



# P E R I F I T

## **PERIFIT CARE+**

### User Guide

[support@perifit.co](mailto:support@perifit.co)



Perifit Care+ - X6 Innovations

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

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

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

### 1.3 Description

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

Perifit Care+ 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 Care+ 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 Care+ 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 Care+**

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

### 2.1 Contra-indications

Do not use Perifit Care+ 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 Care+ in these situations may affect an underlying condition. Consult a medical professional before using the Perifit Care+ 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 Care+ 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 Care+") of this User Guide.
- If Perifit Care+ causes you a feeling of dryness, burning or itching, please stop using Perifit Care+. If the feeling persists, please reach out to a qualified health professional
- In rare cases, insertion of an external object such as Perifit Care+ 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 Care+ before and after every use with warm, soapy water. Read Section 3.5 ("Cleaning your Perifit Care+") of this User Guide carefully and follow all cleaning instructions.
- Do not share Perifit Care+ with others. Even with proper cleaning, sharing the probe increases your risk of infection.
- Do not leave Perifit Care+ in the vagina for more than one hour at a time.
- Keep the Perifit Care+ 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 Care+ as this may increase the likelihood of infection.

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

- The Perifit Care+ 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 Care+, or use detergents or alcohol-based cleaning agents on the Perifit Care+. Refer to Section 3.5 ("Cleaning your Perifit Care+") for proper cleaning instructions.

- Do not use Perifit Care+ if some of its electronic parts are visible.
- Do not use the Perifit Care+ if it feels hot to the touch or if the Perifit Care+ is overheating.
- Do not use Perifit Care+ if you experience persistent pain when inserting or using Perifit Care+, even with water-based lubricant.

#### **In order to avoid muscle pain:**

- Do not use Perifit Care+ 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 Care+ correctly. Read Section 3.6 ("Using Perifit Care+") before beginning to train. In order to protect your device and reduce risk of explosions:
  - No modifications to the Perifit Care+ should be made. Do not take apart the Perifit Care+ nor use the Perifit Care+ 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 Care+ in the dishwasher
  - Do not use Perifit Care+ 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](mailto:support@Perifit.co)

## **2.4 Symbol legend**

See symbol legend page 15.

# **3. Product Information**

## **3.1 Your Device**

See diagram 16.

Perifit Care+ 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 Care+ 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 <sup>3</sup>
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 Care+, 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 Care+. If you have any doubt as to whether is suitable for your condition, please consult medical professional before use.

#### **3.4.2 Device Use Life**

Your Perifit Care+ battery is intended to last for at least 5 years of regular training as detailed in section 3.6 ("Using Perifit Care+"). 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 Care+, the green flashing light does not appear, contact customer service.

#### **3.4.3 Inspecting your Perifit Care+**

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 Care+ and contact customer service.

### **3.5 Cleaning Perifit**

#### **3.5.1 Before using Perifit Care+ for the first time**

The device must be thoroughly cleaned before first use and after each use. Thoroughly cleaning your Perifit Care+ removes bacteria and reduces the risk of infection. Failing to thoroughly clean your Perifit Care+ 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 Care+.

1. Wash your hands thoroughly with soap and water before touching Perifit Care+.
2. Rinse the Perifit Care+ 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 Care+ 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

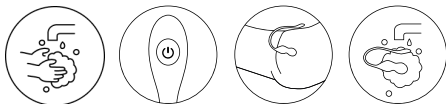
The device must be thoroughly cleaned after each use. Thoroughly cleaning your Perifit Care+ removes bacteria and reduces the risk of infection. Failing to thoroughly clean your Perifit Care+ increases the risk of bacterial growth and subsequent infection. Do not clean the probe in an autoclave or dishwasher.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

1. Wash your hands thoroughly with soap and water before touching Perifit Care+.
2. Rinse the Perifit Care+ 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 Care+ 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 Care+**

1. Start by cleaning your hands and your Perifit Care+ with warm, soapy water
2. Turn Perifit Care+ 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 Care+ 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 Care+ off by clicking on the ON/OFF button
7. Clean your Perifit Care+ 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 Care+. 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](mailto: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](mailto:support@Perifit.co) or by clicking on the ' ? ' in the app) or consult a pelvic health practitioner.

### 3.9 Other precautions

Perifit Care+ 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 Care+ 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 Care+ away from direct sun, radiators and naked flames
- The Perifit Care+ 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 Care+ 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 Care+ 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 Care+ device with your smartphone, you will not be able to use the Perifit Care+ device. Bluetooth communication has a limited range. For best performance, place the Smartphone you are using within two meters of the Perifit Care+ device.

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

### **3.12 Electromagnetic compatibility (EMC)**

The Perifit Care+ 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 Care+. Interferences might create delays with the Bluetooth communication and the connexion with the Perifit Care+ device Environments for use that are suitable for the use of the Perifit Care+ 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	± 2, ± 4, ± 8, ± 15 kV (air)	± 2, ± 4, ± 8, ± 15 kV
Electrostatic discharge (ESD)	EN 61000-4-2:2009 IEC 61000-4-2:2008	± 2, ± 4, ± 6, ± 8 kV (contact)	± 2, ± 4, ± 6, ± 8 kV
Electrostatic discharge (ESD)	EN 61000-4-2:2009 IEC 61000-4-2:2008	± 2, ± 4 (horizontal coupling plane/ vertical coupling plane)	± 2, ± 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 Care+

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

## 4. Key features of the Perifit Care+

- Perifit Care+ probe uses sensors to detect the pressure exerted by contractions of your pelvic floor muscles (including levator ani)
- Perifit Care+ 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](mailto: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 Care+ and contact us. Any serious incident that has occurred in relation to Perifit Care+ 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 Care+ 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 right to revise and/or update this manual without being obligated to notify any users.

## 6. Warranty

The Perifit Care+ 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 Care+ 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 Care+ 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 Care+. 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 Care+, any replacement Perifit Care+ 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.

#### FCC WARNING:

This device complies with part 15 of the FCC rules. 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 the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

## RADIATION EXPOSURE STATEMENT

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

## ISED Warning

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- 1) L'appareil ne doit pas produire de brouillage;
- 2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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



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 Care+ 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

