

# leva<sup>®</sup>

***Pelvic Digital Health System  
Instructions for Use***



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**PLEASE READ THE INSTRUCTIONS THOROUGHLY BEFORE USING  
LEVA® PELVIC DIGITAL HEALTH SYSTEM.**

## Contents

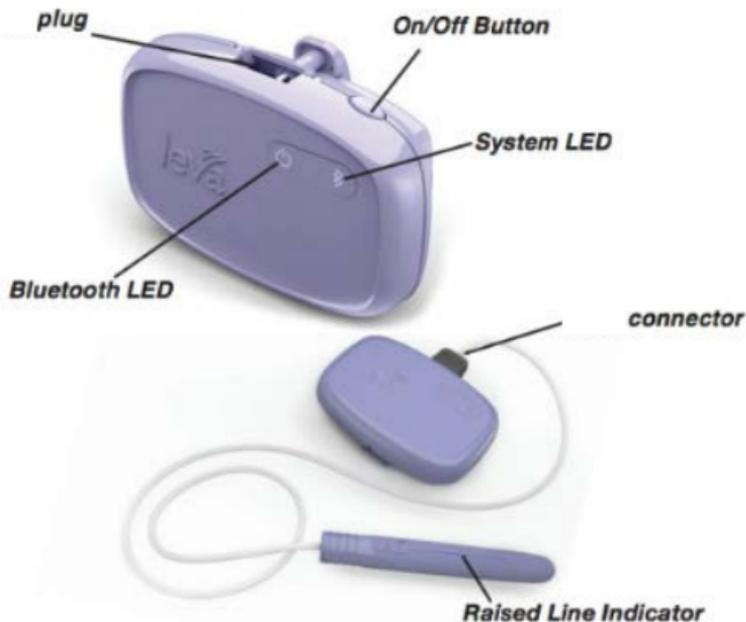


Your *leva* Pelvic Digital Health System (*leva* PDHS) package includes the following:

1. Probe and Connector
2. Transmitter box
3. Two alkaline AA batteries
4. USB with Instructions for Use
5. Documentation: Quick Start Guide



## Features



## 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 in women.

This device interacts with the user via smartphone technology.

The *Ieva* PDHS is compliant with part 15 of FCC regulations for Class B computing devices.

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 (once in the morning and once in the evening). 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**

Serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

- Do not use the *leva* PDHS while pregnant, or if you think you may be pregnant, unless authorized by your doctor.
- Do not leave the probe in your body for longer than necessary to complete the training session. Remove the probe after each training session.
- Do not use the *leva* PDHS in any other place in your body.
- Do not have sexual intercourse while the probe is inserted.
- Do not insert the probe if there is any damage to the *leva* PDHS.
- Keep the *leva* PDHS out of reach of children. If left unattended, *leva* PDHS could prove to be a strangulation or choking hazard to a child and could

result in death.

- Do not share the *leva* PDHS. The *leva* PDHS is a single-user medical device.
- 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 silicone rubber.
- Do not use 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 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 *leva* PDHS.

## Precautions

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

- Do not bend the probe. Do not twist the probe.
- Do not bend or wrap the wire around the probe, as this may result in damaging the sensors.
- Do not submerge the probe in water or liquid.
- Do not use the *leva* PDHS in the shower, bathtub or submerge it in liquid of any kind. *leva* PDHS is not designed to be used underwater.
- Do not submerge the transmitter box in any kind of liquid or expose to running water.
- Do not get the connector wet.

- Do not bathe, shower, swim, or submerge yourself in water while the probe is inserted.
- Do not use the toilet while the probe is inserted.
- Do not soak the *leva* PDHS.
- Do not put the *leva* PDHS in the dishwasher.
- Do not clean the *leva* PDHS with anything but mild soap and water.
- Do not use oil or petroleum-based lubricants with the *leva* PDHS. Use water-based lubricants only. Do not leave the *leva* PDHS in the sun, near an open fire, or in a hot parked car. Excessive or direct heat can damage the *leva* PDHS.
- Do not modify the *leva* PDHS in any way or use it in combination with any accessory not mentioned in this document. This could result in deformation of the *leva* PDHS which could cause painful insertion or could damage the electronics.
- Always wash your hands before inserting the probe to prevent harmful bacteria which may be present on your hands from entering your vagina.
- Always ensure you can maintain your balance when inserting the probe and operating the *leva* PDHS.

## Smartphone Compatibility

The *leva* Pelvic Digital Health System is compatible with both iOS and Android™ smartphones.

## Register *leva* PDHS

- Visit [www.renoviainc.com](http://www.renoviainc.com) and click on the *leva* Login on the top navigation bar at the end.
- Enter your username and the *leva* PDHS serial number, which you received in an email from Renovia.

- Confirm your name and email address.
- Review the Privacy Policy to confirm whether you agree to the terms and conditions.
- Create a password.

If you need to reset your password, click the reset password button and enter your email. You can then set a new password.

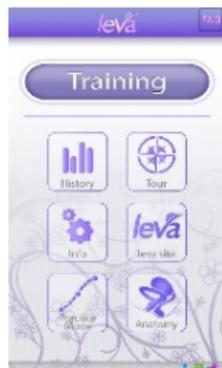
## Installing the Digital Health App

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

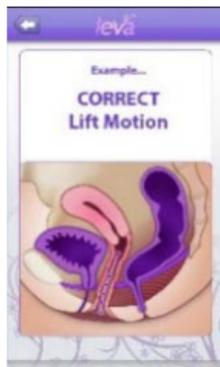


The *leva* PDHS connects to your smartphone via Bluetooth. Once the **your leva** app is installed, you will need to pair your smartphone under the Bluetooth settings on your smartphone.

The **your leva** app has the following features: **Practice** Mode, **Training** Mode, **Tour**, **Anatomy**, **Info** and **History**, as well as a link to *leva* PDHS Frequently Asked Questions (FAQs).



Watch the animated video on your app by clicking on the **Anatomy** icon for an illustration of how to perform a pelvic floor lift correctly.



## Getting Started

Wash your hands. This is an important step to prevent harmful bacteria which may be present on your hands from contaminating the probe.



Remove *leva* PDHS from the storage container.

**Install the batteries.** Turn the clip on the back of the transmitter box to the side to access the battery compartment. Open the battery compartment and install the two alkaline AA batteries. Close the battery compartment and turn the clip back into place.





Plug the connector into the transmitter with the arrows facing the back clip and **the screws facing the front**. Be sure to push the connector in until it clicks.

Turn *leva* PDHS on by pressing down on the **ON/OFF** button on the top right of the transmitter.

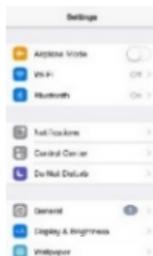
Upon startup, both LEDs on the transmitter will cycle through **red**, **green**, and then **blue**. After this, the system LED will light up **green**, indicating the connector is attached.

*leva* PDHS is now powered on and the Bluetooth is ready to be paired.

## Pairing *leva* PDHS

On your smartphone, tap on the Settings icon, and select Bluetooth to search for your *leva* PDHS.

**iOS**

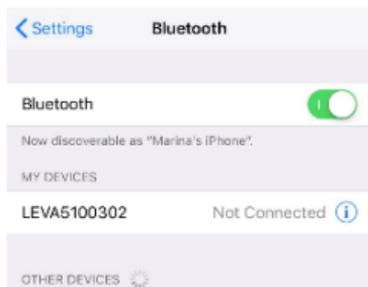


**Android™**



Make sure the *leva* PDHS and your smartphone are no more than 16 feet (5 meters) away from each other. If they are further than this, they may not discover each other.

*leva* PDHS is depicted by the name **LEVA** and the 7-digit serial number, e.g. LEVA1234567. The serial number can be found on the bottom of the transmitter.



Next to the *leva* name/serial number it will indicate 'Not Paired'. Click on the name to pair it.

Once this is successfully completed, the Bluetooth status LED will be **green** and your smartphone will say 'Connected' next to the device name.



The *leva* PDHS can only pair to one smartphone at a time.

If you switch between smartphones to use *leva* PDHS, you must remember to pair *leva* PDHS every time you switch.

Once paired, open the ***your leva*** app. The LED light will then turn blue.

### Inserting the *leva* probe

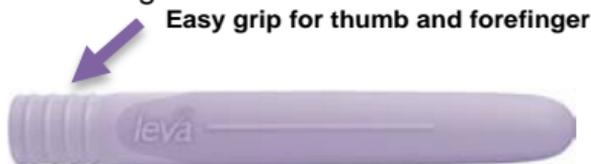
Wash your hands again. You should always wash your hands before inserting the probe to prevent harmful bacteria which may be present on your hands from entering your vagina.

Wash the probe according to the instructions in the Maintenance section below.

Find a comfortable 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 something so one leg is higher than the other. Inserting the probe is much easier if you are relaxed and the process is much like inserting a tampon.

**Always ensure you can maintain your balance when inserting the probe and operating the *leva* PDHS.**

Hold the probe lightly on the easy grip with your thumb and middle finger.



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

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 when 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.



## Starting Your Session

Once the probe is inserted, open the **your leva** app and login.

The **your leva** app has two Modes to help you visualize your

pelvic floor muscle movements: a Practice Mode and a programmed Training Mode.

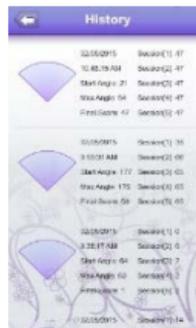
Open **Practice** Mode first. Unlike the Training Mode, the Practice Mode allows access for as long as you need so you can learn how to properly lift and relax.



**Training** should be used during your daily sessions. Each training session can be completed in 2½ minutes.

The **History** icon in the **your leva** 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 by using your login and password.



## Removing the *leva* probe

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

## Technical Specifications

The *leva* PDHS uses 6 sensors to provide positional feedback on the shape and movement of your vagina as you perform pelvic floor lift exercises. In **Practice** Mode, 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. In fact, when it is parallel to the floor, the *Angle* is 90°. 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 how long your **Practice** session has been going for. 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 Conditions**.

## Practice and Training Mode measures:

Measure	Range	Accuracy	Precision
<i>Angle</i>	0-180°	+/- 0.2°	1°
<i>Start Angle</i>	0-180°	+/- 0.2°	1°
<i>Max Angle</i>	0-180°	+/- 0.2°	1°
<i>Session Score</i>	0-100	+/- 0.5	1
<i>Final Score</i>	0-100	+/- 0.5	1

## Operating Conditions

When using the *leva* PDHS, the following operating conditions should not be exceeded:

**Temperature**  
5-40°C

**Humidity**  
15-93% RH  
Noncondensing

**Pressure**  
700 hPa-1060 hPa

## Maintenance

- Clean the probe with mild warm soapy water after every use, let it air dry or dry it with a towel, and store it in its clean container.
- Do not wash with alcohol, or other chemical cleaners.
- Only wash the probe when it is disconnected from the transmitter.
- To disconnect, press in on the sides of the connector while pulling the connector away from the transmitter.
- Do not get the connector wet.
- Do not wash the transmitter. If the transmitter needs cleaning, wipe it with a damp cloth.
- The battery should be changed when indicated by the

*leva* PDHS or every 4 weeks (see System LED chart).

## Storing *leva* PDHS

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

- Temperature: -25-70°C
- Humidity: 45-93% RH Noncondensing
- Altitudes: 0-20,000 ft.
- Always remember to wash your hands and the probe after every use.
- After washing the probe either allow it to air dry or dry it with a clean towel.
- Store *leva* PDHS in a clean, dry container or in the *leva* PDHS box you received it in.
- Do not bend or wrap the wire around the probe, as this may result in damaging the sensors.
- Do not submerge the probe in water or liquid.
- Although you must wash the probe, you cannot use the *leva* PDHS in the shower, bathtub or submerge it in liquid of any kind.
- *leva* PDHS is not designed to be used underwater.
- Do not leave it in the sun, near an open fire, or in a hot parked car. Excessive or direct heat can damage the *leva* PDHS.

## System and Bluetooth Status Indicators

The two LEDs on the transmitter are there to help you understand what your *leva* PDHS is doing. When your *leva* PDHS is turned on these LEDs will cycle through **red**, **green**, and **blue** and then turn off. After a few seconds the



LEDs will light up to show you the status of your *Ieva* PDHS. The meaning of the color of each LED is summarized in the tables below.



### System LED

LED Color	Status
Cycle through Red, Green and Blue	Power ON
Green	Device is ready for training
Blue	Probe is disconnected
Quickly Blinking Red	Malfunction
Blinking Red Every 2 Seconds	Low battery



### Bluetooth LED

LED Color	Status
Cycle through Red, Green and Blue	Power ON
OFF	Bluetooth not paired
Green	Bluetooth paired
Red	Bluetooth paired but failed to authenticate
Blue	App is communicating with the <i>Ieva</i> PDHS
Quickly Blinking Red	Malfunction

When you have the probe plugged in, your Bluetooth connected, and the app running, the System LED will be green and the Bluetooth LED will be blue. After 30 seconds in this state, the LEDs will turn off. If you want to view the LEDs again, press the on/off button on your transmitter, and the LEDs will light up for another 30 seconds.

## Troubleshooting

### What do I do if my *leva* will not turn on?

If your *leva* PDHS will not turn on, make sure the two new alkaline AA batteries are installed correctly. If they are installed correctly and your *leva* PDHS still will not turn on, replace the batteries. When the *leva* PDHS turns on, it will cycle through red, green, and blue on the LEDs. Do not use rechargeable batteries, they do not have enough voltage to power the *leva* PDHS.

For additional troubleshooting please see the [yourleva.com](http://yourleva.com) website or contact us at 1-866-735-8423.

## User Portal

Your training sessions will be saved on your smartphone as well as online at <https://leva.renoviainc.com>. Whenever you are connected to Wi-Fi or have an active data connection through your smartphone, your training history will be uploaded to the online data portal. If you are not connected to Wi-Fi or you have no data signal, your training history will be saved on your smartphone and the data will upload to the portal when Wi-Fi or data connectivity is restored and you login to the app. You can login to the portal with your username and password on any device with access to the web.

## Electromagnetic Emissions and Immunity

Warning: 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 *leva* PDHS.

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The <i>leva</i> PDHS is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>leva</i> should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	The <i>leva</i> 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.  The <i>leva</i> 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The <i>leva</i> PDHS is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>leva</i> PDHS should assure that it is used in such an environment.			
<b>IMMUNITY test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1] = 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <i>leva</i> PDHS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = \sqrt{\frac{3.5}{E_1}} \sqrt{P}$  $d = \sqrt{\frac{3.5}{E_1}} \sqrt{P}$ 80 MHz to 800 MHz  $d = \sqrt{\frac{7}{E_1}} \sqrt{P}$ 800 MHz to 2.5 GHz  where <i>P</i> is the
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E1] = 3 V/m	

			<p>maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>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></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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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 PDHS is used exceeds the applicable RF compliance level above, the leva 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 leva 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 *løva* PDHS is intended for use in the electromagnetic environment specified below. The customer or the user of the *løva* PDHS should assure that it is used in such an environment.

<b>IMMUNITY test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact  ±8 kV air <sup>1</sup>	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 <sup>2</sup>	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 <sup>3</sup>	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 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 s	Not applicable <sup>3</sup>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>løva</i> PDHS requires continued operation during power mains interruptions, it is recommended that the <i>løva</i> 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 3 meters.
3. The system is powered by internal battery only.

## Electromagnetic Interference

Warning: 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.

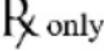
Wireless communications equipment such as wireless home network devices, mobile phones, and cordless telephones and their base stations can affect *leva* PDHS. Keep *leva* PDHS away from other wireless equipment based on the table below:

Rated maximum output power of transmitter (W)	Recommended separation distance between <i>leva</i> ® and communications equipment according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = \frac{3.5}{\sqrt{f_1}} \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \frac{12}{\sqrt{f_2}} \sqrt{P}$	80 MHz to 800 MHz $d = \frac{12}{\sqrt{f_1}} \sqrt{P}$	800 MHz to 2,5 GHz $d = \frac{23}{\sqrt{f_2}} \sqrt{P}$
	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.

## Symbols

	Model Number
	Serial Number
	Date of Manufacture
	Manufacturer
	Follow Operating Instructions
	Type BF Applied Part, Internally Powered
	Keep Dry
IP22	Water ingress protection rating 22. Transmitter protects against solid objects smaller than 12.5mm diameter and can be exposed to vertically dripping water when the enclosure is tilted up to 15 degrees on either side of the vertical. Although the transmitter can be exposed to vertically dripping water without harming the user, it may no longer function
IP27	Water ingress protection rating 27. The probe and connector have an IP rating of 27 which means it protects against solid objects smaller than 12.5mm diameter and can be temporarily submerged in water.
	Non-Ionizing Electromagnetic Radiation

	Temperature Limitation
	Humidity Limitation
 only	Federal law (USA) restricts the sale of this device by or on the order of a Physician.

## FAQs

Please see the *yourleva.com* website for the most up to date list of Frequently Asked Questions.

## Contact

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

### Renovia Inc

263 Summer Street, 5th Fl

Boston, MA 02210

1 (866) 735-8424

[support@renoviainc.com](mailto:support@renoviainc.com)

*Bluetooth*® is a registered trademark of Bluetooth SIG, Inc.

*leva*® is a registered trademark of Renovia Inc.

Android™ - Android is a trademark of Google LLC.

Google Play and the Google Play logo are trademarks of Google LLC.

Apple and the Apple logo are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc., registered in the U.S. and other countries.



The logo for Renovia, featuring the word "Renovia" in a stylized, purple, cursive font. The letter "i" has a dot that is a small circle with a horizontal line through it. The "v" has a distinctive shape with a small loop at the top. The "a" has a similar loop at the top. The entire word is enclosed in a thin, light purple oval outline.