Leva® PELVIC HEALTH SYSTEM

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Read This First

Please read all instructions in this manual before you begin using your device.

This warning symbol appears next to information about possible safety risks.

Please be sure to follow all warning and safety information. Save these instructions for future reference.

Welcome to *Leva*®

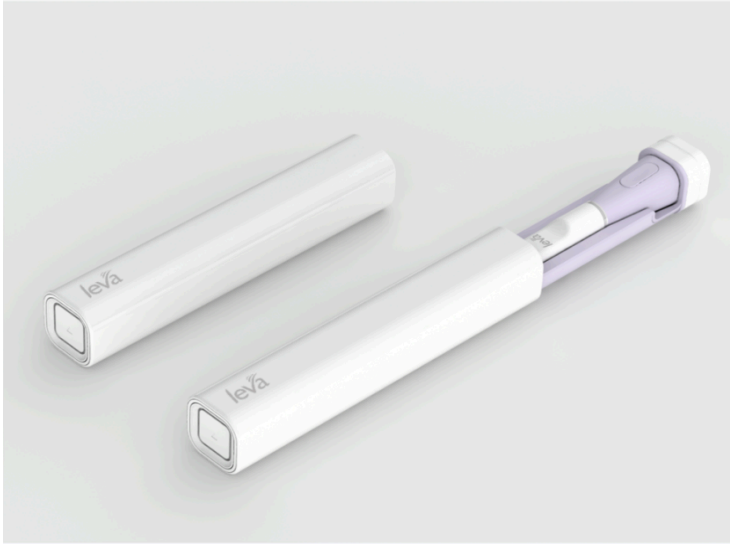
This instruction manual is intended to provide valuable information about *Leva*® Pelvic Health System (*Leva* PHS) to ensure that your use of the device is safe and effective.

As you begin to familiarize yourself with the *Leva* Pelvic Health System, it is normal to have questions. If at any time you have questions or need assistance, contact the *Leva* Women's Center at (866) 735-8423.

Why *Leva*?

Healthy pelvic floor muscles are a key part of overall pelvic health, which includes maintaining urinary continence (i.e., the ability to control your bladder) and fecal continence (i.e., control of your bowel movements).

The Leva Pelvic Health System helps you exercise and strengthen those muscles, so you can treat your pelvic floor muscle weakness as well as your urinary incontinence (also known as bladder leakage) and fecal incontinence (also known as accidental bowel leakage).



What's in the Box?

Your *Leva* includes the following:

- Storage case and case battery
- *Leva* vaginal wand with battery
- Quick Start Guide

What's not in the Box?

Leva Pelvic Health System requires use of a mobile application (***Leva* App**) and mobile device (i.e., smartphone) to visualize pelvic floor exercise during device use. The user is required to download the ***Leva* App** onto their mobile device.

What features does *Leva* have?

The *Leva* vaginal wand was designed as a soft, flexible vaginal device. The *Leva* wand has a raised indicator line along its front to help ensure proper positioning. The *Leva* Pelvic Health System operates on batteries located in the base of both the case and the *Leva* wand.

The *Leva* wand is provided with a sturdy storage case. This case serves two purposes: it protects the *Leva* wand during storage and also serves as a communications bridge between your *Leva* wand and your mobile phone (i.e., a relay).

Because of its communication function, the case also operates on batteries that are located on the front of the tray. The storage case also incorporates a push-button open feature and an air vent to circulate air through the storage case to aid in maintaining a dry storage environment.

Indications for Use

The *Leva* Pelvic Health System is intended for:

1. Strengthening of the pelvic floor muscles;
2. Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary incontinence (including overactive bladder) in women;
3. Rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (≥3-month uncontrolled passage of feces) in women.

This device interacts with the user via smartphone technology.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Use as Prescribed by Your Physician

Recommended use: two and one-half minutes, twice daily. Remove the vaginal wand after each use.

Contraindications

The Leva Pelvic Health System is contraindicated for uses other than those described by the indications for use.

Warnings

Please read this section carefully prior to using your *Leva* Pelvic Health System.

⚠ Do not use your *Leva* Pelvic Health System while pregnant, or if you think you may be pregnant, unless authorized by your healthcare provider.

⚠ Do not share your *Leva* Pelvic Health System with other users. The *Leva* Pelvic Health System is intended for use as a single-user medical device.

⚠ Do not leave the *Leva* wand in your vagina for longer than necessary to complete the training session. Always remove the *Leva* wand after each training session and do not exceed 60 minutes of insertion, including during menstruation.

Do not use the *Leva* wand in any other place in your body. The *Leva* wand is only intended to be used in the vagina.

Do not have sexual intercourse while the *Leva* vaginal wand is inserted.

Do not insert the *Leva* wand if there is any damage to any of the *Leva* Pelvic Health System components.

Keep the *Leva* Pelvic Health System out of reach of children. If left unattended, the *Leva* Pelvic Health System could prove to be a choking hazard to a child and could result in death.

If you experience redness or swelling near the insertion area, contact your doctor, as you may have an allergic reaction to the device material.

Do not use your *Leva* wand and storage case adjacent to or stacked with other equipment as this may

adversely impact normal operation of the device.

⚠ The modification or use of the *Leva* Pelvic Health System with accessories other than those specified and sold by Axena Health, Inc. as replacement parts may result in increased emissions or decreased immunity of the *Leva* Pelvic Health System.

Precautions

Please familiar yourself with the following information for the safe and effective use of the device:

- Do not bend the *Leva* wand. Do not twist the *Leva* wand.
- Do not submerge the *Leva* wand or case in water or liquid.
- Do not use the *Leva* Pelvic Health System in the shower or bathtub, and do not submerge it in liquid of any kind. The *Leva* Pelvic Health System is not designed to be used underwater.
- Do not submerge the battery in any kind of liquid or expose to running water when detached from vaginal wand.
- Do not bathe, shower, swim, or submerge yourself in water while *Leva* wand is inserted.
- Do not use the toilet while *Leva* wand is inserted.

- Do not soak the *Leva* Pelvic Health System.
- Do not put the *Leva* Pelvic Health System in the dishwasher.
- Do not clean *Leva* with anything but mild soap and water.
- Do not use oil or petroleum-based lubricants with the *Leva* wand. Use water-based lubricants only.
- Do not leave *Leva* in the sun, near an open fire, or in a hot parked car. Excessive or direct heat can damage the *Leva* Pelvic Health System.
- Do not modify the *Leva* Pelvic Health System in any way or use it in combination with any accessory not mentioned in this document. This could result in deformation of the *Leva* which could cause painful insertion or could damage the electronics.
- Always wash your hands before inserting the *Leva* wand to prevent harmful bacteria,

which may be present on your hands, from entering your vagina.

- Always ensure there are no obstructions present when inserting the *Leva* wand.
- Always ensure you can maintain your balance when inserting the *Leva* wand and operating the *Leva* Pelvic Health System.
- To ensure hygienic safety, you should clean and dry your *Leva* wand before and after each treatment session.

Smartphone Compatibility

The *Leva* Pelvic Health System is compatible with most iOS and Android™ smartphones. Contact Technical Support at (833) 450-2914 for more information about smartphone compatibility.

Download the *Leva* App

1. Download the free *Leva* App from the App Store® for iOS or from Google Play for Android™.

2. Launch the *Leva* App by pressing the *Leva* App icon on your smartphone
3. Select *Sign Up* located at the bottom of the screen.
4. Enter the following information:
   - First and Last Name
   - Email
   - Password *(minimum of 8 characters)*
   - Indicate if you want to receive emails or stay signed in
   - Click *Sign Up*
   - Then:
     - Accept the Privacy Policy

- Enter the 4-digit code which was sent to your email, then click Submit to finish creating your account.

Set Up *Leva* Pelvic Health System

The *Leva* App will take you through a series of steps to set up your *Leva* Pelvic Health System. These steps include:

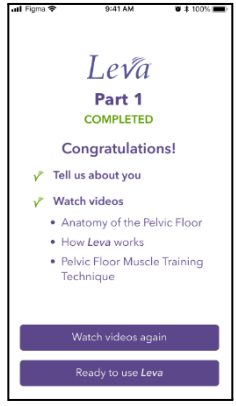
1. **Watch the Welcome message.**

   Log in to the *Leva* App using the email and password that you created.

   Select "Play Video" and watch the Welcome Message.

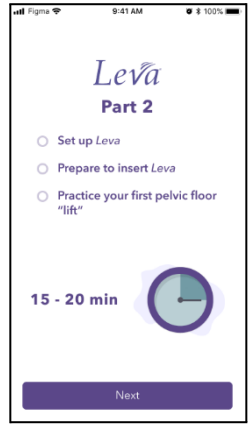
2. Complete Part 1.

Select “Play Video” and watch the educational videos presented. Afterwards, you may choose to watch the videos again or continue to Part 2.



3. Complete Part 2.

Select “Next” and proceed through step-by-step instructions to connect *Leva* and practice your first “lift”.



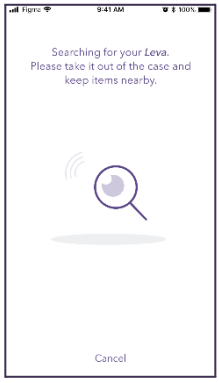
4. Connect *Leva*

Removing the *Leva* wand from the case will automatically turn on the device.

5. Prepare the *Leva* wand by detaching the battery and removing the battery sticker.

6. Reattach the battery by pressing it toward the vaginal insert and rotating it in the direction of the arrow (see below).

7. Search for your *Leva* Pelvic Health System using a Bluetooth signal. The *Leva* App will identify your *Leva* Pelvic Health System and confirm that it is connected and ready to use.



Note: The storage case contains relay electronics that allow communication between your *Leva* wand and smartphone.

To ensure connection, verify the *Leva* wand is removed from the case and that the *Leva* wand, case, and smartphone are no more than 3.2 ft (1 meter) away from each other.

Preparing for Your Session

Wash your hands. Always wash your hands immediately prior to inserting the *Leva* wand to prevent harmful bacteria, which may be present on your hands, from entering your vagina.

Wash Your *Leva* wand

Wash your Leva wand. Wash your *Leva* Motion wand with mild, warm soapy water and gently dry.

Get Comfortable

Prior to starting, empty your bladder and find a place where you can remain standing and spend the next few minutes in privacy, such as your bathroom.

If this is your first-time using *Leva* Pelvic Health System, standing with your knees slightly bent is a very comfortable and easy way to reach your vagina to insert the *Leva* wand.

Another option is standing with one foot propped up on a stool or something of similar height so one leg is higher than the other.

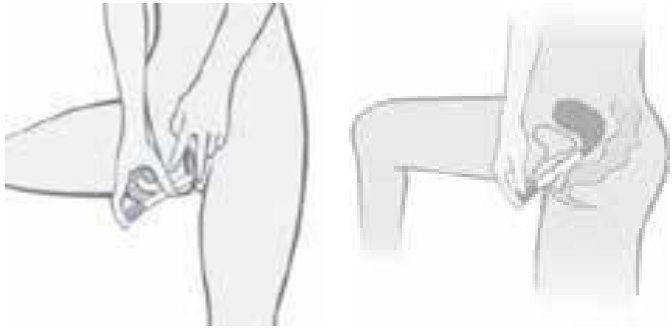
Inserting the *Leva* wand is much easier if you are relaxed. The process is much like inserting a tampon.

⚠ Always ensure you are able to maintain your balance when inserting the *Leva* wand and operating the *Leva* Pelvic Health System.

Insert the *Leva vaginal* wand

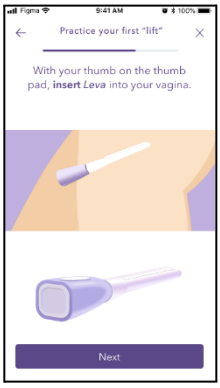
Hold the *Leva* wand lightly by placing your thumb on the white thumb pad and your index and middle finger on the opposite side.

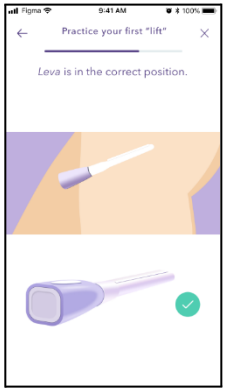
Insert the *Leva* wand into your vagina at a slight upward angle toward the small of your back. If you have trouble inserting the *Leva* wand, use your other hand to separate the skin to give access to the vagina. Gently place the vaginal insert portion of the *Leva* wand into your vagina as far as it will comfortably go.



Stop inserting the *Leva* wand if you feel uncomfortable or when the vaginal insert is flush with the perineum (vaginal opening). If you feel resistance, do not force the *Leva* wand in. If you have inserted the *Leva* wand properly, it should be comfortable.

Rotate the *Leva* wand until the thumb pad on the grip is facing forward and the *Leva* App informs you that your alignment is correct.





Note: If you have vaginal dryness, applying a very small amount of water-based lubricant to the tip of the *Leva* wand may make insertion easier.

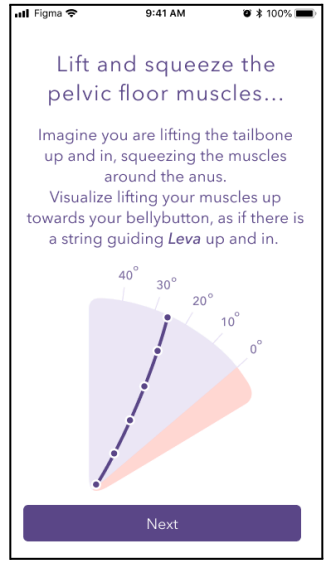
⚠ Do not use oil or petroleum-based lubricants.

Before beginning your exercises, pull your underwear up just enough to gently hold the *Leva* wand in place.

Try to stand in the same position, standing up straight, and wearing no shoes (or wear similar shoes each time you do your exercises).

Practice your first "lift"

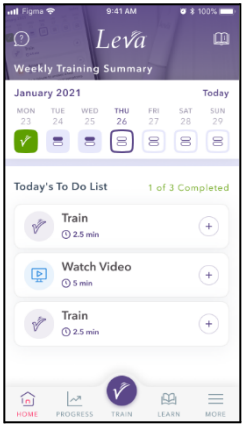
The *Leva* App will provide a tutorial on how *Leva* works and what to expect when Training. During this tutorial, you will use the *Leva* Pelvic Health System for the first time. The *Leva* App will instruct you on how to perform a correct pelvic floor muscle contraction and show you how your pelvic motion is displayed on your



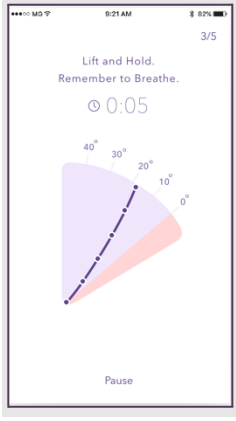
smartphone. Once you are done practicing, you are ready to train.

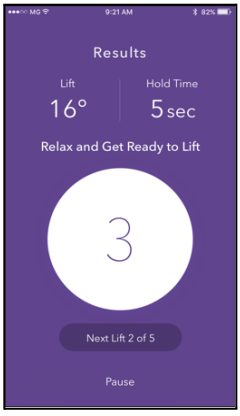
Training Sessions

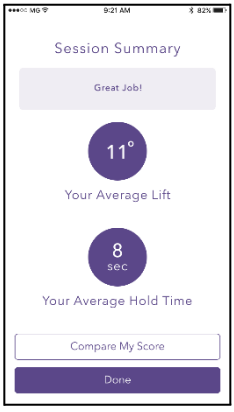
Each training session can be completed in 2 ½ minutes. To begin Training, click on the large "✓" button at the bottom of the screen. The *Leva* App will remind you to always wash your hands and *Leva* wand prior to use and will indicate how to insert the *Leva* wand.



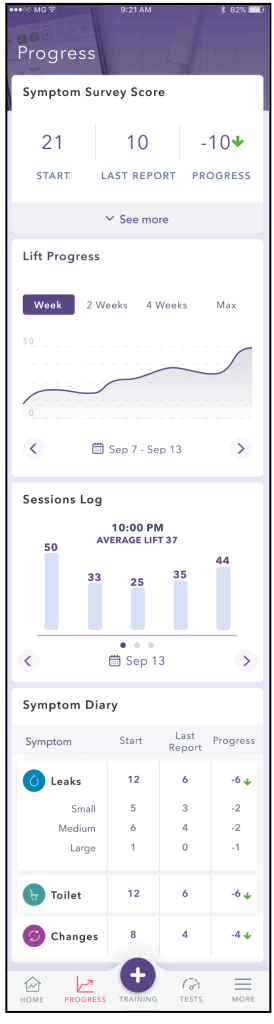
The app will guide you through a series of 5 lifts with resting periods between. After each lift, you will be shown your *Lift* and *Hold Time* results. After all lifts are completed, you will be shown the average of all 5 *Lift* and *Hold Time* results from your session.







The **Progress** screen of the ***Leva* App** keeps a record of the Training Sessions you completed.



Your Training session history is automatically stored on the Axena Health database and is always available to you. You can view a shorter or longer period of progress time by selecting different timepoints in the **Progress** section. You can also click on the plot to see the daily average for any given day. In the **Sessions Log** section, you can see the scores for each session completed on a given day.

Removing your *Leva* wand

Relax. Slowly and gently pull the *Leva* wand downward in the same angle as it was inserted.

Wash your *Leva* wand with mild, soapy water. Gently dry the *Leva* wand and return it to its storage case to preserve battery life and protect it from damage.

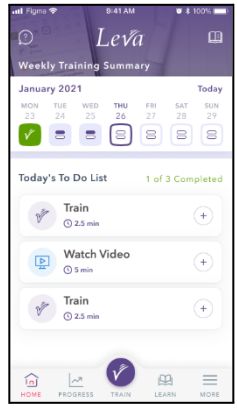
Leva App Features

The ***Leva* App** has several screens that can be reached from the Home screen.

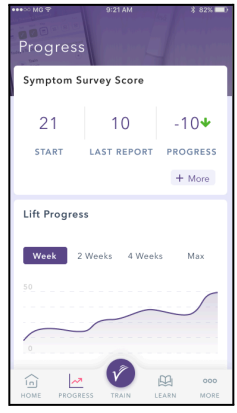
Leva App Navigation Map

Home

- Support
- Instructions for Use

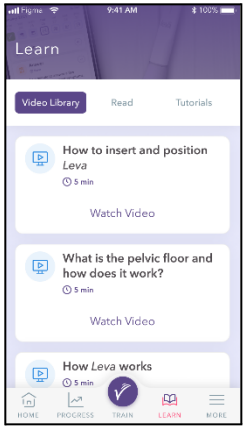


Progress and Training



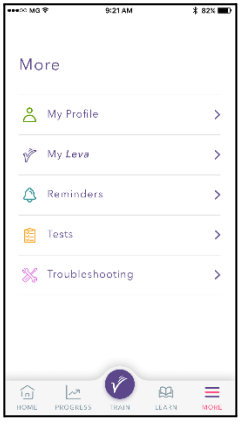
Learn

- Video Library
- Read
- Tutorials



More

- My Profile
- My *Leva*
- Reminders
- Tests
- Troubleshooting



Technical Specifications

The *Leva* Pelvic Health System uses 6 sensors to provide positional feedback on the shape and movement of your vagina as you perform pelvic floor muscle exercises.

In the **Practice** screen, four measures are reported: *Angle, Session Time, Start Angle,* and *Max Angle.*

The ***Angle*** measure refers to the average angle of the device with respect to the floor. If the device is more parallel with the floor, the *Angle* will be smaller. As you lift your pelvic floor muscles and the device rises, the *Angle* will increase. When the device is pointing straight up (perpendicular to the floor), the *Angle* is 90°. The *Angle* measure is updated at a rate of 10 times per second and the value displayed is the current *Angle*.

The ***Session Time*** refers to the duration of your **Practice** session.

The ***Start Angle*** refers to the angle of the device when you start your session. The ***Max Angle*** refers to the highest angle you reach during the session.

In **Training**, you will see *Lift* and *Hold Time* results after each session and your average *Lift* and average *Hold Time* once you complete all 5 lifts.

The *Lift* result represents the highest angle you reached with *Leva*, from 0˚ to 50˚. The *Hold Time* result represents the number of seconds, out of 15 total seconds, that you held *Leva* at its highest point. After completing all five lift exercises, your average *Lift* and *Hold Time* results are shown in the Session Summary screen.

The table below summarizes the range, accuracy, and precision of each measure when the device is operated under the conditions defined in the section titled **Operating Your *Leva*.**

Practice and Training Session Measurements			
Measure	**Range**	**Accuracy**	**Precision**
Angle	0˚ - 180°	+/- 0. 2°	1°
Start Angle	0˚ - 180°	+/- 0. 2°	1°
Max Angle	0˚ - 180°	+/- 0.2°	1°
Lift	0˚ - 50˚	+/- 0.5	1˚
Hold Time	1 - 15 sec	+/- 0.5	1 sec
Average Lift	0˚ - 50˚	+/- 0.5	1˚
Average Hold Time	0 - 15 sec	+/- 0.5	1 sec

Storing Your *Leva*

Storage of the *Leva* Pelvic Health System should not exceed the following conditions:

- Temperature: 5°C to 70°C
- Humidity: 0-90% RH non-condensing
- Altitude: 70kPa

Operating Your *Leva*

Operation of the *Leva* Pelvic Health System should not exceed the following conditions:

- Temperature: 5°C to 70°C
- Humidity: 0-90% RH non-condensing
- Altitude: 70kPa
- Operating Range: <3.2ft (1 meter)

Expected Service Life

- The expected service life of the *Leva* Pelvic Health System is 1 year.
- The Leva Pelvic Health System is warrantied for 6 months from the date of original purchase. Please see Limited Warranty Terms below for further information.
- The *Leva* Pelvic Health System may require a replacement battery set during its service life (see Replacing Batteries in the Maintenance and Servicing Section).
- *Leva* App updates will be pushed to users periodically as needed through the App Store™ or Google Play™.

Limited Warranty

Axena Health warrants the *Leva*® Pelvic Health System ("Leva" or the "device") against defects in materials and workmanship for six (6) months from the date of original purchase. Alleged defects must be reported to Axena Health by the original purchaser prior to the end of the warranty. Warranty claims must be supported with reasonable evidence of the

claimed defect. Axena Health may require the device be returned and if required, will provide customer with a Return Material Authorization number, which must be displayed on the outside packaging sent to Axena Health.

Axena Health reserves the right to determine whether to repair or replace a device determined to be defective. In the event of replacement, the warranty period of the replacement device will be run from the date of the original purchase. Repair or replacement of your device will not extend the time period of this limited warranty.

This limited warranty does not cover cosmetic or battery deterioration or damage caused by excessive wear and tear, physical or natural destruction, accident, misuse, neglect or other external causes. Any attempt to disassemble the device will invalidate this limited warranty and any use of the device that is contrary to this Instructions Manual may invalidate this limited warranty.

REPAIR OR REPLACEMENT OF THE DEVICE OR ITS AFFECTED COMPONENT ARE THE EXCLUSIVE REMEDIES PROVIDED IN CONJUNCTION WITH THE PURCHASE AND USE OF THE DEVICE. TO THE EXTENT PERMITTED BY LAW, THIS WARRANTY AND THE REMEDIES SET FORTH ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL, WRITTEN, STATUTORY, EXPRESS OR IMPLIED. AXENA HEALTH DISCLAIMS ALL STATUTORY AND IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND WARRANTIES AGAINST HIDDEN OR LATENT DEFECTS. IN SO FAR AS SUCH WARRANTIES CANNOT BE DISCLAIMED, AXENA HEALTH LIMITS THE DURATION AND REMEDIES OF SUCH WARRANTIES TO THE DURATION OF THIS EXPRESS WARRANTY AND, AT AXENA HEALTH'S OPTION, REPAIR OR REPLACEMENT AS DESCRIBED ABOVE. SOME STATES DO NOT ALLOW CERTAIN WARRANTY

LIMITATIONS, SO THE LIMITATION DESCRIBED ABOVE MAY NOT APPLY TO YOU.

Please contact Axena Health to confirm the terms of this Limited Warranty prior to purchase. Axena Health reserves the right, at its discretion, to modify its terms at any time prior to your purchase.

Maintenance and Servicing

The *Leva* Pelvic Health System does not have any serviceable parts. Replacement batteries are available per the information provided in this section. Use the following instructions to ensure proper care and maintenance of your *Leva*.

Cleaning your *Leva* wand

To ensure hygienic safety, you should clean and dry your *Leva* wand before and after each treatment session.

- Clean the *Leva* wand with mild, warm, soapy water.
- Do not wash the *Leva* wand with the battery removed.
- Care should be taken to not excessively bend or twist the *Leva* wand during the cleaning and handling process. Excessively bending and twisting the *Leva* wand can damage the device.
- Gently dry the *Leva* wand and return it to its storage case.
- Do not wash the *Leva* wand with alcohol, or other chemical cleaners.
- Do not submerge the *Leva* wand in water or liquid.
- Always return the *Leva* wand to its case to preserve battery life and protect it from damage.

Cleaning the Case

- Do not wash or submerge the case. If the case needs cleaning, wipe the case with a damp cloth moistened with water. Do not wash the case with alcohol, or other chemical cleaners.

Radio Frequency Wireless Technology:

- The *Leva* wand includes a microcontroller with a 915 MHz band ISM radio. The effective RF radiated power output (mW) associated with the 915 MHz radio is 2.582 mW.
- The case includes two microcontrollers: a 915 MHz band ISM radio and a 2.4 GHz band Bluetooth Low Energy (BLE) radio. The effective RF radiated power output (mW) is:
    - 915 MHz band ISM radio is 3.475 mW
    - 2.4 GHz BLE radio is 1.486 mW
- The *Leva* wand and case are considered ME EQUIPMENT.
- The operating range for effective transmission for both the 915 MHz and BLE transmitters are no more than 3.2 ft (1 meter) away from each other.

Batteries

Leva is powered by two (2) custom batteries:

- Wand: One (1) *Leva* wand battery containing four 393 silver oxide button cell batteries that powers the *Leva* wand.
- Case: One (1) Relay battery containing one 2032 Lithium button cell battery that powers the relay device on the case.

Note: Batteries are non-rechargeable and may require replacement.

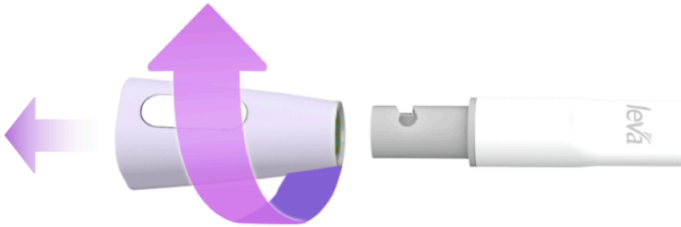
Replacing Batteries

Both the *Leva* wand and case contain batteries that may require replacing. Batteries are intended to be replaced as a set.

Replacing the *Leva* wand Battery:

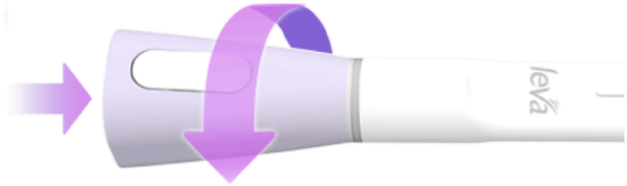
The *Leva* wand battery is located at the base of the vaginal wand.

Step 1. Detach the battery. Hold the base of the vaginal wand and rotate the battery in the direction of the arrow in the picture.



Step 2. Remove the sticker at the top of the replacement battery.

Step 3. Reattach the battery. Press the battery into the vaginal wand and rotate it in the direction of the arrow as pictured.



Replacing the Storage Case Battery

The storage case battery is located at the base of the tray component of the storage case.

Step 1. Open the case by pressing the ejection button on the side of the device.

Step 2. Remove the battery from the case by twisting the end of the tray in the direction of the arrow shown below.

Step 3. We recommend waiting 1 minute before connecting the new case battery by twisting it back on.

Battery and Device Disposal

This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Dispose or recycle this product in accordance with local laws or regulations that apply.

⚠ The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Axena Health as replacement parts for internal components (if any), may result in increased emissions or decreased immunity of the *Leva* Pelvic Health System.

FCC Compliance

The *Leva* Pelvic Health System is compliant with part 15 of FCC regulations for Class B computing devices (47 CFR Part 15).

Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions		
Leva Pelvic Health System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Leva* should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *Leva* Pelvic Health System 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 *Leva* Pelvic Health System 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
Leva Pelvic Health System is intended for use in the electromagnetic environment specified below. The customer or the user of *Leva* Pelvic Health System should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[*V*1] = 3 Vrms [*E*1] =3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of *Leva* Pelvic Health System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 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 meters (m). 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) Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 *Leva* Pelvic Health System is used exceeds the applicable RF compliance level above, the *Leva* Pelvic Health System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Leva* Pelvic Health System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity

The *Leva* Pelvic Health System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Leva* Pelvic Health System 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air 1	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	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable 2	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2 kV	Not applicable 3	Mains power quality should be that of a typical commercial or hospital environment.

	line(s) to earth		
Voltage dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Not Applicable [3]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Leva* Pelvic Health System requires continued operation during power mains interruptions, it is recommended that the *Leva* Pelvic Health System 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	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.

1. If the system stops communicating during use, it is recoverable by turning off and on again.
2. I/O cable is less than 3 meters.
3. The system is powered by internal battery only.

Electromagnetic Interference

Wireless communications equipment such as wireless home network devices, mobile phones, and cordless telephones and their base stations can affect *Leva* Pelvic Health System. Keep *Leva* away from other wireless equipment based on the table below:

Rated maximum output power of transmitter (W)	Recommended separation distance between leva* and communications equipment according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = \frac{3.5}{E1}\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \frac{12}{E2}\sqrt{P}$	80 MHz to 800 MHz $d = \frac{12}{E1}\sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{23}{E1}\sqrt{P}$
	e.g. Navigation, TV/ Radio Broadcast	e.g. Navigation, Radio/TV Broadcast	e.g. TV/Radio	e.g. Navigation, Satellite
0.01	0.12	0.12	0.40	0.23
0.1	0.37	0.38	1.26	0.73
1	1.17	1.20	4.00	2.30
10	3.69	3.79	12.65	7.27
100	11.67	12.00	40.00	23.00

The transmitter utilizes a fully certified Class 2 Bluetooth 2.1+ EDR module with a 128-bit encryption.

⚠ The *Leva* Pelvic Health System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, *Leva* should be observed to verify normal operation in the configuration in which it will be used.

⚠ The *Leva* Pelvic Health System should not be used closer than 12 inches to any portable RF communications equipment, including peripherals, such as antenna cables and external antenna's otherwise degradation of the performance of this equipment could result.

Symbols

	Model Number
	Serial Number
	Date of Manufacture
	Manufacturer
	Follow Operating Instructions
	Type BF Applied Part, Internally Powered
	Keep Dry
IP54	The *Leva* device and storage case are protected from dust. They are also protected against splashing water from all directions, but they should not be submerged in water.

	Non-Ionizing Electromagnetic Radiation
	Temperature Limitation
	Humidity Limitation
	Federal law (USA) restricts the sale of this device by or on the order of a Physician.
	This product contains electrical and electronic components that may contain materials which, if disposed of with general waste, could be damaging to the environment. Dispose or recycle this product in accordance with local laws or regulations that apply.
	Radio Frequency Devices (US). Federal Communication Commission Number (FCC ID #) Complies with United States Radio

	communication requirements. (47 CFR Part 15)
	Unique Device Identifier (UDI)

Troubleshooting

What do I do if my Leva will not connect to my mobile device?

If your *Leva* will not connect to your mobile device, make sure the batteries on both the *Leva* wand and the case are properly connected. If it still does not connect, make sure Bluetooth is enabled in your mobile device's settings.

For troubleshooting assistance please contact the Axena Health Technical Support at (833) 450-2914.

Error Messages

On occasion the *Leva* App will display a pop-up alert with an error message. The error messages contain information on how to troubleshoot as well as a support phone number to contact.

If you need assistance with an error message, you may call Technical Support at (833) 450-2914.

Contact

Contact Axena Health, Inc. support for assistance if needed in setting up, using, or maintaining the equipment, or to report unexpected operations or events.

Axena Health, Inc.

Corporate Headquarters: (866) 735-8424

Leva Women's Center: (866) 735-8423

Technical Support: (833) 450-2914

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