leva

Pelvic Digital Health System

Renovia

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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 the *leva*® Pelvic Digital Health System *(leva* PDHS*)* to ensure that your use of the device is safe and effective.

As you begin to familiarize yourself with the *leva* PDHS, it is normal to have questions. If at any time you have questions or need assistance, contact the Renovia's 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).

Your *leva* PDHS helps you exercise and strengthen those muscles, so you can treat your pelvic floor muscle weakness or your urinary incontinence (commonly known as leakage).

What's in the Box?

Your *Ieva* PDHS includes the following:

- Storage case and battery
- Vaginal probe and battery
- Quick Start Guide

What's not in the Box?

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

What Features does the *Ieva* PDHS have?

Your *Ieva* PDHS was designed as a soft, flexible vaginal device. The *Ieva* PDHS has a raised indicator line along the front of the vaginal probe to ensure proper positioning. The *Ieva* PDHS operates on batteries located in the base of both the case and the probe.

The *Ieva* PDHS is provided with a sturdy storage case. This case serves two purposes: it protects the device during storage and also serves as a communications bridge between your *Ieva* 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 *Ieva* Pelvic Digital Health System (*Ieva* PDHS) 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.

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 after use.

Contraindications

Situations in which the device should not be used because the risk of use clearly outweighs any possible benefit:

- No known contraindications.

Warnings

Please read and understand this section carefully prior to using your *Ieva* PDHS.

⚠ Do not use your *Ieva PDHS* while pregnant, or if you think you may be pregnant, unless authorized by your healthcare provider.

⚠ Do not share your Ieva PDHS with other users. The Ieva PDHS is intended for use as a single-user medical device.

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

⚠ Do not use the *Ieva* probe in any other place in your body. The *Ieva*

probe is only intended to be used in the vagina.
⚠ Do not have sexual intercourse while the *Ieva* probe is inserted.
⚠ Do not insert the probe if there is any damage to any of the *Ieva PDHS* components.
⚠ Keep the *Ieva* PDHS out of reach of children. If left unattended, the *Ieva* PDHS could prove to be a choking hazard to a child and could result in death.
⚠ If you experience odor, fever, vomiting, diarrhea, any signs of infections, or any flu-like symptoms, contact your doctor immediately.
⚠ 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 *Ieva* PDHS adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the *Ieva* PDHS should be observed to verify normal operation in the configuration in which it will be used.
⚠ The use of accessories, transducers, and cables, other than those specified, with the exception of transducers and cables sold by Renovia Inc. as replacement parts for internal components (if any), may result in increased emissions or decreased immunity of the *Ieva* PDHS.

Precautions

Information regarding special care to be exercised for the safe and effective use of the device.

- Do not bend the device. Do not twist the device.
- Do not submerge the device in water or liquid.
- Do not use the *Ieva* PDHS in the shower or bathtub, and do not submerge it in liquid of any kind. *Ieva* PDHS is not designed to be used underwater.
- Do not submerge the battery pack in any kind of liquid or expose to running water when detached from vaginal insert.
- Do not bathe, shower, swim, or submerge yourself in water while the device is inserted.
- Do not use the toilet while the device is inserted.
- Do not soak the *Ieva* PDHS.
- Do not put the *Ieva* PDHS in the dishwasher.
- Do not clean the *Ieva* PDHS with anything but mild soap and water.

- Do not use oil or petroleum-based lubricants with the *Ieva* PDHS. Use water-based lubricants only.
- Do not leave the *Ieva PDHS* in the sun, near an open fire, or in a hot parked car. Excessive or direct heat can damage the *Ieva* PDHS.
- Do not modify the *Ieva* PDHS in any way or use it in combination with any accessory not mentioned in this document. This could result in deformation of the *Ieva* PDHS which could cause painful insertion or could damage the electronics.
- Always wash your hands before inserting the device 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 device.
- Always ensure you can maintain your balance when inserting the device and operating the *Ieva* PDHS.
- To ensure hygienic safety, you should clean and dry your *Ieva* probe before and after each treatment session.

Getting Started

Before handling your *Ieva*, wash your hands. This is an important step to prevent harmful bacteria, which may be present on your hands, from contaminating the probe.

1

Remove storage case from the packaging box.

Remove the *leva* PDHS from the storage case.

2

Detach the battery pack from the vaginal insert by holding the base of the vaginal insert firmly and rotating the battery pack counterclockwise.

3

Remove the sticker at the top of the battery pack.

4

Reattach the battery pack by pressing it toward the vaginal insert and rotating it clockwise.

Smartphone Compatibility

The *leva PDHS* is compatible with iOS and Android™ smartphones.

App Download

The **Renovia App** is free and can be downloaded from either the App Store or from Google Play.

Device Registration

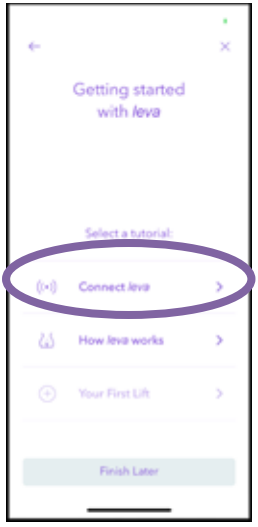
- Open the Renovia App
- Select *Sign Up* located at the bottom of the login screen
  - Enter the following information:
    - First Name
    - Last Name
    - Email
    - Password
    - Indicate if you want to opt out of emails
    - Indicate if you want to be kept logged in
  - Click *Register* to create your account

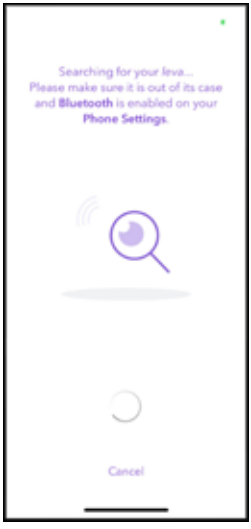
Note: The storage case contains relay electronics that allow communication between your *leva* PDHS and smartphone. **To ensure connection, verify the probe is removed from the case and that the probe, case and smartphone are no more than 3.2 ft (1 meter) away from each other.**

Pairing Your Device

Login to the app using the account email and password that you created. Then follow the pairing process as indicated on the app by first selecting the "*leva*-02" device, then selecting "Connect leva." The app will search for the *leva*-02 Bluetooth signal and when found will show the device ID. Once found select "proceed." See below screenshots of the pairing process.


Welcome to the
Renovia app.
Select your device:
leva 02
Skip Device Selection


Getting started
with leva
Select a tutorial:
Connect leva
How leva works
Your First Lift
Finish Later


Searching for your leva...
Please make sure it is out of its case
and Bluetooth is enabled on your
Phone Settings.
Cancel


Success! Your leva
is connected
leva
Device ID:
Leva02-000110278
Proceed

App Features

The **Renovia App** has several screens that can be reached from the Dashboard.

Renovia App Dashboard

Practice Mode	More
Training Mode	About You
Tests	Device Information
Support	Education
Frequently Asked Questions (FAQs)	Reminders

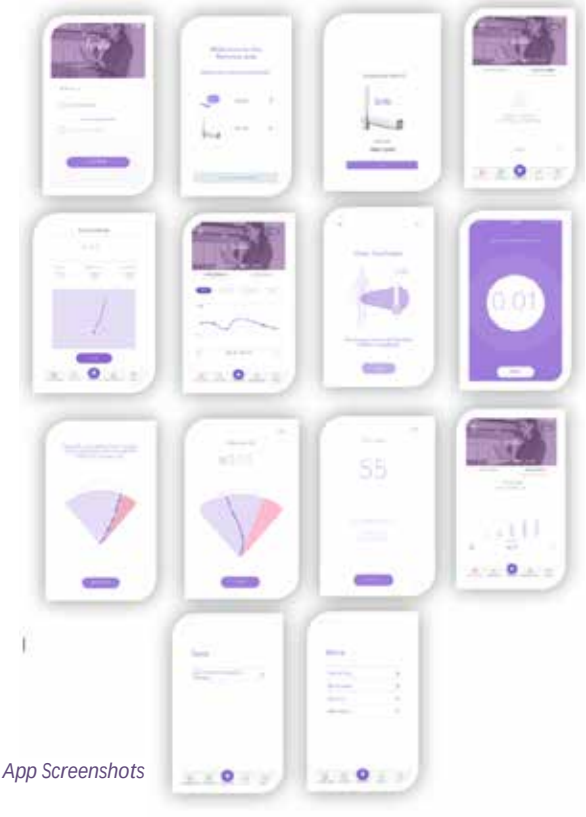


Figure 1. Renovia App Screenshots

Inserting the *leva* Probe

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

Wash Your *leva* Probe

Wash your *leva* probe with mild, warm soapy water and gently dry.

Get Comfortable

Find a comfortable standing position and relax. If this is your first-time using *leva* PDHS, standing with your knees slightly bent is a very comfortable and easy way to reach your vagina.

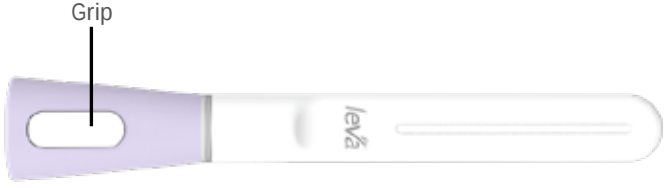
Another option is standing with one foot propped up on a stool or something of similar height so one leg is higher than the other. Inserting the probe is much easier if you are relaxed. The process is much like inserting a tampon.

> ⚠ Always ensure you are able to maintain your balance when inserting the vaginal probe and operating the *leva* PDHS.

Insert the *leva* Probe.

Hold the *leva* probe lightly by placing your thumb on the grip and your index and middle finger on the opposite side.

Remember to keep the probe aligned with the raised line and logo facing forward.



Note: If you have problems with vaginal dryness, applying a very small amount of water-based lubricant to the tip of the probe may make insertion easier. Do not use oil or petroleum-based lubricants.

Insert the probe into your vagina at a slight upward angle toward the small of your back. If you have trouble inserting the probe use your other hand to separate the skin to give access to the vagina.

Gently place the probe into your vagina as far as it will comfortably go.

Stop inserting the device if you feel uncomfortable or when the probe is flush with the perineum (vaginal opening).

If you feel resistance, do not force the probe in. If you have inserted the probe properly, it should be comfortable.

Before beginning your exercises, pull up your underwear up only enough to gently hold the *leva* in place.

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

Starting Your Session

The **Renovia App** has two modes to help you visualize your pelvic floor muscle movements; a Practice Mode and a programmed Training Mode. Both modes can be accessed from the Dashboard.

Open **Practice Mode** first. Unlike the Training Mode, the Practice Mode allows access for as long as you need so you can learn how to properly lift and relax your pelvic floor.

Training should be used during your daily sessions. Each training session can be completed in 2.5 minutes. To access the Training mode, click on the large "+" button at the bottom of the screen. The app will remind you to always wash your hands and *leva* prior to use and will indicate how to insert the device.

The app will then guide you through a series of exercises and rest periods. After each exercise, you will be shown a *Session Score* and after all sessions are completed, you will be shown a *Final Score.*

The Dashboard in the **Renovia App** keeps a record of the sessions you have completed in Training Mode.


Your *leva* PDHS session history is automatically stored on the Renovia database and is available to you right from the Dashboard. You can view a shorter or longer period of progress time by selecting different timepoints in the **Progress** view. You can also click on the plot to see the daily average for any given day. By clicking on the **Sessions** link, you can see the scores for each session completed on a given day.

Removing the *leva* Probe

Relax. Slowly and gently pull the probe downward in the same angle as

it was inserted.

Wash your *Ieva* probe with mild, warm soapy water, gently dry the device, and return the device to its storage case.

Technical Specifications

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

In **Practice Mode**, four measures are reported: *Angle, Session Time, Start Angle,* and *MaxAngle.*

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 Mode**, you will see a *Session Score* after each session and a *Final Score* once you complete all 5 sessions.

The ***Session Scores*** are calculated using an algorithm that considers how high you lift your pelvic floor and for how long you sustain that lift. After completing all five sessions, a *Final Score* is shown which is the average of all five *Session Scores.*

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 *Ieva*.**

Practice Mode and Training Mode 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°
Session Score	0-100	+/- 0.5	1
Final Score	0-100	+/- 0.5	1

Storing Your *leva*

Storage of the *leva* PDHS should not exceed the following conditions:

- Temperature: +5°C to +40°C
- Humidity: 90% RH non-condensing
- Pressure/Altitude: 3000m or 70kPa

Operating Your *leva*

Operation of the *leva* PDHS should not exceed the following conditions:

- Temperature: +5°C to +40°C
- Humidity: 90% RH non-condensing
- Pressure: 700hPa to 1060hPa
- Operating Range: <3.2 ft (1 meter)

Expected Service Life

- The expected service life of the *leva* PDHS is 1 year.
- The *leva* PDHS requires periodic battery changes to maintain reliability (see Replacing Batteries in the Maintenance Section).
- App updates will be pushed to users periodically as needed through the App Store™ or Google Play™.

Maintenance

Use the following instructions to ensure proper care and maintenance of your *leva* PDHS.

Cleaning the Probe:

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

- Clean the *leva* probe with mild, warm, soapy water.

- Do not wash the *leva* probe with the battery removed.
- Care should be taken to not excessively bend or twist the probe during the cleaning and handling process. Excessively bending and twisting the probe can damage the device.
- Gently dry the *leva* probe and return it to its storage case.
- Do not wash the *leva* probe with alcohol, or other chemical cleaners.
- Do not submerge the device in water or liquid.

Cleaning the Case:
Do not wash or submerge the *leva* case. If the case needs cleaning, wipe the case with a damp cloth.

Radio Frequency Wireless Technology:
- The *leva*-02 probe 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 *leva*-02 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) associated with the:
    - 915 MHz band ISM radio is 3.475 mW
    - 2.4 GHz BLE radio is 1.486 mW
- The *leva*-02 device and *leva*-02 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
The *leva* is powered by two (2) custom battery packs:

- Probe: One (1) Device battery pack containing four 393 silver oxide button cell batteries that powers the probe.
- Case: One (1) Relay battery pack containing one 2032 Lithium button cell battery that powers the relay device on the case.

Note: Batteries are non-rechargeable and require periodic replacement

To view the current battery level of your *leva*:
- Open the **Renovia App**
- Login
- Select “More” on the dashboard

- Select “Device Info”
- Connect to your *Ieva* device
- Once connected, the battery level information will be displayed

The device will also show a pop-up screen when the battery is low, prompting you with instructions on how to order replacement batteries.

See below for reorder and replacement steps.

Replacing Batteries
Both the probe and case contain battery packs that are intended to be replaced as a set.

The batteries should be changed when indicated by the *Ieva* PDHS on the Renovia App.

- To purchase replacement batteries, please contact Renovia at (833) 450-2914.

Replacing the Probe Battery:
The probe battery is located at the base of the probe.

Step 1. Detach the battery pack from the vaginal insert by holding the base of the vaginal insert firmly and rotating the battery pack counter-clockwise.

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

Step 3. Attach the replacement battery pack by pressing it toward the vaginal insert and rotating it clockwise.

Step 1

Remove battery pack

Step 2

Remove sticker

Step 3

Attach replacement battery pack

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 the device.

Step 2. Detach the battery from the storage case by rotating the base of the battery counterclockwise.

Step 3. Attach the replacement battery pack by pressing it toward the vaginal insert and rotating it clockwise.

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 Renovia as replacement parts for internal components (if any), may result in increased emissions or decreased immunity of the *Ieva* PDHS.

FCC Compliance

The *Ieva* PDHS is compliant with part 15 of FCC regulations for Class B computing devices (47 CFR Part 15). 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. Changes or modifications not expressly approved by Renovia Inc. could void the user's authority to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the receiving antenna; Increase the separation between the equipment and receiver; Connect the equipment into an outlet on a circuit different from that to which the receiver is connected; Consult the dealer or an experienced radio/TV technician for help.

Electromagnetic Emissions and Immunity

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

The *Ieva* PDHS is intended for use in the electromagnetic environment specified below. The customer or the user of the *Ieva* PDHS 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 the *Ieva* PDHS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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 *Ieva* PDHS is used exceeds the applicable RF compliance level above, the *Ieva PDHS* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Ieva* PDHS.

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* PDHS is intended for use in the electromagnetic environment specified below. The customer or the user of the *leva* PDHS 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 line(s) to earth	Not applicable [3]	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input line 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[3]	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *leva PDHS* requires continued operation during power mains interruptions, it is recommended that the *leva PDHS* 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 3meters.
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* PDHS. Keep *leva* PDHS 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 $d = \frac{3.5}{V1}\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \frac{12}{V2}\sqrt{P}$	80 MHz to 800 MHz $d = \frac{12}{E1}\sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{23}{E2}\sqrt{P}$
	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* PDHS should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the *leva* PDHS should be observed to verify normal operation in the configuration in which it will be used.

⚠ The *leva* PDHS 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-02* 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 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* PDHS will not connect to your mobile device, make sure the battery pack on both the probe 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 Renovia Technical Excellence Center at (833) 450-2914.

Error Messages

On occasion the 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. The Error messages are included here.

Bluetooth Disconnect

"Bluetooth Connection Failure: Please ensure *leva* case is nearby and try again. Contact support at (833) 450-2914 if this issue persists."

Probe Disconnect

Probe Connection Failure: This could be due to low batteries or poor signal. Contact support at 1 (833) 450-2914 if this issue persists.

Low Battery

This error is displayed when the reported battery level is below 35% but above 5%:

"Low Battery: Warning your *leva* battery level is getting low. You may continue with your exercises, but you will need to contact support at (833) 450-2914 to order a replacement battery pack."

Replace Battery

This error is displayed if the actual battery level reported is 5% or below:

"Low Battery: Please replace the battery pack on your leva. Contact support at 1 (833) 450-2914 to order a replacement battery pack."

Sensor Error

"Probe Sensor Error: Please close your app and wait a few minutes, then reopen the app and try to proceed with your exercises with leva. Contact support at (833) 450-2914 if this issue persists."

FAQs

Please see the Frequently Asked Questions section of the **Renovia App**.

Contact

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

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