

PERIFIT+

User Guide

support@perifit.co

Perifit+ - X6 Innovations



128 rue de la Boetie, 75008 Paris, France

TF-IFU-PF-v20221122- Latest revision date: 2022-11-22

PERIFIT+



1. Intended use, intended user description



READ ALL INSTRUCTIONS BEFORE USE.

Failure to follow the instructions and safety information can lead to injury or damage to the device.

1.1 Intended use

Perifit+ is a wireless Kegel exerciser intended to increase precision, motivation and regularity of your pelvic floor workouts.

Perifit+ is composed of a device and an app that form an interactive platform that will guide you through Kegel exercises.

Perifit+ is intended for: encouraging regular pelvic floor exercises; strengthening of the pelvic floor muscles; rehabilitation and training of weak pelvic floor muscle; treatment of stress, urge and mixed urinary incontinence in women; improving sexual pleasure or function in women with existing pelvic floor dysfunction; improving pelvic floor function in the post-partum period, including improving strength, reducing dysfunction, reducing urinary incontinence and improving sexual function; improving mild to moderate prolapse symptoms.

1.2 Intended Users

Perifit+ is intended for vaginal use by adults. The body of the probe is meant to be inserted into the user's vagina. The Perifit+ is intended for a single user only and is not to be shared.

1.3 Description

Perifit+ is a wireless Kegel exerciser intended to increase precision, motivation and regularity of your pelvic floor workouts. Perifit+ is composed of a device and an app that form an

interactive platform that will guide you through Kegel exercises.

It helps users to perform Kegel exercises that may improve bladder control, pelvic floor muscle strength and sexual pleasure.

Perifit+ has three main functions:

- It allows users to visualize their pelvic floor contractions on the screen of their smartphone through visual biofeedback.
- It makes Kegel exercises fun and entertaining and helps keep track of the user's progress
- It provides training programs that facilitate effective pelvic floor muscle exercise by following the training principles of specificity and progression

Perifit+ gamifies your Kegel routine and provides guidance for your workouts. It detects the force exerted by pelvic floor muscle contractions and allows the user to visualize this information in real time via smartphone. Using the device and corresponding app is like having a personalized coach giving the necessary motivation and live feedback to help you step up your pelvic floor workouts.

1.4 Benefits related to the use of Perifit+

The pelvic floor is composed of several layers of muscles which provide pelvic organ support; passage for the urinary, genital, and digestive tracts; ensure urinary and anal continence while also allowing voiding and defecation; and can accommodate sexual intercourse, pregnancy and delivery. Dysfunction of the pelvic floor may develop after specific events (such as weakness following pregnancy or delivery), or may be progressive and idiopathic in nature (such as the development of urinary incontinence with advancing age). Strengthening of the pelvic floor muscles through Kegel exercises is recommended as first-line conservative treatment for a variety of pelvic floor disorders.

The Perifit+ is an adjunct to pelvic floor muscle training. Benefits related to pelvic floor muscle training include:

- Improving overall pelvic floor muscle fitness (such as muscular strength and endurance);
- Treatment or reduction in symptoms of stress, urge, and mixed urinary incontinence;
- Improving sexual pleasure or function in women with existing pelvic floor dysfunction;

- Improving pelvic floor function in the post-partum period, including improving strength, reducing dysfunction, reducing urinary incontinence, and improving sexual function;
- Improving mild to moderate prolapse symptoms.

2. Safety Information



Perifit+ is not intended to diagnose any medical condition. If you are unsure of whether or not you should use Perifit+, please consult a qualified healthcare professional.

2.1 Contra-indications

Do not use Perifit+ if:

- you have abnormal vaginal discharge (bleeding or otherwise) including bleeding after sexual intercourse, hematuria (blood in your urine), bleeding from the anus,
- you are experiencing back pain severe enough for you to need pain-killers,
- you have recently undergone surgery,
- you have symptoms of bladder, vaginal, or urinary tract infection are present,
- you have a history of urinary retention or symptoms thereof,
- you are pregnant,
- you have given birth within the last 6 weeks,
- you have neurological issues such as difficulties controlling your muscles, numbness, loss of sensitivity,
- you have severe pelvic pain or muscle spasms, new pain after menopause, or the appearance of a mass or lump in the pelvis,
- you have hypertonic pelvic floor (muscles in the pelvic floor becoming too tense and are unable to relax), vaginismus,
- you have neurological issues such as difficulty controlling your muscles, numbness, loss of sensitivity,
- you have moderate to severe prolapse, and you have not yet consulted a medical professional,
- you are allergic to medical-grade silicone.

Using Perifit+ in these situations may affect an underlying condition. Consult a medical professional before using the Perifit+ for any of these situations.

2.2 Warnings and risks

Please be aware that in rare cases, you may experience the following:

- Performing too many pelvic floor contractions may cause muscle

fatigue which may result in muscle soreness, and in some rare cases may cause muscle damage. Limit your sessions by the duration and frequency specified in Section 3.2 ("How often and for how long should I train?")

- Although Perifit+ is made with medical grade silicone, in very rare cases some particularly sensitive users may experience allergic reaction. Please read and carefully follow the instructions in Section 3.5 ("Cleaning Perifit+") of this User Guide.

- If Perifit+ causes you a feeling of dryness, burning or itching, please stop using Perifit+. If the feeling persists, please reach out to a qualified health professional

- In rare cases, insertion of an external object such as Perifit+ into your vaginal cavity may result in vaginal bleeding. In this case, please stop using your device immediately and reach out to a qualified health professional.

2.3 Precautions

In order to avoid risk of contamination or infection:

- Wash your hands and your Perifit+ before and after every use with warm, soapy water. Read Section 3.5 ("Cleaning your Perifit+") of this User Guide carefully and follow all cleaning instructions.

- Do not share Perifit+ with others. Even with proper cleaning, sharing the probe increases your risk of infection.

- Do not leave Perifit+ in the vagina for more than one hour at a time.

- Keep the Perifit+ out of reach of infants and children, and away from dogs, cats, and other pets. In case of animal contamination or damage to the probe, do not use the Perifit+ as this may increase the likelihood of infection.

In order to reduce risks of irritation, allergy, or burns:

- The Perifit+ is made of medical grade silicone. However, if skin irritation occurs, stop using the device and seek medical advice.

- Do not try to sterilize your Perifit+, or use detergents or alcohol-based cleaning agents on the Perifit+. Refer to Section 3.5 ("Cleaning your Perifit+") for proper cleaning instructions.

- Do not use Perifit+ if some of its electronic parts are visible.

- Do not use the Perifit+ if it feels hot to the touch or if the Perifit+ is overheating.

- Do not use Perifit+ if you experience persistent pain when inserting or using Perifit+, even with water-based lubricant.

In order to avoid muscle pain:

- Do not use Perifit+ anally
- Do not overtrain. Read Section 3.2 ("How often and for how long should I train?") for guidelines on training session duration. If you feel muscle soreness after using Perifit+, please reduce the duration and frequency of your sessions. If the pain worsens or persists, please reach out to a qualified health professional for advice
- Make sure you have inserted the Perifit+ correctly. Read Section 3.6 ("Using Perifit+") before beginning to train. In order to protect your device and reduce risk of explosions:
 - No modifications to the Perifit+ should be made. Do not take apart the Perifit+ nor use the Perifit+ if it has been re-assembled by any person other than a technician authorized by the manufacturer. Doing so may lead to injury
 - Do not boil, microwave, or clean Perifit+ in the dishwasher
 - Do not use Perifit+ in the bath or shower
 - Avoid extreme heat (above 40°C/104°F), extreme cold (below 0°C/32°F), or pressure outside of the range from 700 hPa to 1060 hPa.

If you experience any of the symptoms mentioned above or have any questions, please reach out to support in the app by clicking on the "?" or via email to support@Perifit.co

2.4 Symbol legend

See symbol legend page 14.

3. Product Information

3.1 Your Device

See diagram 15.

Perifit+ contains a battery and is not chargeable. It allows for 5+ years of training. Please refer to the Warranty section of your User Guide for further information. Perifit+ is made from medical grade silicone.

Battery voltage: 3V / Battery capacity: 220mAh.

Technical Data	
Dimensions	117 mm x 70 mm x 30 mm
Weight	40 g
Volume	41,3 cm ³
Minimum applied pressure	10 g

Applied pressure range	10 g – 2 kg	
Type of communication with the Smartphone	Bluetooth	
Bluetooth range for best performance	2 meters	
Smartphone application name	Perifit	
Operation and storage condition	Humidity	15% - 80%
	Pressure	700 hPA – 1060 hPa
	Temperature	0°C – 40°C

3.2 How often and how long should i train?

Frequency and duration of use depends on each individual. A recommendation is to start by doing 3 to 5 ten-minute sessions per week. Do not exceed this training time.

3.3 Setting up

1. Download the app



2. Press the ON/OFF button



3. Launch the app



4. Follow instructions



Learn Tab

Ensure the Bluetooth function on your phone is enabled. However do not use your phone's Bluetooth settings to connect! Connection should be done through the Perifit+ app. Need Help? Click on "?" in the Perifit+ app, or reach out to support@Perifit.co.

3.4 Before you begin

3.4.1 Reminder of Contraindications

Since purchasing the Perifit+, you may have developed a condition

for which pelvic floor training is not recommended. Please review Section 2.1 ("Contraindications") before beginning to use your Perifit+. If you have any doubt as to whether it is suitable for your condition, please consult a medical professional before use.

3.4.2 Device Use Life

Your Perifit+ battery is intended to last for at least 5 years of regular training as detailed in section 3.6 ("Using Perifit+"). A chart showing your cumulative training time can be visualized in the 'Train' tab by clicking on the Time Goal section. If, when turning on your Perifit+, the green flashing light does not appear, contact customer service.

3.4.3 Inspecting your Perifit+

You should inspect your probe before each use. If you see any damage such as a cracked or torn outer surface, visible electronics, stains, discoloration, peeling and cracked seals, corrosion, or any other indication of damage do not use the Perifit+ and contact customer service.

3.5 Cleaning Perifit

3.5.1 Before using Perifit+ for the first time

The device must be thoroughly cleaned before first use and after each use. Thoroughly cleaning your Perifit+ removes bacteria and reduces the risk of infection. Failing to thoroughly clean your Perifit+ increases the risk of bacterial growth and subsequent infection. Do not clean the probe in an autoclave or dishwasher. Do not use detergent or alcohol-containing cleaning agents on Perifit+.

1. Wash your hands thoroughly with soap and water before touching Perifit+.
2. Rinse the Perifit+ under a stream of warm water.
3. Use a mild household soap to thoroughly scrub all surfaces. You may use your hands or a soft cloth but do not use abrasive material.
4. Scrub all surfaces of the device thoroughly the probe surface and the curved antenna.
5. Rinse the Perifit+ under warm running water.
6. Dry with a soft clean cloth or let air dry on a clean surface.
7. Visually inspect the device, and if the device is not visually clean, repeat the cleaning process.

3.5.2 After each use

The device must be thoroughly cleaned after each use. Thoroughly cleaning your Perifit+ removes bacteria and reduces the risk of infection. Failing to thoroughly clean your Perifit+ increases the risk of bacterial growth and subsequent infection. Do not clean the probe in an autoclave or dishwasher. Do not use detergent or alcohol-containing cleaning agents on Perifit+.

1. Wash your hands thoroughly with soap and water before touching Perifit+.
2. Rinse the Perifit+ under a stream of warm water.
3. Use a mild household soap to thoroughly scrub all surfaces. You may use your hands or a soft cloth but do not use abrasive material.
4. Scrub all surfaces of the device thoroughly: the probe surface and the curved antenna.
5. Rinse the Perifit+ under warm running water.
6. Dry with a soft clean cloth or let air dry on a clean surface.
7. Visually inspect the device, and if the device is not visually clean, repeat the cleaning process.

3.6 Using Perifit+

1. Start by cleaning your hands and your Perifit+ with warm, soapy water
2. Turn Perifit+ ON by clicking on the ON/OFF button
3. Lie down comfortably with your knees bent and legs slightly apart.
4. Insert the probe into your vagina, with its tail directed towards your belly. Make sure that both pebble-shaped sensors are inserted. Don't worry about its exact depth: your Perifit+ will naturally find its position after a couple of contractions. Use water-based lubricant if needed. You can wear panty during your session for more comfort.
5. Follow the app instructions
6. When you are done, turn your Perifit+ off by clicking on the ON/OFF button
7. Clean your Perifit+ with warm soapy water, dry it completely and store it in a safe, clean and dry environment for future use (see next Section)



You do not need to charge Perifit+. It is not chargeable. The battery is intended to last at least 5 years at a training duration and training frequency specified in the Section 3.2 ("How often and for how long should I train"). If you have any questions, please reach out to support in the app by clicking on "?" or via email at the address support@Perifit.co.

3.7 Tracking Progress

You can visualize your pelvic floor training statistics in the 'Progress' tab of the app. If you have been training regularly for 8 to 12 weeks and have not seen any improvement in symptoms, we recommend that you consult a medical professional as your leak symptoms may be due to another underlying issue.

3.8 Proper Kegel Technique

If you are having difficulty or are unsure of your Kegel technique, we recommend that you reach out to our support team (support@Perifit.co or by clicking on the '?' in the app) or consult a pelvic health practitioner.

3.9 Other precautions

Perifit+ is water-resistant, and can thus be placed in a stream of water, but it should not be submerged or used in the bathtub. Avoid storing your Perifit+ in a place that is either too hot or cold (lower than 0°C (32°F) or higher than 40°C (104°F)). Take special care do not to leave the system in a car during summer, as extreme temperatures may damage the internal circuitry of the probe.

Also we recommend you to:

- Avoid dust by storing the device in its box between uses.
- Do not drop the probe, subject it to strong forces or to continual vibration. Doing so may damage its outer covering or its internal circuitry.
- Do not freeze or microwave the probe, nor place it in an oven. Before inserting the probe, feel the body of the probe. The temperature should feel comfortable. If the probe feels too hot, run the body of the probe under clean cool water for a few minutes before checking the temperature again. If the probe feels too cold, run the body of the probe under clean warm water for a few minutes before checking the temperature again. Hold the probe in your hand when running under the water so that you can feel when the temperature is right for you.
- Keep Perifit+ away from direct sun, radiators and naked flames

- The Perifit+ is not sterile and is not intended to be sterilized

3.10 Smartphone Requirements

Minimum smartphone requirements: compatible with BLE (Bluetooth Low Energy) and iOS 13 and above or Android 6 and above. An internet connexion (3G, LTE or WIFI) is needed.

3.11 Operating systems

The Perifit+ device system currently works only with Smartphones running the Android operating system (version 6 and later) or iOS operating system (version 13 and later). Your phone should be able to tell you what version of the operating system it is running. It is also able to be used with Android tablets or iPads with the previously mentioned operating systems. Consult the instruction manual that accompanied the phone or tablet if you are unsure how to find this information. Some compatible phones If your Smartphone was purchased after 2010, it should be compatible with the Perifit+ system. The phone must be Bluetooth communication capable and run version 6 of the Android operating system (or later) or for iPhone, 6S or later.

In the event of failure to pair the Perifit+ device with your smartphone, you will not be able to use the Perifit+ device. Bluetooth communication has a limited range. For best performance, place the Smartphone you are using within two meters of the Perifit+ device.

Bluetooth communication has a limited range. For best performance, place the Smartphone you are using within two meters of the Perifit+ device.

3.12 Electromagnetic compatibility (EMC)

The Perifit+ device complies with the IEC 60601-1-2:2014. However, electronic and mobile communications equipment may transmit electromagnetic energy through the air and there is no guarantee that interference will not occur in a particular usage or environment. If this occurs, it may be beneficial to temporarily turn off the Wi-Fi feature on your Smartphone while using Perifit+. Interferences might create delays with the Bluetooth communication and the connexion with the Perifit+ device Environments for use that are suitable for the use of the Perifit+ device include: the home and indoor environment.

Manufacturer's declaration – Electromagnetic Emissions			
Emission test	Standard		Compliance
Radiated disturbance	CISPR 11:2016		Class B (30MHz to 100MHz)
Manufacturer's declaration – Electromagnetic Immunity			
Immunity test	Standard	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD)	EN 61000-4-2:2009 IEC 61000-4-2:2008	$\pm 2, \pm 4, \pm 8, \pm 15$ kV (air)	$\pm 2, \pm 4, \pm 8, \pm 15$ kV
Electrostatic discharge (ESD)	EN 61000-4-2:2009 IEC 61000-4-2:2008	$\pm 2, \pm 4, \pm 6, \pm 8$ kV (contact)	$\pm 2, \pm 4, \pm 6, \pm 8$ kV
Electrostatic discharge (ESD)	EN 61000-4-2:2009 IEC 61000-4-2:2008	$\pm 2, \pm 4$ (horizontal coupling plane/ vertical coupling plane)	$\pm 2, \pm 4$
Radio-frequency, Continuous radiated disturbance	EN 61000-4-3:2006+A1:2010 IEC 61000-4-3:2010	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz
Power frequency magnetic field	EN 61000-4-8:2010 IEC 61000-4-8:2009	30 A/m	30 A/m

3.13 Disposing of Perifit+

Perifit+ is an electronic device. Please refer to your country and state law for the disposal of Perifit+.

4. Key features of the Perifit+

- Perifit+ probe uses sensors to detect the pressure exerted by contractions of your pelvic floor muscles (including levator ani)
- Perifit+ also detects variations in your intra-abdominal pressure. Patented algorithms process this information to monitor the pressure resulting from contractions of muscles unrelated to your pelvic floor (abs, buttocks, etc) that should NOT be voluntarily engaged during pelvic floor training. You will see your "contraction quality" metrics inside the Perifit+ App
- The contraction data registered by the probe is displayed live on your smartphone, and even allows you to control video game characters with your pelvic floor
- The app helps you to remain motivated by sending you regular reminders, showing your training history, displaying your stats, allowing you to interact with other users and much more!

5. Troubleshooting, Feedback and Complaint

Customer support can be reached by clicking on "?" directly in the app or via email at the address support@Perifit.co. If you have any technical issue, please first refer to the Help articles of the App. If you notice any change in device performance or any malfunction please turn off your Perifit+ and contact us. Any serious incident that has occurred in relation to Perifit+ should be reported to us and your local authority having jurisdiction. If you have any complaint, please contact us. Any feedback is welcome.

DISCLAIMER:

Users of Perifit+ do so at their own risk. Neither X6 Innovations nor its retailers assume any responsibility or liability associated with or for the use of this product. X6 Innovations reserves the right to revise and/or update this manual without being obligated to notify any users.

6. Warranty

The Perifit+ device is backed by a limited manufacturer's guarantee against any defects in materials and/or workmanship for 2 years from the date of purchase, except for low battery defects for which the guarantee is 5 years. Defects discovered within the guarantee period should be reported to X6 Innovations. X6 Innovations reserves the right to exercise its discretion in determining whether or not to replace a defective Perifit+ free of charge. This guarantee does not cover cosmetic deterioration or damage caused by general wear and tear, physical or natural destruction, accident, misuse, neglect or other external causes.

Any attempt to take the Perifit+ apart will invalidate this guarantee. Any guarantee claims must be supported with reasonable evidence, including proof of date of purchase, alongside these guarantee conditions. X6 Innovations must be notified of any defective Perifit+. We will then provide you with a Return Merchandise Authorisation number, which must be displayed on the outside packaging. In the event that X6 Innovations decides to replace your Perifit+, any replacement Perifit+ will not extend the life of this guarantee.

Except as provided in this warranty and to the maximum extent permitted by law, X6 Innovations is not responsible for direct, special, incidental or consequential damages resulting from any breach of warranty or condition, or under any other legal theory, including but not limited to loss of use; loss of revenue; loss of actual or anticipated profits (including loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of reputation; loss of, damage to, compromise or corruption of data; or any indirect or consequential loss or damage howsoever caused including the replacement of equipment and property. Some states (countries and provinces) do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

2.4 Symbol legend



This packaging contains a printed user guide (as you can see).



This is a medical device certified CE class 1.



Type BF applied part - Electrical classification of the device part that contacts the patient.



This device should be kept between 0°C and 40°C (32°F and 104°F).



This device should be kept between 15% and 80% humidity.



Indicate the range of atmospheric pressure to which the medical device can be safely exposed (between 700 hPa and 1060 hPa)



Perifit+ is an electronic device. Please refer to your country and state law for the disposal of Perifit+.



This device receives and transmits RF electromagnetic energy for the purpose of its operation.

RoHS

This device is compliant with the RoHS directive about hazardous substances.

IP54

Perifit+ can be temporarily submerged in water.



Indicates the manufacturer's serial number so that a specific medical device can be identified.



Indicates a carrier that contains unique device identifier information.



Indicates the manufacturer's batch code so that the batch or lot can be identified.



Indicates the date when the medical device was manufactured.



Indicates the name of the Medical Device Manufacturer.

3.1 Your Device

