minutes) and Two sessions(10 minutes) in the evening daily.

(A) Silicone oval block

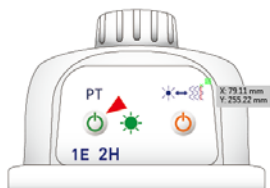


Note: Hold the silicone oval block when rotating the pressure level knob

How to Turn On and Off the device

- I. Turn On: Press the PT button 1 time to enter EASY mode (Fig. C), press PT button 2 times to enter HARD mode (Fig. D). The green LED will flash 3 times rapidly when PMEM-16 is turning on. It will flash periodically during exercise.

(C) Press PT button 1 time
to enter: EASY mode

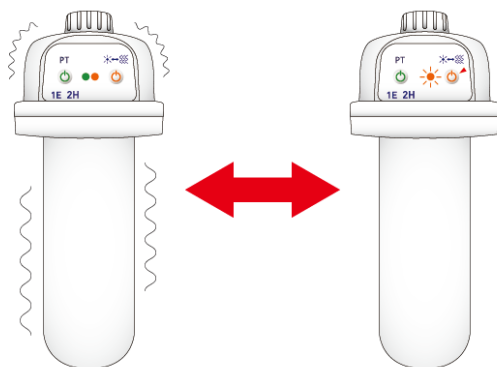


(D) Press PT button 2
times: HARD mode



- II. Biofeedback Switch Button: Biofeedback functions can be switched by pressing the button (orange LED), the default setting is vibration. You can change it based on your preference. (Fig. C)

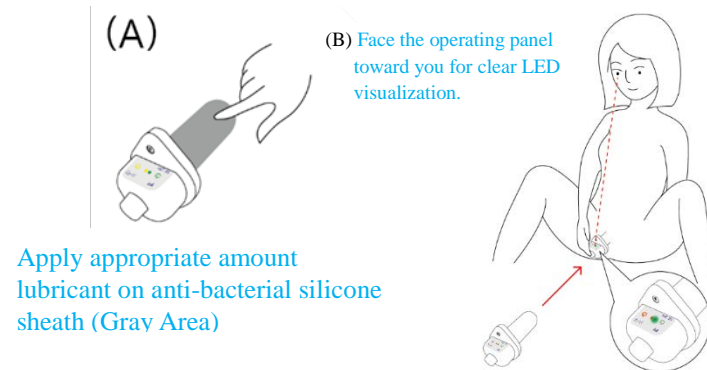
(C)



- III. Turn off: PMEM-16 will be turned off automatically when the training session is over. You can also turn it off by pressing PT button during training session.

9. DIRECTIONS FOR USE

- I. Lie on your back and relax your body. Apply an appropriate amount of lubricant on the sheath (Fig. A). Gently insert PEME-16 into the vagina. The silicone oval block should cling snugly to the vagina without any space in between to maximize the training result.

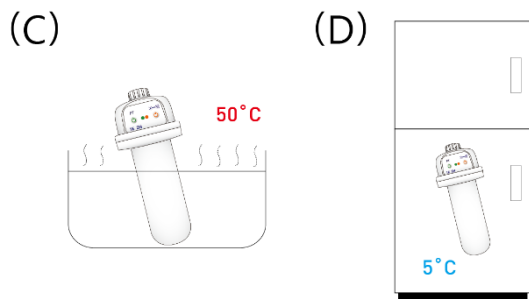


- II. Start the pelvic floor muscle exercise by clenching and contracting your pelvic floor muscle. When you feel vibration or see the orange LED is on, you have exercised the correct muscle.

Why does the biofeedback not work when you are clenching and contracting pelvic floor muscles?

- Make sure your abdominal (belly or buttock) muscle is relaxed
- Adjust pressure level to level 1
- Make sure PMEM-16 clings to your vagina snugly
- Discuss with your healthcare provider for correct pelvic floor muscle training

- III. PMEM-16 is the only device with patented heating and cooling technology which is effective for up to 10 minutes. In winter time, you can immerse PMEM-16 in 50°C warm water for 2~3 minutes, (Fig. C) to warm up the surface of silicone sheath for a more comfortable use, it can increase blood circulation and enhances the muscle flexibility. After each use, you can put PMEM-16 in the refrigerator for 2~3 minutes, and gently insert into your vagina to soothe the exercised pelvic floor muscles and reduce muscle soreness (Fig. D).



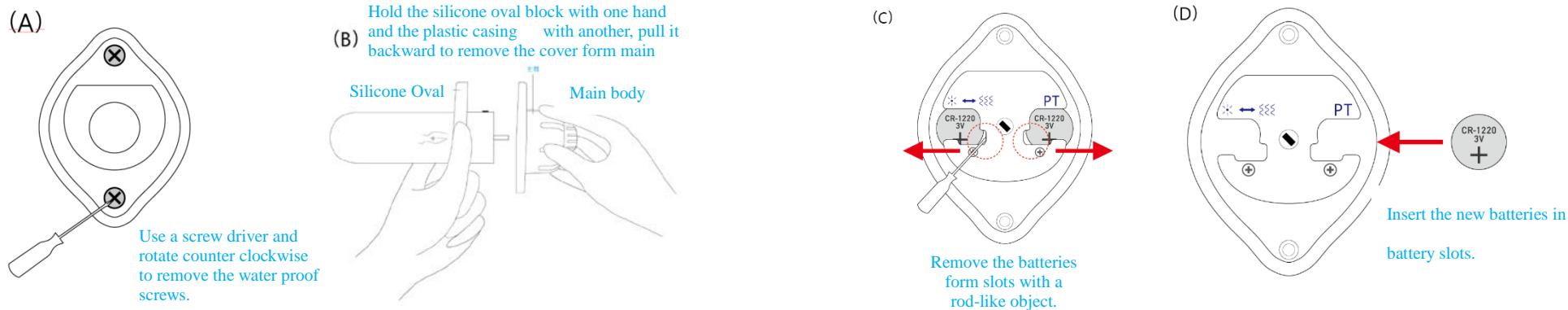
10. CLEANING AND STORAGE

Please clean PMEM-16 before and after each use. Apply a mild soap to the device and rinse thoroughly. Put PMEM-16 in its storage casing in a dry and cool place.

Warning: Do not use bleach as this may damage to the silicone rubber parts.

11. BATTERY

- I. PMEM-16 uses CR1220 3V batteries(not included). To insert the batteries correctly, ensure the flat(+) side is facing towards you. Slide the batteries into the battery slots, one for PT button and one for Biofeedback modes setting. When the LED on operating panel or biofeedback vibration is turning weakened, please change both.
- II. After new batteries are replaced, put the cover(plastic casing) onto the main body and screws in the hole of bolt, rotate the screw driver clockwise to close up the cover firmly.(A)→(B)→(C)→(D)



- III. If the device will be not in use for a long time, suggest to tack out batteries form battery slots to avoid battery consumption or oxidation. When placing the screws back after battery replacement, the screw driver should be inserted in the cross hole of the bolt and drive the screw clockwise into the base.

12. Signs



Manufacturer



Reference No.



Lot No.



Consult instructions for Use



Do not use if package is damaged



Date of Manufacture



Authorized representative in
the European community



Use by



Non-sterile



Type BF Applied Part
Equipment providing a particular degree of protection against electric shock, with isolated or floating (F - type) applied part or parts.



WEEE Recycling Symbol

13. SHELF LIFE

The shelf life is three years. This product has passed the three-year aging test.

14. WASTE DISPOSAL

This product should not be disposed with other household wastes to prevent possible harm to the environment or human health from uncontrolled waste disposal. Please recycle this product responsibly.

Note: Consult your local waste or disposal organization for information about recycling or proper disposal.

15. PRODUCT MAINTAIN

- Silicone sheath: Please clean silicone sheath before and after each use. Use a mild soap to wash the device and rinse thoroughly. Put PMEM-16 in its storage casing in a dry and cool place.
- Battery replace: When the LED on operating panel or biofeedback vibration is turning weakened, please change both.
- Battery separate placed: If the device will not be in use for a long time, suggest taking out batteries to avoid consumption or oxidation.
- Stored condition: If the device will be not in use, put PMEM-16 in its storage casing and stored under appropriate condition.(See PRODUCT SPECIFICATIONS)

16. PASS INGRESS PROTECTION

IP27


- Capable of preventing ingress of moderate-sized solids and solid matters with a diameter of more than 12 mm and a length of not exceeding 80 mm, e.g. finger.

- Ingress of water in harmful quantity shall not be possible when the enclosure is immersed in water under defined conditions of pressure and time (up to 1 m of submersion).

17. ELECTRONIC SPECIFICATION AND ELECTROMAGNETIC COMPATIBILITY (to be completed)

| Guidance and manufacturer's declaration-electromagnetic emissions | | |
|--|----------------|---|
| The PMEM-16 is intended for use in the electromagnetic environment specified below. The customer or the user of the PMEM-16 should assure that it is used in such an environment. | | |
| Emission test | Compliance | Electromagnetic environment-guidance |
| RF emissions CISPR 11 | Group 1 | The PMEM-16 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The PMEM-16 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations /flicker emissions IEC 61000-3-3 | Not applicable | |

| Guidance and manufacturer's declaration-electromagnetic immunity | | | |
|--|---|--|--|
| The PMEM-16 is intended for use in the electromagnetic environment specified below. The customer or the user of the PMEM-16 should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
| Electrostatic discharge(ESD) IEC 61000-4-2 | ± 8 kV contact ± 8 kV air | ± 8 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2kV for power supply lines ± 1kV for input/output lines | Not applicable Not applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV line(s) to line(s) ± 2kV line(s) to earth | Not applicable Not applicable | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s | Not applicable Not applicable Not applicable Not applicable | Mains power quality should be that of a typical commercial or hospital environment. If the user of the PMEM-16 requires continued operation during power mains interruptions, it is recommended that the PMEM-16 be powered from an uninterruptible power supply or a battery. |
| Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | The PMEM-16 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration-electromagnetic immunity | | | |
|---|-----------------------------|------------------|---|
| The PMEM-16 is intended for use in the electromagnetic environment specified below. | | | |
| The customer or the user of the PMEM-16 should assure that is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 KHz to 80 MHz | Not applicable | Portable and mobile RF communications equipment should be used no closer to any part of the PMEM-16 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80MHz to 2.5 GHz | 3 V/m | <p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. | | | |
| NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| <p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PMEM-16 is used exceeds the applicable RF compliance level above, the PMEM-16 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PMEM-16.</p> <p>b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

| Recommended separation distance between portable and mobile RF communications equipment and the PMEM-16 | | | |
|--|--|---|--|
| The PMEM-16 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PMEM-16 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PMEM-16 as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
| | 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$ |
| 0,01 | N/A | 0,12 | 0,23 |
| 0,1 | N/A | 0,38 | 0,73 |
| 1 | N/A | 1,2 | 2,3 |
| 10 | N/A | 3,8 | 7,3 |
| 100 | N/A | 12 | 23 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. | | | |
| NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

18. Manufacture and Brand Company

Brand Company: Woman Gard Biomedical Technology Corp.

Address: 3F., No.10, Aly. 3, Ln. 45, Baoxing Rd., Xindian Dist., New Taipei City 23145, Taiwan (R.O.C.)

Manufacture: Panpac Medical Corp.

Address: 6F-2, NO.202, Sec.3, Ta-Tong Road, Shi-Chih Dist., New Taipei City 22103, Taiwan (R.O.C)