



P E R I F I T

PERIFIT CARE+

User Guide

support@perifit.co



Perifit Care+ - X6 Innovations

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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 Care+ is a perineometer designed to treat stress, mild-moderate urge and mixed urinary incontinence in women, by strengthening of the pelvic floor muscles through exercise. This device provides biofeedback via smart phone technology.

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.

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 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Perifit Care+. Otherwise, this may impact the performance of the Perifit Care+.

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 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 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.
- 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 exceed 15 minutes in a single training session. The device should be removed when not in use. 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 Care, 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)
- Avoid high pressure (above 1060 hPa) and low pressure (below 700 hPa) by training in your typical home environment
- Do not cut the Bluetooth Antenna of your Perifit Care+ (see image in section 5.5 of the User Guide)

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 13.

3. Product Information

3.1 Your Device

See diagram 14.

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 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 (6 feet)	
Smartphone application name	Perifit	
Operation and storage condition	Humidity	15% - 80%
	Pressure	700 hPa – 1060 hPa
	Temperature	0°C – 40°C
Smartphone application unique identifier	PER004	
Effective radiated power	0 dBm (1 mW)	

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 on the App Store or Google Play
2. Enable Bluetooth on your phone
3. Open Perifit App
4. Follow the instructions on the screen

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+"). Once the device stops working after approximately 5 years, you can dispose of the device in accordance with local regulations. Refer to section 5.3 ("Disposing of Perifit Care+"). If you wish to dispose of the device, log in to your device account and initiate the account deletion process. Deleting your account will permanently remove all stored data associated with it.

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 egg-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.

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 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

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. Other information

5.1 Operating systems and smartphone requirements

The Perifit Care+ device system currently works only with Smartphones running the Android operating system (version 8 and later) or iOS operating system (version 13 and later). An internet connection (3G, LTE or Wi-Fi®) is needed. 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. 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 8 of the Android operating system (or later) or for iPhone, iOS 13 or later.

The Perifit Care+ utilizes BLE (Bluetooth Low Energy) for wireless communication with the associated mobile application. Bluetooth communication has a limited range. For best performance, place the Smartphone you are using within two meters (6 feet) of the Perifit Care+ device. Our device relies on an internet connection to sync your health data to our secure cloud storage. Our cloud servers are data-center compliant and adhere to the health data regulations of your specific country. If you cannot connect to

the internet or in rare instances where our cloud service may be temporarily unavailable, your device will store the data locally until a stable connection is available. Once reconnected, the data will be automatically uploaded to our secure cloud storage.

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.

To keep your data safe, we recommend you to:

- Regularly check the notifications of the Perifit application for available firmware and software updates. If updates are available, follow the on-screen instructions to download and install them. Ensure your device is connected to a secure and stable internet connection during this process. After the updates are installed, restart your device to apply the changes effectively.
- Ensure that the application of perifit Care+ is regularly updated to the latest versions.
- Use strong passwords, avoid using easily guessable passwords like "password123"
- Ensure your Wi-Fi network is password-protected and encrypted (WPA3 or WPA2) to prevent unauthorized access.
- Be cautious with email attachments and links, especially from unknown or suspicious senders.

The Perifit Care+ is equipped to detect various cybersecurity events, including unauthorized access attempts, data breach attempts, and firmware/software tampering. In the event of any such incident, users will be promptly informed through the mobile app with real-time alerts. These alerts will provide clear instructions on recommended actions to ensure the security of your device and data. Cybersecurity support for this device will continue as long as X6 Innovations is in operation. If X6 Innovations ceases its operations, cybersecurity support for the device will end. Please be aware that any continued use of the device beyond this point will be at the sole risk of the customer.

If you suspect or identify a cybersecurity issue with your

Perifit Care+, please follow these steps:

- Immediately stop using the Perifit Care+ and disconnect it from any network connections, including Wi-Fi or cellular data, to isolate it from potential external threats.
- Contact our support team at support@Perifit.co, providing detailed information about the issue you encountered. Please include any error messages or unusual behavior you observed.
- Our support team will guide you through the necessary steps to address the issue. This may include providing software updates, patches, or further instructions for remediation.

For a comprehensive list of software components used in this device, you can contact our customer support team to request the full Software Bill of Materials (SBOM).

5.2 Electromagnetic compatibility (EMC)

The Perifit Care+ device complies with the IEC 60601-1-2:2014. It has no essential performance; 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 connection 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 (30 MHz to 1 GHz)	
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)	$\pm 2, \pm 4$

- 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.

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Electromagnetic Immunity

The device has been evaluated to meet general RF exposure requirements. The device can be used in portable exposure condition at a distance of 30 cm (12 inches) and greater .

In Canada:

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device. The digital apparatus complies with Canadian CAN ICES-3 (B)/NMB-3(B).

This radio transmitter has been approved by Industry Canada to operate with the antenna types listed with the maximum permissible gain indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

5.3 Disposing of Perifit Care+

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

5.4 Symbols



This is a medical device certified CE class 1.



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



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.



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



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.



This item is a medical device.

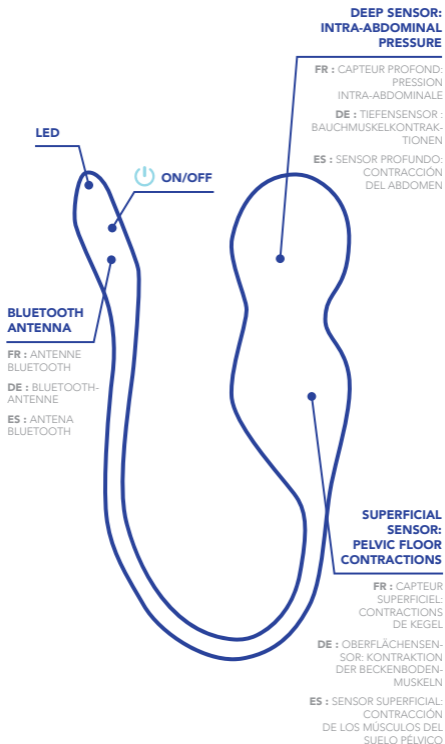


Indicates the date when the medical device was manufactured.



Indicates the name of the Medical Device Manufacturer.

5.5 Your Device



6. 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 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.

7. 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.