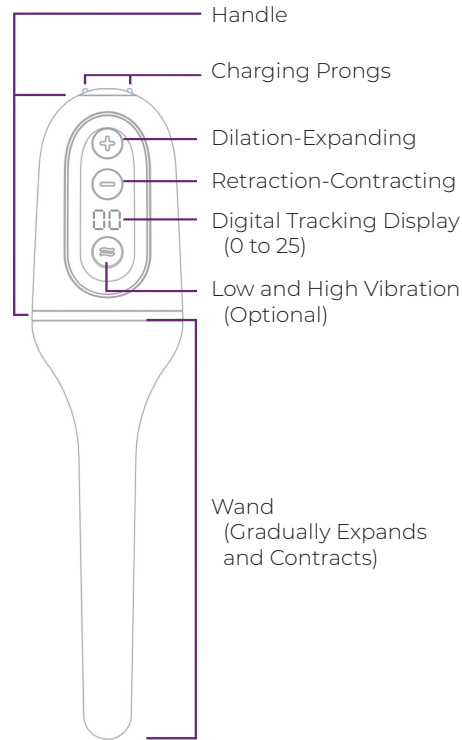


# Milli Instructions for Use

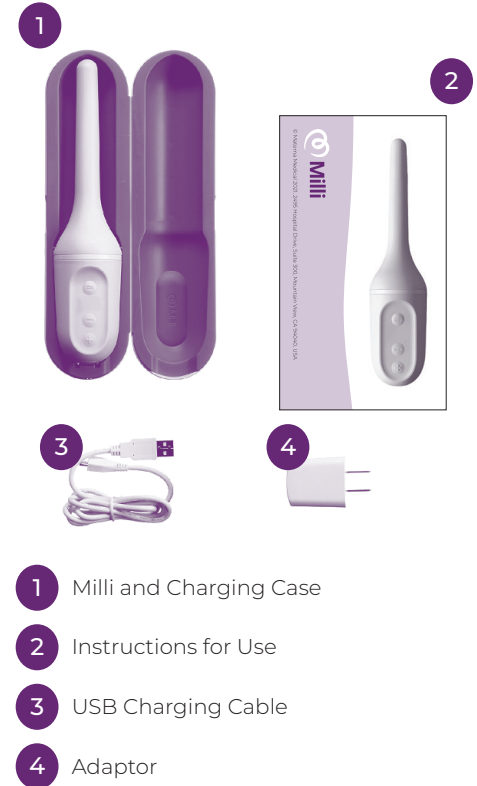
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## MILLI AND MILLI'S CONTROL PANEL

The Milli Vaginal Dilator, Intended to use at home, helps women expand, stretch, and relax their pelvic floor muscles using millimeter-by-millimeter gradual expansion and built-in vibration.



## MILLI COMPONENTS



## WARNING

- Prolonged use of Milli Vaginal Dilator may cause vaginal abrasion or ulceration
- If symptoms, such as bleeding, vaginal discharge, unpleasant odor, pain, or severe itching occur, stop use of the device and contact your healthcare provider
- Use of Milli adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, Milli and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Milli could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- No modification of this equipment is allowed.

## PRECAUTIONS

- Milli is for single patient use only. Do not share your device with others.
- Do not soak Milli's handle or submerge Milli under water.
- Do not bathe with Milli.
- Do not use silicone-based lubricant with Milli.
- Do not use if you have a sensitivity to silicone.
- Use only water-based lubricant with Milli.
- Do not use Milli if the silicone cover, device, or case is damaged.
- Do not place Milli in the microwave, dishwasher, or refrigerator.
- Do not store Milli near extreme heat or cold.
- Do not wash Milli with products containing alcohol, acetone, or petroleum.
- Do not squeeze, twist, or bend Milli's wand.
- Do not use Milli in other orifices other than the vagina.
- Do not force Milli into your vagina.
- While inserted into the vagina at desired depth, but at least halfway, gradually increase the dilation diameter at a comfortable level.
- Contact your physician if prolonged or worsening symptoms occur.

## INDICATIONS

The Milli Vaginal Dilator is a tool intended for controlled dilation of the vagina. It can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related to painful sex.

## CONTRAINDICATIONS

Women with active pelvic infections, or women who have open wounds in the tissue surrounding the vagina should not use vaginal dilators. Pregnant women should refer to their physician for guidance prior to use.

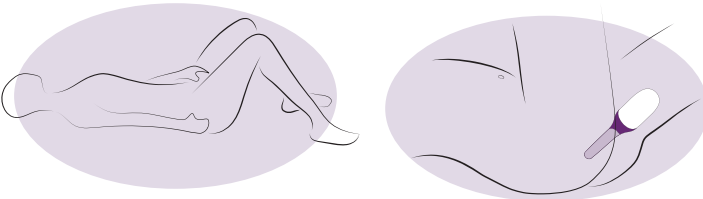
## SPECIFICATIONS

- Adjustable diameter range: 15mm to 40mm
- Digital tracking display: 0 (15mm) to 25 (40mm) gradual dilation
- Silicone coated
- Usable length: 10.5cm
- Total length: 20cm
- Milli weight: 5.2oz
- Milli plus case weight: 10oz
- USB cable length: 36in
- USB cable type: USB Type A to USB micro B
- Built-in vibration: low and high settings
- Use temperature: 5° to 30° C
- Transport: -25°C to + 5°C
- 25°C to + 35°C at a relative humidity up to 90%, non-condensing
- >35°C to + 70°C at a water vapor pressure up to 50 hPa

## OPERATING INSTRUCTIONS

### TREATMENT PLAN

- Typical treatment duration is 5 to 20 minutes, 3 to 5 days per week but may vary.
- Water based lubricants may be used as desired prior to insertion.
- Milli should be inserted into the vagina when the setting is at 15mm (tracking displays "0").
- Lie down on your back and using gentle pressure, slowly insert the Milli wand into your vagina. It may be easier to insert it with the tip pointed slightly towards the tailbone.
- If there is resistance or a sensation of tightness or pressure, pause and determine if it is uncomfortable or painful. If there is discomfort, slowly pull Milli back to any place in the vagina closer to the opening where you no longer feel discomfort.



- Insertion depth may vary, gradually progress until Milli can be fully inserted.
- While inserted into the vagina at desired depth, gradually increase the dilation diameter to your comfort level.
- Maintain Milli in the vagina for the recommended or desired treatment duration, continuing to increase diameter as desired/ tolerated.
- Remove Milli after the desired treatment duration is reached.
- The range or dilation size should be large enough for its indication, yet not cause any undue pressure or discomfort to the vagina or surrounding regions.
- Remove Milli at any point if the pain becomes unbearable.
- The vibration feature may be used at any setting.
- When treatment duration completes, Milli may be removed from the vagina in its dilated state. If preferred, Milli may also be contracted to "0" inside the vagina prior to removal.
- It is recommended to note the dilation setting achieved during the treatment duration (0 to 25) to track progress.

- Repeat dilation treatment until the desired setting can be achieved.

### FIRST TIME USE

- Wash Milli prior to the first use.
- Wash Milli after each use per the Milli Care Instructions (located in this Instructions for Use manual).

### TURNING MILLI ON

- Press the (+) button to turn Milli on.

### TURNING MILLI OFF

- Press the (-) button to contract Milli one setting (millimeter increments).
- Hold the (-) button for 2-seconds to fully contract and turn off Milli.
- Milli's tracking display will flash the highest setting reached during each use while it contracts and turns off.

### CONTROL PANEL

- Milli's tracking display will show the current dilation setting.
- Milli's tracking display is oriented to be read in the direction of insertion into the vagina.
- When the tracking display reads "0", the wand is completely closed (retracted) and has a starting diameter of 15mm.
- When the display reads "25", the wand is completely expanded (dilated) and has a total diameter of 40mm. This is the starting diameter of 15mm plus 25mm maximum dilation size.
- The display may read "25" while the wand is gradually increasing to the total diameter.
- The adjustable diameter dilation range is 15mm to 40mm. The total expansion range of the wand is 25mm.
- If the tracking display is flashing "Lo" this means that Milli is low on battery. When the battery is near empty, Milli will contract to the "0" setting (15mm starting size) and wait to be charged.
- When Milli is turning off, the display will flash the highest setting reached during use.
- When turning Milli on, the display will read "0".

## OPERATING INSTRUCTIONS (cont.)

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### DILATION - EXPANDING MILLI

- Press the (+) button to expand Milli using one-millimeter increments.
- Milli gradually expands a total of 25mm, starting at 15mm and ending at 40mm.
- For continued millimeter-by-millimeter gradual expansion, hold the (+) button.
- When the (+) button is released, Milli will stop expanding. Alternatively, press the (+) button several times until the tracking display reads a desired setting. Milli will continue expanding until the desired setting is reached.
- Press the (-) button to immediately stop ongoing expansion.
- The (+) button has a raised (+) symbol, to identify it easier by touch.

### RETRACTION - CONTRACTING MILLI

- Press the (-) button to decrease Milli in one-millimeter increments.
- Holding the (-) button for more than 2 seconds will tell Milli to contract (retract) Milli and turn off.
- To stop Milli contracting (retraction) at any point, press the (+) button.
- The (-) button has a depressed (-) symbol, to identify it easier by touch.

### VIBRATING MILLI

- Milli has two optional vibration settings, low vibration and high vibration.
- Press the (≈) button once to turn the vibration on low and twice to turn the vibration on high.
- Press the (≈) button a third time to turn the vibration off.

### CHARGING MILLI

- Attach the USB cable to the adaptor (included) and connect the adaptor to a power outlet.
- Attach the end of the USB cable not inserted in the adaptor into the exterior case charging opening.

- Place Milli inside the case. Ensure Milli is properly nestled and oriented in the case where the metal prongs at Milli's base make contact with the metal charging pads inside the case.
- An orange light on the case at the cable connection will indicate the connection is successful and Milli is connected to its charging case.
- When charging, Milli will flash "Ch" on the tracking display.
- When Milli is fully charged, approximately 2-hours, the display will read "FL".

### MILLI CARE

- Milli is not waterproof. Do not submerge Milli in water. Failure to follow this guidance may result in damage to Milli.
- Milli should be washed before first time use and after each use with mild soap and lukewarm water. Be sure to wash the wand portion only. The handle should be wiped down with a damp cloth of water only.
- Wipe Milli down with a dry towel and let it dry completely before placing back in the charging case or prior to use.
- If using lubricants with Milli, do not use silicone-based lubricants. Failure to follow this guidance will result in damage to the silicone coating.
- Use only water-based lubricants, which are easy to wash off with soap and water and recommended for silicone coated devices.

### TRAVELLING WITH MILLI

- Milli is within TSA guidelines for a carry-on-object.
- When traveling outside the USA, you may need to use an adaptor to charge Milli. Consult the specific country guidance on what type of USB power supply or adaptor may be needed.
- Milli is designed to be used with outlets up to 240 volts.

### DISPOSING OF MILLI

- Milli should be disposed in accordance with local and/or state regulations for electronic waste.

## TROUBLESHOOTING

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### WHAT IF...

#### ...THE POWER DIES?

Milli needs to charge. Place Milli in its case and plug the case into an outlet. Charging time may vary.

#### ...THE DEVICE DOES NOT TURN ON?

Milli may need to charge. Place Milli in its case and plug the case into an outlet. If Milli still doesn't turn on after charging, please contact [support@hellomilli.com](mailto:support@hellomilli.com) for further assistance.

#### ...MILLI IS OFF, BUT NOT FULLY CLOSED?

Milli's battery is probably dead. Place Milli in its case and plug the case into an outlet.

#### ...MILLI FEELS WARM?

It is normal for Milli to get warm during use or after being

used for an extended time. Should you find Milli overheating and impacting the way it operates, please contact [support@hellomilli.com](mailto:support@hellomilli.com) for further assistance.

#### ...MILLI ISN'T RESPONDING WHEN I PUSH UP OR DOWN?

Milli may be responding to earlier commands. Wait for the device to stop moving, then re-enter your (+) or (-) command by pushing the desired button.

#### ...THE DEVICE WON'T CHARGE?

Make sure Milli is nested correctly in the case and the charging prongs are touching the contacts on the case. You shouldn't need to use force to properly cradle Milli.

#### ...(+) IS PRESSED AND MILLI IS MAKING NOISE BUT WON'T EXPAND?


Milli may not be functioning correctly. Please contact [support@hellomilli.com](mailto:support@hellomilli.com).

## WARRANTIES









Milli is warrantied for a use life of 1 year. To register your Milli for this warranty, please visit [hellomilli.com/warranty](http://hellomilli.com/warranty).




Questions? Contact us at:  
[support@hellomilli.com](mailto:support@hellomilli.com).

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Guidance and manufacturer's declaration – electromagnetic emissions		
The Milli Vaginal Dilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Milli Vaginal Dilator should assure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The Milli Vaginal Dilator 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.  The Milli Vaginal Dilator 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

EXPLANATION OF SYMBOLS:	
	Manufacture Date
	Manufacturer
	Model Number
	Consult Instructions for Use
	Nonsterile
	Single Patient-Multiple Use
	Type BF Applied Part
	Non-Ionizing Electromagnetic Radiation
<b>IP22</b>	Degree of Ingress Protection

Guidance and manufacturer's declaration – electromagnetic immunity		
The Milli Vaginal Dilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Milli Vaginal Dilator 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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment.
	0% UT for 1 cycle and 70% UT for 25/30 cycles <sup>a</sup>	If the user of the Milli Vaginal Dilator requires continued operation during power mains interruptions, it is recommended that the Milli Vaginal Dilator be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	0% UT for 250/300 cycles <sup>a</sup>	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_t$ is the a.c. mains voltage prior to application of the test level		
<sup>a</sup> For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.		

Guidance and manufacturer's declaration – electromagnetic immunity				
The Milli Vaginal Dilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Milli Vaginal Dilator should assure that it is used in such an environment.				
<b>Immunity test</b>	<b>IEC 60601 Test level/Compliance level</b>			<b>Electromagnetic environment (Guidance)</b>
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V in ISM and amateur bands between 150 kHz to 80 MHz <sup>c</sup> 80% AM at 1kHz			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz			
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test Frequency (MHz)	Band (MHz)	Modulation	Immunity Test Level (V/m)
	385	380-390	Pulse modulation 18 Hz	27
	450	430-470	FM ±5 kHz deviation 1 kHz sine	28
	710	704-787	Pulse modulation 217 Hz	9
	745			
	780			
	810	800-960	Pulse modulation 18 Hz	28
	870			
	930			
	1720	1700-1990	Pulse modulation 217 Hz	28
	1845			
	1970			
	2450	2400-2570	Pulse modulation 217 Hz	28
5240	5100-5800	Pulse modulation 217 Hz	9	
5500				
5785				
NOTE - 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 Milli Vaginal Dilator is used exceeds the applicable RF compliance level above, the Milli Vaginal Dilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Milli Vaginal Dilator.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</p> <p>c) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz</p>				