

PERICOACH

INSTRUCTIONS FOR USE

Version 2.26 English



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2. BEFORE YOU BEGIN

It is essential for your own safety - and for those who could come in contact with the PeriCoach system - that you read this instruction manually carefully before using the system. In particular, make sure you read and understand the safety and other precautions set out in the following two sections.

If you have any questions or doubts about the PeriCoach system that are not answered in this instruction manual, consult your doctor before using the system.

- **PLEASE CHARGE YOUR PERICOACH PROBE BEFORE FIRST USE.** Charging instructions are provided on page 63.
- **SAVE THIS DOCUMENT** on the smartphone, that you will use with PeriCoach, so that you can refer to it when required.

Do not use the PeriCoach if the packaging has been damaged in transport. In case of damaged packaging, contact Stratos MedTech (manufacturer).

Items in the PeriCoach kit

The PeriCoach kit comprises a case, probe and a USB cable.

Table 1: Contents on Delivery

Item	Purpose
PeriCoach probe	To indicate the force applied by each contraction of the pelvic floor muscle.
PeriCoach case	To securely store and charge the probe.
Type-A USB-to-mini-Type-A USB cable	To recharge the battery inside the probe.

If an item is missing, contact Customer Service. See “Getting help” on page 68.

See "Environmental limits" on page 72 for advice on the optimum conditions for storing and using the PeriCoach kit.

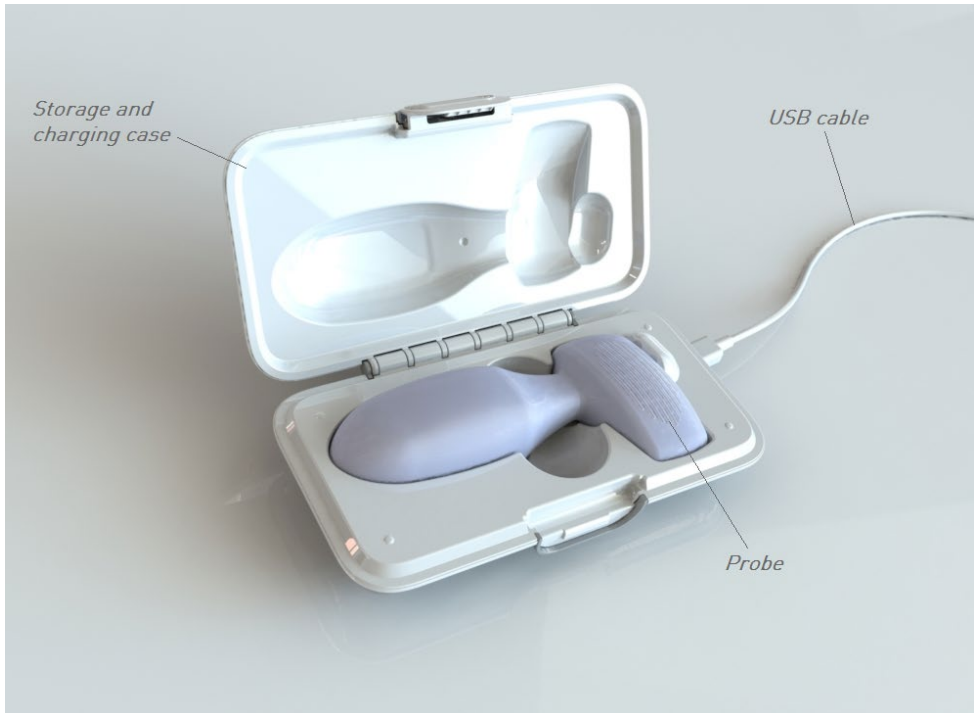


Figure 1: PeriCoach Kit Contents

Other items you will need

In addition to the PeriCoach kit, you will need a smartphone running an Android or iOS operating system. The PeriCoach App is installed on the smartphone system and enables you to choose an exercise program, and then to display and record pelvic muscle contractions during an exercise session.

Other items you might want to consider

A power adapter

Purpose: although you can charge the PeriCoach probe by connecting it to a PC (see "Maintaining power" on page 63), you might find it more convenient to charge it from regular mains power. For this you will need a power adapter with a USB socket. (This is not provided in the PeriCoach kit.)

A computer with a spare USB port

Purpose: provides an additional way of charging the PeriCoach probe (see "Maintaining power" on page 63). You might also find it easier to view your exercise history on a larger screen than that offered by a smartphone. (Your exercise details are automatically updated to a secure website that can be accessed by any web browser.)

Minimum smartphone requirements

Bluetooth

The PeriCoach probe and the smartphone that records your exercises communicate using Bluetooth wireless communication. Your smartphone must offer Bluetooth as a communication option.

On some phones, tapping Settings on the home screen displays a list of features, one of which will be wireless and network options. Bluetooth should be listed as an option as shown in Figure 2.

Consult the instruction manual that accompanied the phone if you are unsure how to find this information.

Operating system

The PeriCoach system works with smartphones running an Android operating system (version 2.3 and later) or iOS operating system

(version 7.0 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 these 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 PeriCoach system.

Ensure your Smartphone security updates are installed and kept up to date.

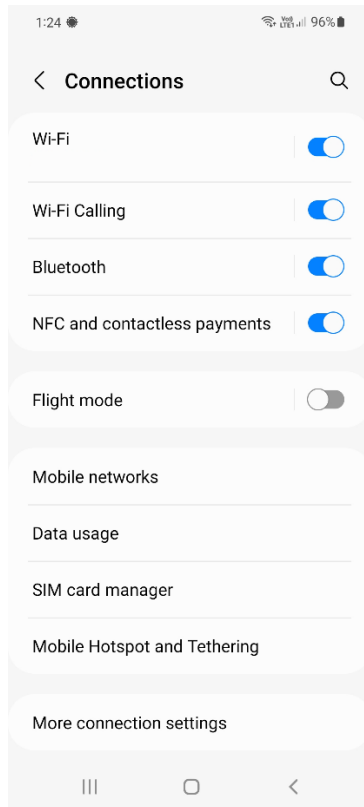


Figure 2: Android Settings menu showing Bluetooth

Intended Purpose - Australia & EU

The device may be used to assist in the correction of urinary incontinence and pelvic organ prolapse by means of exercise. It may also be used by a health care practitioner to assist in the diagnosis and monitoring of urinary incontinence. The device consists of a rigid probe for temporary intravaginal use which offers resistance to a patient's voluntary pelvic floor muscle contractions and can provide an indication of the strength of these muscles.

The PeriCoach is intended to assist the user to strengthen their pelvic floor muscles through exercise. The integrity of pelvic floor is essential in maintaining urinary and fecal continence to support the abdominal and pelvic organ (Tailor et al., 2020).

The benefits of pelvic floor muscle exercise with PeriCoach are a reduction in the symptoms of urinary incontinence and pelvic organ prolapse, and improvement in quality of life.

Indications for Use - USA

The PeriCoach 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.

Application of the PeriCoach system

The intended user is an adult female. If the user is impaired, then a capable care giver may be required to support in the PeriCoach's use.

The body of the probe is meant to be inserted into the user's vagina. The PeriCoach system is for one user only and is not to be shared.

Typically, the PeriCoach should be used at least 5 days per week, with a period of rest in between sessions. The system is typically used in

the user's home, with privacy and a relaxed environment, but may also include clinical environments.

Safety precaution symbols



This symbol is used to indicate that the accompanying instructions are especially important and should be read carefully to ensure that you fully understand them. Failure to do so might result in injury or damage to equipment.



This symbol is used to indicate that caution is necessary when operating the device, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences. Consult the instructions for use if unsure of any instruction or the meaning of any symbol or indicator.



This symbol is used to indicate a mandatory prohibition - you must not do this.

Other symbols marked on the underside of the PeriCoach case and on other labelling are explained in Chapter 10, "Symbols Glossary" starting on page 82 of this manual.

Contraindications







- Do not use the PeriCoach system if you are experiencing abnormal vaginal discharge (bleeding or otherwise) as doing so may affect an underlying condition.



- Do not use the system if you are experiencing back pain severe enough for you to need pain-killers as doing so may affect an underlying condition.





- Do not use the system if you have recently undergone surgery, as doing so may affect an underlying condition.

-  • Do not use the system if symptoms of bladder infection are present, as doing so may affect an underlying condition.
-  • Do not use the system if symptoms of a vaginal infection are present, as doing so may affect an underlying condition.
-  • Do not use the system if you have a history of urinary retention or symptoms thereof, as doing so may affect an underlying condition.
-  • Do not use the system if you have an anatomical vaginal morphology and/or structure that does not permit proper insertion of the probe.

Consult with your doctor if needed for all the above contraindications.

Warnings

-  • Do not use the system if the covering of the probe appears to be cracked, torn or damaged in any way, as use of the probe in this condition may increase likelihood of infection.
 - Inspect the probe before every use. If damaged, then do not use it.
-  • Do not share the probe with others. There is risk of infection, even if you wash the probe between exercises.
 - Sharing the probe may also corrupt your data and void any medical reimbursement arrangements you have with healthcare providers.

- **Keep the system out of reach of young infants and children. The probe is a choking hazard, and the USB cable could cause strangulation.**
- **Keep the probe away from cats, dogs, and other pets. If you suspect any animal contamination or damage to the probe, stop using the system, as this may increase the likelihood of infection.**
- **Do not disassemble any parts of the PeriCoach system nor use the system if it has been reassembled by any person other than a technician authorised by the manufacturer.**
- **Do not use the PeriCoach probe for more than 30 minutes.**
- **On rare occasions the probe may cause skin irritation. If that occurs, cease using the probe and seek advice from your doctor.**
- **It is recommended to use a small amount of water-based lubricant with the probe.**
- **No modifications to any item in the PeriCoach system should be made. Unauthorised modifications will render your warranty null and void. They might also lead to injury to yourself or damage to the equipment.**
- **PeriCoach users with a Pelvic Organ Prolapse (POP) note:**
 - **Pelvic floor exercises alone may not be sufficient to treat more severe cases of POP. If you suspect that you may have POP, consult your doctor to determine if treatment other than pelvic floor exercise is required.**
 - **Take care inserting the PeriCoach. Rough handling could cause bleeding or lead to risk of infection. If you experience severe discomfort or pain when inserting the PeriCoach, discontinue use of PeriCoach. Consult your doctor for treatment options.**
 - **If you are unable to correctly insert or position the PeriCoach due to your POP, discontinue use of the PeriCoach. Consult your doctor for treatment options.**

- **Do not use the PeriCoach as a pessary device. The PeriCoach is not designed to support your POP for the purposes of mobility or assist with toileting. Using the PeriCoach in this way could expose you to the risk of infection.**

Precautions

- **Do not store or use this device in excessively hot or cold environments or environments of extreme humidity (see "Environmental limits" on page 72). Take special care not to leave the system in a car during summer, as extreme temperatures may damage the internal circuitry of the probe.**
- **The PeriCoach is designed to work best within certain temperature, humidity and atmospheric pressure ranges. Make sure that the ranges specified in the "Environmental Limits" in the Instructions for Use apply before beginning an exercise session.**
- **Avoid dust by storing the device in its case between uses.**
- **Do not immerse any part of the system other than the probe in water. Only the probe is waterproof. The charging case and USB cable are not waterproof.**
- **Do not expose the PeriCoach probe to direct sunlight for lengthy periods.**
- **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.**
- **To minimise the risk of infection, wash your hands thoroughly-preferably with anti-bacterial soap-before touching the probe.**
- **Do not freeze or microwave the probe, nor place it in an oven in order to bring it to a comfortable temperature. If the temperature of the probe is not comfortable, run the body of the**

probe under cold or warm water until the temperature is acceptable.

- Use only the charging case provided when recharging the probe's battery.
- Do not attempt to insert or use the probe while it is being charged.
- Before transporting the probe, place it in the PeriCoach charging case. This will minimise the risk of damage to its outer covering or its internal circuitry.
- The PeriCoach is medical electrical equipment and requires precautions to prevent electromagnetic interference to the probe and its correct operation, and to prevent potential interference to other equipment. Operate the PeriCoach in accordance with this Instructions for Use manual.
- Wireless communications equipment such as wireless home network devices, mobile phones (other than smartphone being used for PeriCoach), cordless telephones and their base stations, walkie-talkies can affect this equipment and care should be taken to ensure that they are not operated outside the conditions required for the successful function of the PeriCoach.
- Ensure your Smartphone security updates are installed and kept up to date.
- Refer to the electromagnetic compatibility (EMC) information provided in Section 8 of this manual and operate the PeriCoach in accordance with this information.
- Do not incinerate the PeriCoach probe or discard it as general waste. The lithium battery inside it is a potential environmental and fire hazard. Consult your local council for advice on how best to dispose of such equipment.

Conventions used in this manual

Text

The names for screens, fields, buttons and menus that you see on your smartphone or on your computer are set in bold text. Thus: "... tapping **Settings** displays a list of features ..." means tap on the button labelled **Settings**.

Where a series of consecutive actions is required, each action is separated by the > character. Thus: "... tapping **Settings > About phone** displays a list ..." means first tap on the button labelled **Settings** and then on button labelled **About phone**.

Audience for this manual

In this manual, the audience is addressed in the second person ("you").

However, there will be circumstances where more than one person is involved in the set-up, operation, and maintenance of the PeriCoach system. This may be the case where the primary user of the system has an impairment that requires them to rely on others if they are to take full advantage of it (For example, the primary user may have an auditory, visual, or cognitive impairment.)

In these cases, the instructions are to be interpreted as being directed at whoever has assumed responsibility for doing a particular action. For example, a health professional might take responsibility for installing the PeriCoach app on the primary user's smartphone, in which case Chapter 3 is primarily directed at them.

Likewise, the care giver of the primary user might take responsibility for keeping the battery charged and the probe clean, in which case Chapter 6 is primarily directed at them.



Where more than one person is responsible for a PeriCoach exercise regime, it would be prudent if each person

familiarised themselves with the contents of this manual before the regime begins.

3. INTRODUCTION

Urinary incontinence and prolapse are commonly caused by the weakening of the pelvic floor muscles. This often occurs during childbirth, but it can also be a symptom of menopause, ageing, persistent constipation, being overweight, and other causes. Health practitioners will often recommend exercises designed to help strengthen the pelvic floor muscles. As these muscles strengthen and tone over the course of the exercise regime, incontinence symptoms will improve.

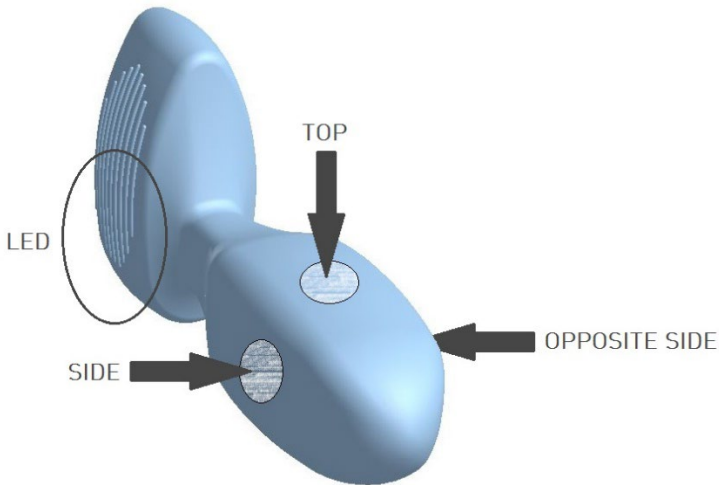


Figure 3: The PeriCoach probe showing the location of the three sensors

PeriCoach® is a unique device that can help visualise and indicate the strength improvement of the pelvic floor muscles. It has a number of key features, including the probe that is shaped in such a way that once inserted into the vagina, it can show the “lift and squeeze” modes of contraction:

- The sensor on top of the probe indicates the force applied to the urethral wall, thus capturing the lift strength during a contraction.

- The two side sensors indicate the squeeze strength during a contraction.

Combining these forces provides an understanding of the overall strength of the pelvic floor muscles.

The visual feedback of muscle action - being immediately available to you via a smartphone - will help you maintain consistency during your exercise regime and help you know when to move to more advanced exercise programs.

Key features of the PeriCoach

- The unique shape is designed to capture the complete movement of the levator ani (comprising the iliococcygeus, puborectalis and pubococcygeus muscles). These muscles are partly responsible for continence.
- The top sensor determines the lift activation of the levator ani.
- The two side sensors determine the squeeze activation of the levator ani.
- The muscle-specific information provided may also help in treating overactive pelvic floor muscles.
- You get a visual representation of the force of a contraction, and an audio prompt to begin and end each contraction.
- Unique movement detection within the probe assists in correctly performing exercises through the use of icons shown after each repetition indicating "good", "bad" or "unknown" technique.
- A history of each exercise is kept and can assist clinicians in assessing an exercise regime and in diagnosing problems needing to be remedied.
- The associated PeriTrack feature contains a Bladder Diary and Surveys that can consistently monitor fluids, pads, leaks and visits to toilet for valuable insight into your bladder control progress over time, as well as recording objective Quality of Life measures

for you to use as a comparison tool over the course of your program.

- The probe is covered in a silicone material that has been tested for biocompatibility. This material has been selected such that it should not irritate or damage the vaginal or nearby tissues. Moreover, the device has a high ingress protection rating (IP27). This means that internal bodily fluids will not penetrate the material and damage the inside of the probe.

Indicator Lights

The probe uses different coloured lights to indicate the probe status:

- Green = power on
- Blue (continuous) = Bluetooth connected
- Purple = charging indicator - battery is currently being recharged

The location of the indicator LED lights is shown in Figure 6 on page 24.

Brief overview of treatment

It is recommended to make your first Bladder Diary entry prior to starting your exercise program so you can track your progress from the beginning. Follow the prompts once app is installed and make regular entries for more accurate results.

The Surveys section also serves to monitor improvements in your quality of life over time. These should be filled out at the start of your program, and you will then be prompted every four weeks to fill out the questionnaires.

Once you have set up your PeriCoach (see “How to exercise” on page 28), you can begin your pelvic floor exercises. You will need to have the phone on which you installed the PeriCoach app handy. At the start of your exercise regime, you insert the probe and record your

current maximum contraction force. This becomes the baseline level for assessing the progress of your subsequent exercise regime, and also customises the sensor settings for your abilities.

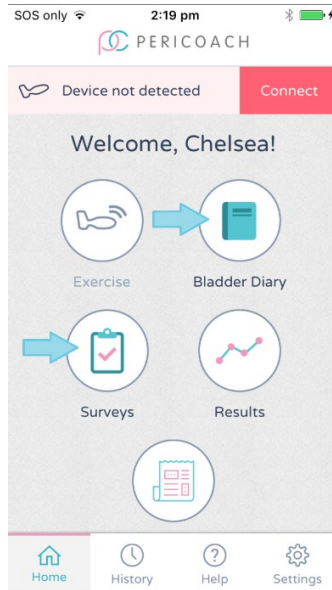


Figure 4: The Bladder Diary and Surveys feature to track bladder control progress.

With your current maximum force recorded, you can begin the first exercise of the regime. You start by selecting an appropriate exercise program and level on your phone. During the exercise, you can see a graph on your phone of the strength of your contractions relative to your baseline level.

If sound and vibration are enabled on your phone, you will hear a beep and phone vibrates to let you know when to contract your muscles, and then again when to relax. This contraction-relaxation cycle continues until the exercise session ends.

At the end of a session, PeriCoach provides a summary of your improvement since your last session. You can also view the details of each contraction (as a percentage of your baseline level) and review

the graph of your contraction activity. The details of the session are automatically uploaded to the PeriCoach online database (<https://my.pericoach.com>) where the complete history of your exercise regime is securely stored.

4. SETTING UP PERICOACH

It is recommended that you recharge the probe before using it for the first time. Charging instructions are provided on page 64.

Once the battery is fully charged, you can set up the PeriCoach system in readiness for your exercise regime. The set-up process involves three steps:

1. Install the PeriCoach app on your smartphone.
2. Turn on the probe and connect it to the app.
3. Complete registration.

You only need to do these tasks once.

Installing the PeriCoach App

1. Navigate to your Google Play store or App Store on your phone.
2. In the "Search" bar type in "PeriCoach".
3. Select the PeriCoach app and follow prompts to download and install.

Note: For security reasons, only install the PeriCoach App from the Google Play store or App store on your phone. Do not install the PeriCoach App from any other location.

Note: It is important that you have the most up-to-date app version, so it is recommended that you have Auto-update Apps turned on. Refer to instructions on page 66.

Registering for PeriCoach

Registering the PeriCoach system enables the system to store the results of your exercises on a secure server and for you to be able to retrieve them anywhere and at any time. (You might, for example, want to show your doctor or clinician the results from following a

particular exercise regime.) You will need to have received and charged your probe to be able to register.

Turn on Bluetooth on your phone.

On some phones, tapping Settings displays the Wireless and network list as shown in Figure 2. If Bluetooth is off, tap On to turn it on. Consult the instruction manual that accompanied your phone if you are unsure about this.

To register to the PeriCoach system:

1. Make sure your phone can connect to the internet and Bluetooth (see above).
2. Have your fully charged probe nearby.
3. If the PeriCoach app is not open, open it. You do this by tapping once on the PeriCoach icon on one of the home pages on your phone.
4. On the PeriCoach home screen, tap Register.

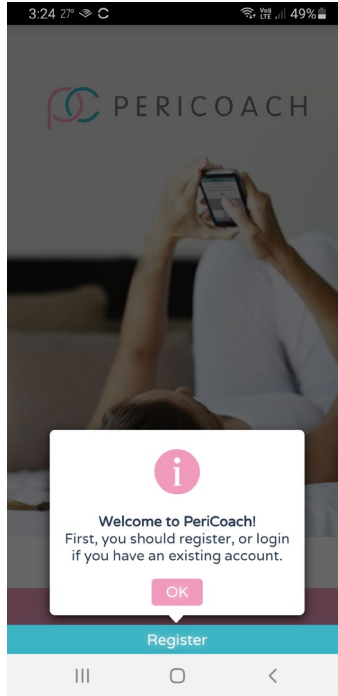


Figure 5: Registering

5. Turn on the probe by removing it from the charging case. A green LED should come on in the base of the probe as shown in Figure 6. If the green light does not come on, give the sensor a quick shake with your hand. The light should come on. The probe is now powered on and in Bluetooth discoverable mode.

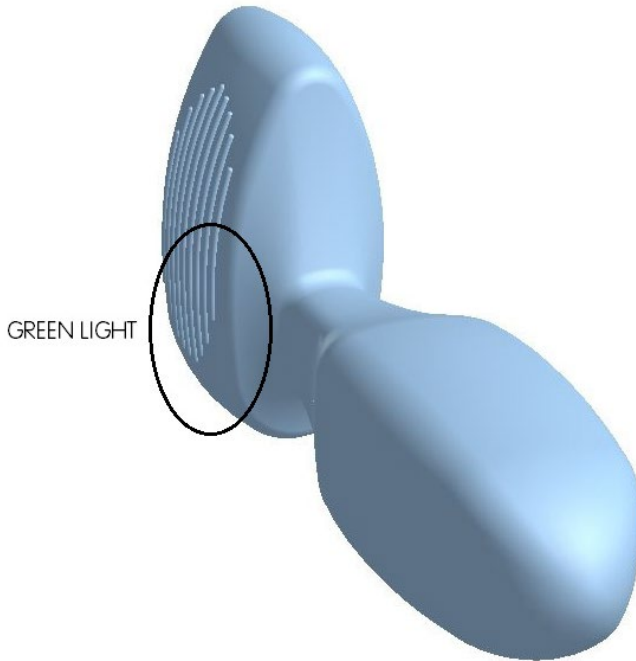


Figure 6: Location of LED lights.

- 6. Follow the prompts to connect device.**
- 7. Fill out the required details for registration, including selecting a secure password using a mixture of lowercase, uppercase, numbers and special characters. Do not share your password with anyone.**

3:42 28° VoLTE 44%

< Register

First name

Last name

example@pericoach.com

Confirm Email

Phone number

Password

Use 8 or more characters with a mix of letters, numbers & symbols

Confirm Password

10/29/2005 ▼

How did you hear about PeriCoac ▼

By registering you are agreeing to the Website Terms and Conditions, the End User Software License Agreement, and the Privacy Policy.

Figure 7: Filling out registration details

- 8. Tap Register once complete.**
- 9. You now have an account login and can begin setting up your probe.**

Pairing the App and the probe (when already registered)

The PeriCoach system works by the probe passing information from the probe to your smartphone using Bluetooth. For this communication to work, you need to set your smartphone to allow information to be shared between it and the PeriCoach probe. This is called 'pairing' the devices.

Bluetooth communication has a limited range. For best performance, place the smartphone you are using within two metres of the PeriCoach probe.

Open the PeriCoach app and select Connect to Device. In the available list, one of the items should have a name similar to "PeriCoach-12345678901234" as shown in Figure 8. Tap on the name to initiate pairing and connection. Select Pair when prompted.

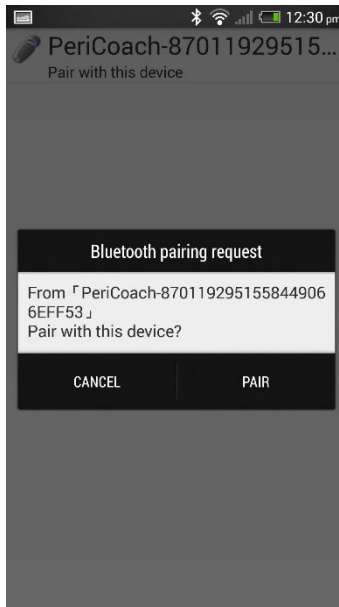


Figure 8: Bluetooth devices list

In a few seconds, you should see **Connected** appear in the app and the light in the base of the probe should turn solid blue.

If you don't see a PeriCoach Bluetooth device in the list of available services after a couple of minutes, it may be because the probe has turned off. (It has been designed to turn off automatically if it has not been used for 2 minutes.) If the base of the probe is not showing a green light, it has turned off. Repeat step 1 to turn it on again and then repeat this step.

Once connected, you will be returned to the app home screen where the message PeriCoach: Connected appears on the screen.

If you get a Connection failed message, you may not have successfully enabled Bluetooth on the phone. Repeat this procedure from "[Turn on Bluetooth on your phone](#)" section.

NOTE

Android phone users can alternatively pair to the probe through the phone's Bluetooth settings by navigating to Settings > Bluetooth > Scan > Tap on the PeriCoach listing > Pair. Once paired, return to the app to connect.

5. DOING YOUR EXERCISES

How to exercise

Pelvic Floor Contraction

You should see a health professional if you have difficulty identifying the correct muscles, are unsure if you are performing the exercises correctly or continue to experience symptoms.

Exercise Basics

In a lying position, relax your stomach and other muscles, and breathe normally. Envision stopping the flow of urine or the passing of gas and squeeze those muscles. The feeling should be of a lift and squeeze action. If you're unsure of this lift and squeeze, place a finger on the tip of the device that is sitting in front of your pubic bone once inserted. As you pull in the muscles, this tip should move forward away from your finger and towards the floor if you're lying down.

Then completely relax the muscles and the probe tip should return to the original position. If muscles are very weak, this may be a small movement.

If performed correctly, a contraction should not result in movement of the stomach - place a hand on your stomach during a contraction to check this.

In order to practise this action, you can use the Free Exercise mode within the exercise session options. You should see the real-time trace line on the graph moving up and down with your contractions. During a guided exercise session (e.g., Beginner Level 1) you will also see a tick, cross or question mark indicating if you are performing a correct contraction.

Before you begin



Since purchasing the PeriCoach system, you may have developed a condition that makes the use of the system unsuitable.

In particular, you should not use the system if you:

- are experiencing abnormal vaginal bleeding, or
- have debilitating back pain requiring pain-killers or
- have recently undergone surgery, or
- have symptoms of bladder infection present, or
- have symptoms of vaginal infection present, or
- have a history of urinary retention or symptoms thereof, or
- have an anatomical vaginal morphology and / or structure that does not permit proper insertion of the probe.

In these circumstances-and in others that give you reason to be cautious about using the system (such as unstable pregnancy)-seek the advice of your doctor.



Wash the probe thoroughly before each use (including the very first use). It is important that you use a cleaning agent that both protects the probe and minimises the risk of contamination and infection. See "Cleaning the probe" on page 68 for advice.



Do not use the probe if it has been used by others. There is a significant risk of cross-infection even if the probe has been washed between exercises. If others have used the probe, cease the exercise regime and consult your doctor.

Using another user's probe may result in a corruption of exercise history and may void any reimbursement agreement from healthcare providers.



You should inspect the probe before every use. If it is damaged-for example, the outer covering has become cracked or torn-do not use it. If the PeriCoach is still within its warranty period, contact the manufacturer (see "Getting help" on page 68).



The PeriCoach system is designed to work best within certain temperature, humidity and atmospheric pressure ranges. Make sure that the ranges specified in "Environmental limits" on page 72 apply before beginning an exercise session.

Exercise programs

The PeriCoach system offers seven exercise programs:

- **Beginner**
- **Intermediate**
- **Advanced**
- **Ongoing**
- **Quick Flex**
- **Free Exercise**
- **Milestone Measurement**

The Beginner, Intermediate and Advanced programs each have three levels, and the Quick Flex program has two levels and a random option. The programs and levels vary according to the time you squeeze, the time you relax between squeezes and the number of squeezes you need to do at or above your initial maximum force for you to achieve a pass result. When you have achieved a pass on three consecutive occasions, you can move to the next level (or the next program if you are already at level 3).

Milestone Measurement consists of a combination of the different programs, in order to capture Max Force, Endurance, and Reaction Time at that point in time. You should complete a Milestone

Measurement at the start of your program, and again every two weeks thereafter. The app will prompt you when it is time to complete a Milestone Measurement.

What constitutes a "pass"?

The force of each contraction you make during an exercise session is compared with your initial maximum contraction force. (How you determine your initial maximum force is explained in "Establishing a starting point" on page 38). The aim is to maintain a contraction force close to, equal to or above your initial maximum force for an entire contraction period (that is, a period during which you are to squeeze). If you can do that for every contraction period in an exercise session, that session is considered a pass. If you can achieve a pass on three consecutive sessions, you can move on to the next level in the program, or to the next program if you have just completed the highest level for the program. Table 2 describes the programs and levels currently available. New programs and levels may become available from time to time and you can download them to your phone (see "Manual Sync" on page 35).

NOTE

You don't have to time your squeeze-relax cycles, as your phone will emit a sound and vibrate when it is time to squeeze and again when it is time to relax as well as provide a graph to follow.

Table 2: Exercise programs

Program	Level	Squeeze for (seconds)	Relax for (seconds)	Number of times
Beginner	1	3	9	8
	2	3	6	10
	3	3	3	15
Intermediate	1	5	7	8

Program	Level	Squeeze for (seconds)	Relax for (seconds)	Number of times
	2	5	5	10
	3	6	3	15
Advanced	1	8	7	8
	2	10	5	10
	3	10	3	15
Ongoing	3	10	3	15
Quick Flex	1	1	5	8
	2	1	2	10
	Random	Random	Random	10
Free Exercise	-	Your choice	Your choice	Your choice
Milestone Measure	-	Varies	Varies	Varies

Ongoing

When you have met the requirements of level 3 of the Advanced program, you can select the Ongoing program. The squeeze-relax cycles are the same as those for level 3 of the Advanced program. This is simply a maintenance program to help you maintain muscle condition and is recommended to be performed once a week.

Free Exercise Mode

In this mode you can exercise as you please. There are no specific targets or minimum squeeze and relax periods. You can stop the exercise at any time. Unlike the other programs, the results you get

are not recorded, so you will not be able to view them in your exercise history.

You may want to practice squeezing by using this mode.

Milestone Measurement

This program has three sections: Max Force, Endurance and Reaction Time. Max Force asks you to squeeze as hard as you can to measure your max squeeze force. Endurance is a set of three repetitions, 4 secs, 7 secs and 10 secs, with a 5 second rest in between. Reaction Time is similar to Quick Flex in that you need to squeeze when the app tells you to, to measure your reaction time. This program should be completed when prompted every 2 weeks as it records the three key measures as an indication of your progress over time.

Choosing a program and level

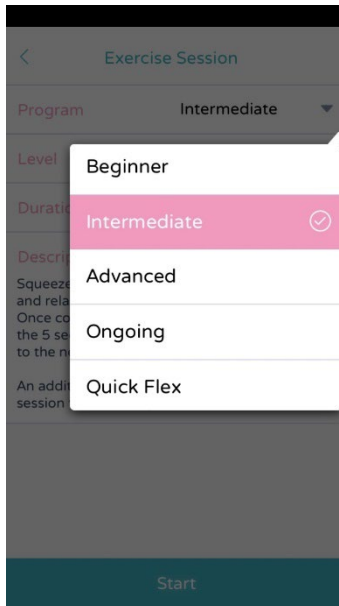


Figure 9: Choosing a Program and Level

You choose a program (and a level where applicable) when you choose to start an exercise. The app remembers your last program and level and assumes that you want to continue with it. You can change the prior program and/or level before you begin the actual exercise. Just tap in a field that you want to change: Program or Level. A list of options appears under the name. Swipe through the options until the one you want is listed and press on the name.

In the example in Figure 9, the Program field has been tapped and the Intermediate program is about to be selected.

NOTE

The duration of a program-level combination cannot be changed.

PeriCoach 8 Week Challenge

In addition to the seven exercise programs, PeriCoach also offers an "8 Week Challenge", which all new customers are automatically enrolled in.

The 8 Week Challenge involves the following:

- **Exercise with PeriCoach 5 days a week**
- **Record your bladder habits, liquid intake & pad use in the Bladder Diary 3 days a week**
- **Complete milestone measurements every couple of weeks when prompted, to get strength, endurance and speed progress**
- **Fill in a Quality of Life Survey at the start of the program, then again at week 4 and week 8.**

During the 8 Week Challenge, your app will guide you through each of the aspects, providing reminders and encouragement messages to keep you on track. At the end of the program, you will be emailed a summary of your results.

Settings

The Settings icon on the home window of the PeriCoach app gives you access to a number of useful options. See Figure 10. Tap the icon to display a list of the settings (or tap Back to return to the home window).



Figure 10: Settings Icon

Login/Register

Once you have registered and logged in once, you shouldn't need to do it again. However, if you need to log out for any reason, or log in with a different account, you will need to tap on the Logout button on the Settings window. The button will change back to Login/Register.

Manual Sync

If your smartphone is connected to the web at the time, you complete an exercise session, your details are automatically uploaded to the PeriCoach website. If that doesn't happen, you can manually upload the details later by tapping Manual Sync on the Settings window. Doing so will also download to your phone any new exercise programs or questionnaires that have become available.

Set Passcode

It is recommended to set a passcode to ensure safety of your data. When setting your passcode choose a secure sequence of numbers. You can lock the app by using this passcode. (A passcode is just like

a password or a PIN.) Only those who know the passcode will be able to open the app.

To set a passcode:

1. Tap Settings on the home page of the app.
2. Tap Set Passcode.
3. Enter a four-digit code.
4. Re-enter the code.
5. Click OK on the message that informs you that the passcode has been saved.

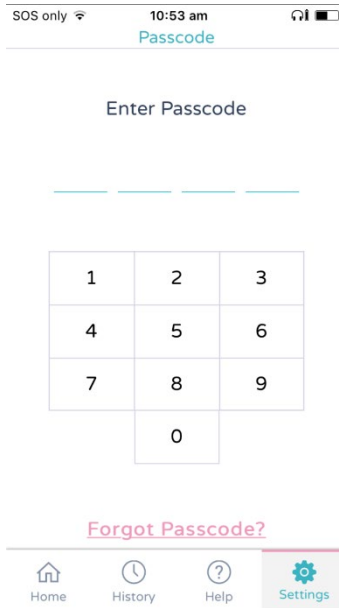


Figure 11: Passcode screen

NOTE

If a message appears telling you that re-entered code is incorrect, tap OK and either try again or tap Back.

You can cancel at any time by tapping the Back button.

Change Passcode

To change the passcode:

1. Tap **Settings** on the home page of the app.
2. Tap **Set Passcode**.
3. Enter your current passcode.
4. Enter a new four-digit passcode.
5. Re-enter the code.
6. Click **OK** on the message that informs you that the passcode has been saved.

Remove Passcode

To remove the passcode:

1. Tap **Settings** on the home page of the app.
2. Tap **Remove Passcode**.
3. Enter your current passcode.
4. Click **OK** on the message that informs you that the passcode has been removed.

Max Force Calibration

Before you begin your exercise regime, you need to have the PeriCoach system record your initial maximum contraction force. This is the baseline value against which your subsequent performances will be compared. If you are following your exercise regime you should gradually be able to do better than your baseline value. Instructions on how to set your maximum contraction force are given in the next section. If you need to change that setting, follow those instructions again. (You may want to set a new maximum contraction force once you have gained three consecutive passes of the Advanced (Level 3) program and before you start the Ongoing program.)

Establishing a starting point

Before you begin your exercise regime, you need to have the PeriCoach system record your initial maximum contraction force as well as customise the sensitivity of the sensor for your body. This is the baseline value against which your subsequent performances will be compared. If you are rigorously following your exercise regime you should gradually be able to do better than your baseline value.

Step 1

Wash the probe thoroughly. See "Cleaning the probe" on page 68 for advice.

Step 2

Inspect the probe thoroughly. If it is damaged—for example, the outer covering has become cracked or torn—do not use it and ignore the rest of this procedure. Contact Customer Service to discuss a replacement.

Step 3

Wash your hands thoroughly, preferably with an anti-bacterial soap.

Step 4

With washed and dried hands, turn on the probe.

You do this by removing it from the charging case. A green LED should come on in the base of the probe as shown in Figure 6 on page 24. If the green light does not come on, give the sensor a quick shake with your hand.

The light should come on.

Step 5

Place the smartphone within two metres of the probe and open the PeriCoach app on the phone.

The PeriCoach: Connected message should appear on the screen and the base of the probe glows blue. If this doesn't occur, the probe and

the phone have not been properly paired. Follow the instructions in "Registering for PeriCoach" on page 21 before continuing.

Step 6

Before inserting the probe, feel the body of the probe (see below). 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. Repeat if necessary, until the probe is at a comfortable temperature.

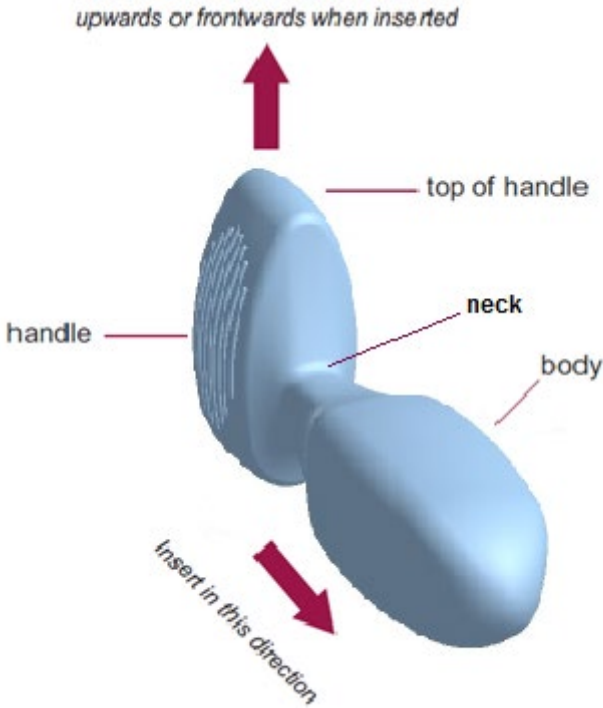


Figure 12: Probe insertion directions



Only the body of the probe should be inserted. Do not attempt to insert the device past the neck (identified in Figure 12).

You can use the probe while lying down or standing up. If you insert it while lying down, the top of the handle must be pointing upwards. If you insert it while standing up, the top of the handle must be pointing frontwards.

Step 7

With your legs slightly apart and your pelvic floor muscles relaxed, insert the probe into your vagina. Follow the directions shown in Figure 13.

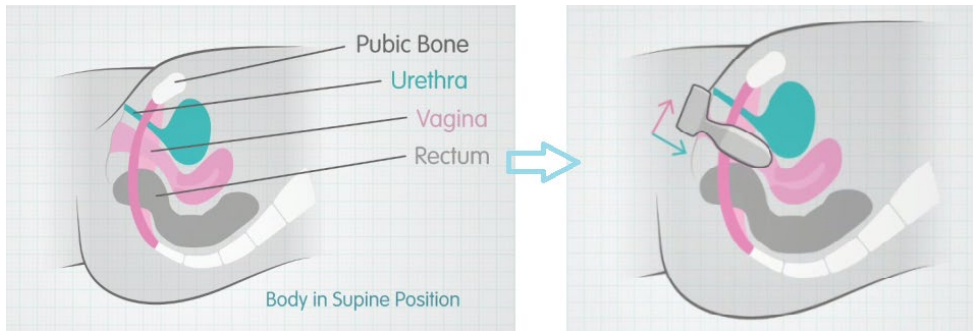


Figure 13: Probe insertion

If necessary, you can apply a small amount of water-based lubricant to the inserting end of the probe.



Care providers please note: through regular communication with the user, please take care when assisting to insert and remove the probe that the user is comfortable at all times

If you have trouble keeping the probe in place, wearing underpants after insertion may help. Alternatively, do the exercises lying down until your muscles have strengthened enough for you to do them standing up.

Step 8

Position the phone so that it is within your reach and the screen is clearly visible. See Figure 14 and Figure 15 below.

If the phone is too far away from the probe, the wireless connection between it and the probe will fail.

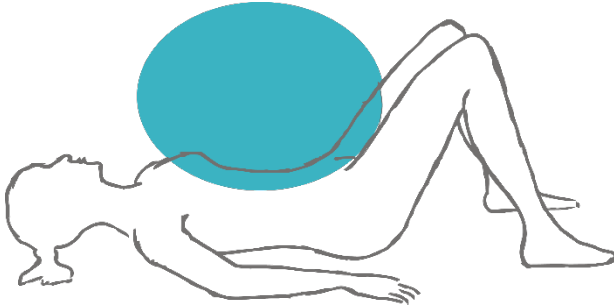


Figure 14: When lying down, the smartphone should be held in the region shown

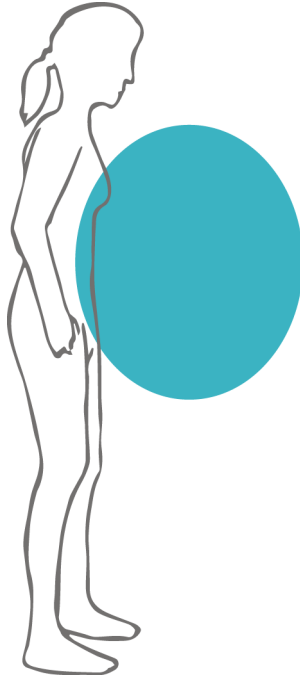


Figure 15: When standing up, the smartphone should be held in the region shown

Step 9

On your phone, tap Settings > Calibration > New Device Setup

Step 10

Read the message titled New Device Setup (Figure 16). It explains what to do.

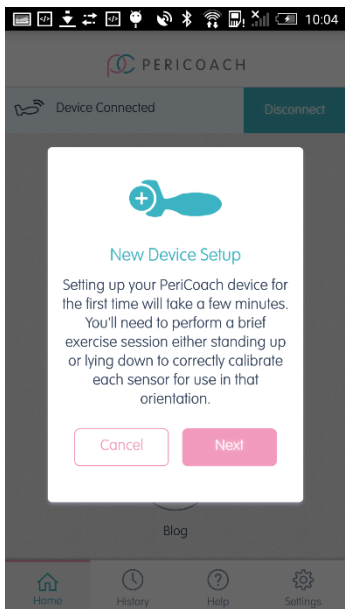


Figure 16: New Device Setup instructions

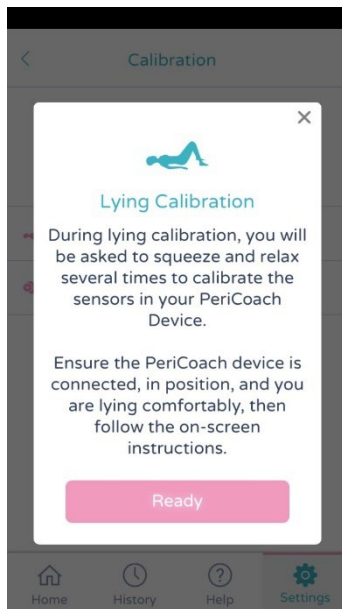


Figure 17: Lying Calibration instructions

Step 11

Tap **Next** and select the **Orientation** you would like to set up at this time.

Step 12

Read the message titled **Standing** or **Lying Calibration** (Figure 17). It explains what to do.

Step 13

Tap **Ready** and you will be taken to the **Calibration** screen. Press **Start** when ready and follow instructions.

Step 14

When instructed to **Squeeze**, squeeze your pelvic floor muscles as hard as you can, being careful not to engage other muscles such as legs or buttocks. As you squeeze you will notice an aqua bar rising on

the force meter on the phone (see Figure 18). During your hardest squeeze press Next.

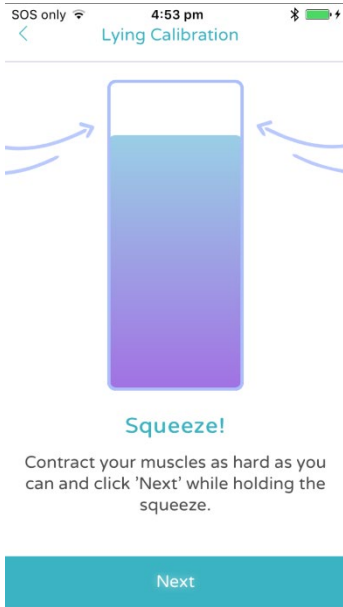


Figure 18: Calibration Squeeze screen

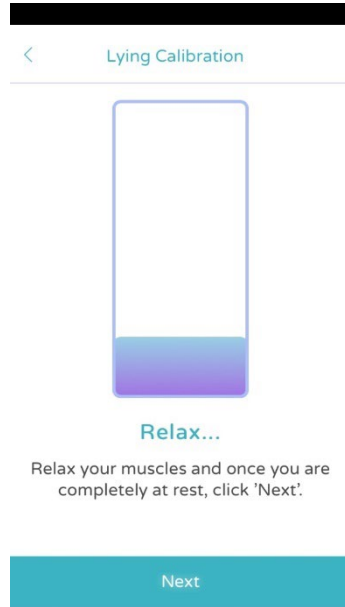


Figure 19: Calibration Relax screen

Step 15

Now relax your muscles and press Next when you are completely at rest (Figure 19).

Step 16

Repeat steps 12 and 13 a few more times until you receive the message that you have successfully completed the calibration. Press Save if you are satisfied that you correctly followed the on-screen instructions, and you will be returned to the Home screen. Press Cancel if you want to try again.

The force you exert in subsequent exercise sessions will be presented as a percentage of this initial maximum force calibration.

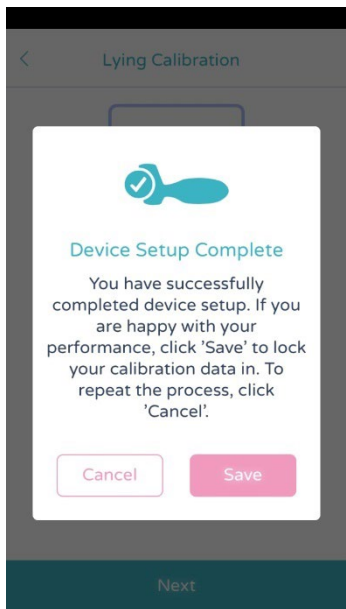


Figure 20: Calibration success message

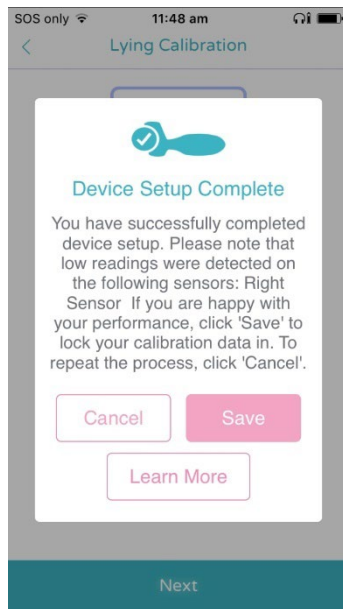


Figure 21: Low reading message

If you receive a message like the one shown in Figure 21, the probe is having trouble picking up significant muscle movement on the sensor listed. If you try to calibrate again and receive the same message, you should press Save and continue to exercise to strengthen that muscle.

Step 17

Tap Back to return to the home page of the PeriCoach app. You are now ready to begin your exercise regime.

Follow one of the following two sections.

I don't want to start an exercise session now

1. Remove and wash the probe. See "Cleaning the probe" on page 68.

2. Dry the probe with a clean cloth and place it in the case.
3. If you wish, recharge the probe's battery. See "Charging the battery" on page 64.

When you do want to start an exercise session, follow the instructions in "Exercising" on page 48.

I want to start an exercise session now

Back at the home page of the app.

1. Tap Exercise.
2. The Exercise Session screen appears. A description of the currently selected program-level combination is showing near the bottom half of the screen.

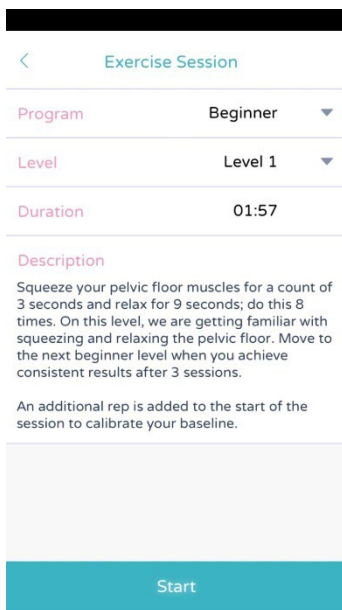


Figure 22: Currently selected program-level combination

The programs available to you are described in "Exercise programs" on page 30. If you want to change the exercise program currently showing:

- a. Tap anywhere in the Program field.
- b. Swipe through the list until you see your preferred program.
- c. Press on the name of your chosen option.

Most programs have various levels (described in "Exercise programs" on page 30). If you want to change the level currently showing:

- Tap anywhere in the Level field.
- Swipe through the list of options that appears in the dropdown list and press on the name of your chosen option.

3. Tap Start. The Orientation message appears.



Figure 23: Orientation message

4. Tap Standing or Lying down, whichever is appropriate.

The Get Ready message appears. Continue with "Task 4: Start the exercise" on page 52.

NOTE

If unsure of which program or level you should begin with, it is recommended to start at Beginner Level 1 and then move up levels when you have achieved 3 consecutive passes.

Exercising

Once you have set your initial maximum contraction force (see "Establishing a starting point" on page 38), you can begin your exercise regime. Each exercise session involves five main tasks:

1. Prepare the probe.
2. Prepare the app.
3. Insert the probe.
4. Start the exercise.
5. Review and finish up.

Before you begin

Before beginning an exercise session, check that the phone has sufficient power. If the charge remaining is less than 15%, recharge the phone. (Consult the instruction manual that accompanied the phone for advice on checking the power and recharging the phone's battery.)

Task 1: Prepare the probe

1. Wash the probe thoroughly. See "Cleaning the probe" on page 68 for advice.
2. Inspect the probe thoroughly. If it is damaged—for example, the outer covering has become cracked or torn—do not use it and ignore the rest of this procedure. If the PeriCoach is still within its warranty period, contact the manufacturer (see "Getting help" on page 68).
3. Wash your hands thoroughly, preferably with anti-bacterial soap.
4. With washed and dried hands, turn on the probe.

You do this by removing the probe from the charging case. A green LED should come on in the base of the probe as shown in

Figure 6 on page 24. If the green light does not come on, give the sensor a quick shake with your hand. The light should come on.

Task 2: Prepare the app

- 1. Make sure the probe is still on. Turn it on if it has gone off (See instructions above).**
- 2. Place the phone and probe within 2 metres of each other.**
- 3. Open the PeriCoach app on your phone.**
- 4. If the app does not automatically connect to the probe, tap Connect to Device.**
- 5. If Bluetooth is not currently activated on your phone, a message asking to turn on appears. Tap Yes to turn on Bluetooth. Bluetooth must be on for the probe to be able to communicate with the phone.**
- 6. Tap Settings, Device and check that the Battery Level reading for the probe is greater than 20%. If it is not, recharge the probe's battery and begin again from step 1 of "Task 1: Prepare the probe" on page 48.**

See "Charging the battery" on page 64 for instructions.

- 7. Tap Back to return to the home page of the app.**
- 8. Tap Exercise.**

The Exercise Session screen appears. A description of the currently selected program-level combination is showing near the bottom of the screen.

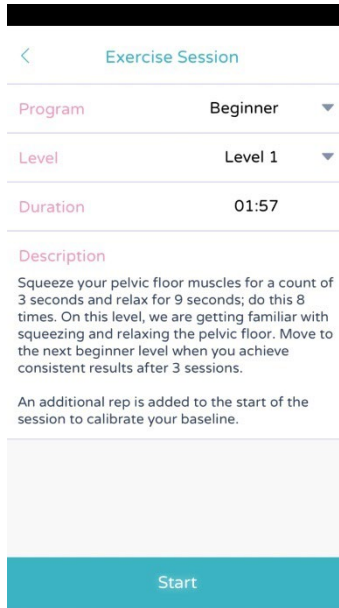


Figure 24: Currently selected program-level combination

The programs available to you are described in "Exercise programs" on page 30. If you want to change the exercise program currently showing:

9. Tap anywhere in the Program field.

Swipe through the list of options that appears underneath the name until you see the option you want.

10. Press on the name of your chosen option.

Most programs have various levels (described in "Exercise programs" on page 30). If you want to change the level currently showing:

Tap anywhere in the Level field.

Swipe through the list of options that appears in the dropdown list and press on the name of your chosen option.

11. Insert the probe as instructed below.

Task 3: Insert the probe

1. With your legs slightly apart and your pelvic floor muscles relaxed, insert the probe into your vagina. Follow the directions shown in Figure 25 below.

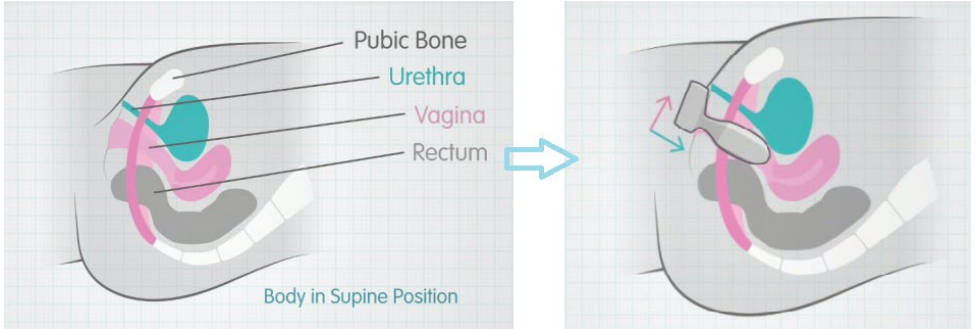


Figure 25: Probe Insertion



Only the body of the probe should be inserted. Do not attempt to insert the device past the neck (identified in Figure 12).

You can use the probe while lying down or standing up. If you insert it while lying down, the top of the handle must be pointing upwards. If you insert it while standing up, the top of the handle must be pointing frontwards.

If necessary, you can apply a small amount of water-based lubricant to the inserted end of the probe.

If you have trouble keeping the probe in place, wearing underpants after insertion may help. Alternatively, do the exercises lying down until your muscles have strengthened enough for you to do them standing up.

2. Position the phone so that it is within your reach and the screen is clearly visible. See Figure 14 and Figure 15 on page 41 for guidance.

Task 4: Start the exercise

1. With the probe and phone in place, tap **Start**. The **Orientation** message appears.

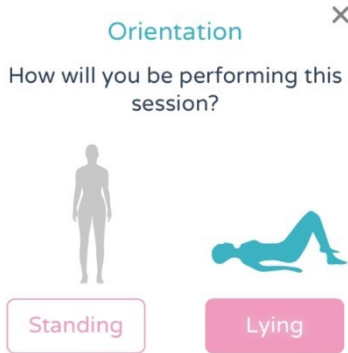


Figure 26: Orientation message

2. Tap **Standing** or **Lying down**, whichever is appropriate. The **Get Ready** message appears (Figure 27).
3. Press **Start**.

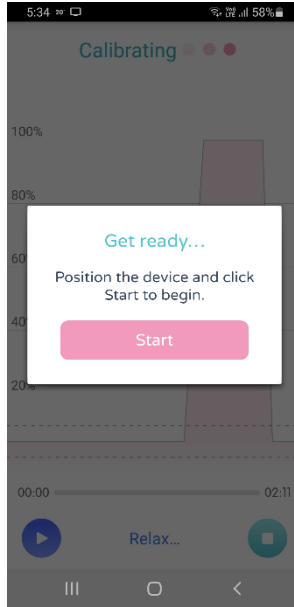


Figure 27: Get ready message



It is essential that you relax and squeeze your muscles as prompted during the first two repetitions of the session. PeriCoach needs to determine your resting force while your muscles are relaxed. This process is called calibration. You will see a Calibrating message during the first two repetitions while this occurs.

If you get an alert (shown in Figure 28) that the sensors are having trouble sensing muscle movement, you will need to try to calibrate again. Press Restart. If you keep receiving this message, you may be having difficulty fully relaxing your muscles, or your strength may not be high enough to register on the sensors.

Follow the instructions on the screen. Initially a message on the screen will say Relax. In a few seconds, the message changes to Squeeze!

During the exercise, you can see a graph on your phone of the strength of your contractions relative to your baseline level.

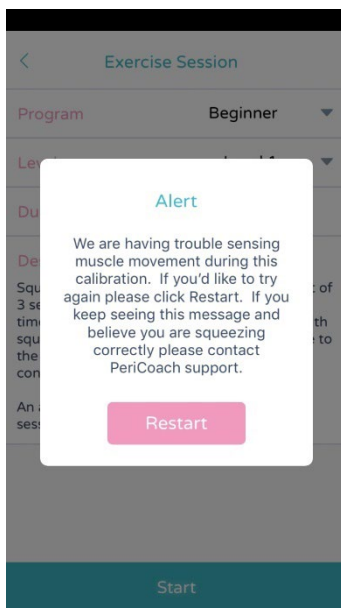


Figure 28: Calibration alert

If sound and vibration are enabled on your phone, you will hear a beep and phone vibrates to let you know when to contract your muscles, and then again when to relax. This squeeze-relax cycle continues until the exercise session ends.

A visual representation of the force of your contraction appears on the screen. As you squeeze and relax, one or more lines rise and fall. Your aim with each contraction is to at least reach, if not exceed, the 100% mark on the screen.

You will also see a technique indicator (icon) at the end of each squeeze-relax cycle in the form of a tick, cross or question mark. A tick indicates good squeeze technique, while a cross suggests there is a need for improvement with your technique. A question mark indicates that the technique performance could not be

determined, in which case it is recommended to focus on better technique.

The duration of the session and the time remaining are shown below the graph along with a progress bar.

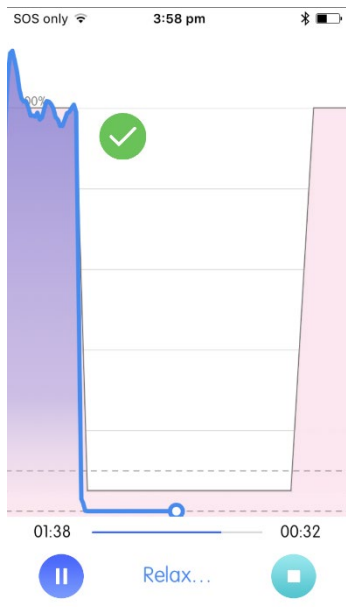


Figure 29: Exercise Session Graph showing tick icon (good technique)

Pausing, resuming and stopping

If at any time you feel uncomfortable with the probe in place, you can pause or stop the exercise session (see Figure 30) and remove the probe. If you pause it, tap the resume button after you have repositioned the probe.

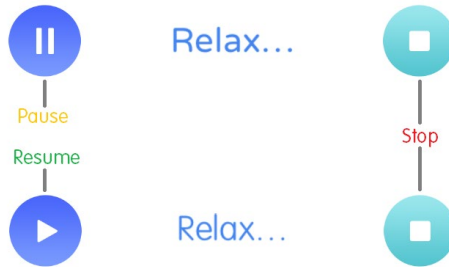


Figure 30: Pausing, resuming and stopping

An interrupted session (pressing stop) will need to be restarted from the beginning and no data will be recorded.

What is graphed?

The blue-green line graphed during an exercise session represents the average of the forces applied to all three sensors in the probe. This line is a real-time indication of your muscle activity.

At the end

If you complete the session, the result summary appears on the screen. Your performance is given a descriptive word such as "Good", and a bar graph showing the reps for the session. In the example in Figure 31 below, Chelsea has just completed a session and her performance was OK, with rep performance varying from 50% to 100% throughout.



Figure 31: Session complete message

Options are also available for you to revisit the session. These are explained in "Task 5: Review and finish up" below.

Low reading message

If you receive the message in Figure 32 at the end of a session, this indicates that little to no muscle activity was detected for the listed sensor, and this is consistent with the readings recorded during New Device Setup. Continue to exercise to strengthen the muscle.



Figure 32: Low reading message at end of session



Figure 33: Unexpected low reading message at end of session

If you receive the slightly different message shown in Figure 33, this means that little to no muscle activity was detected, and that this was unexpected based on the New Device Setup results.

Relaxation Warning

It is important to fully relax your muscles in between squeeze repetitions. If you receive a warning at the completion of a session that you are not fully relaxing between contractions (as shown in the image below), you may need to focus on completely relaxing your muscles at the right time. If you get this message several times, we recommend you seek advice from a women's health specialist.

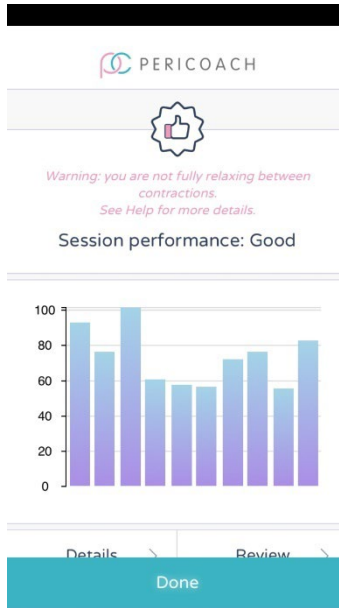


Figure 34: Relaxation warning

Task 5: Review and finish up

1. Remove and wash the probe. See "Cleaning the probe" on page 68.
2. Dry the probe with a clean cloth and place it in its case.
3. If you wish, recharge the probe's battery. See "Charging the battery" on page 64.
4. To review the details of the exercise just completed:
 - a. Tap Details.

The details of each contraction are listed. A technique icon appears beside each contraction to indicate how good the technique was for that cycle. The average for the entire session is shown in the panel above the list.

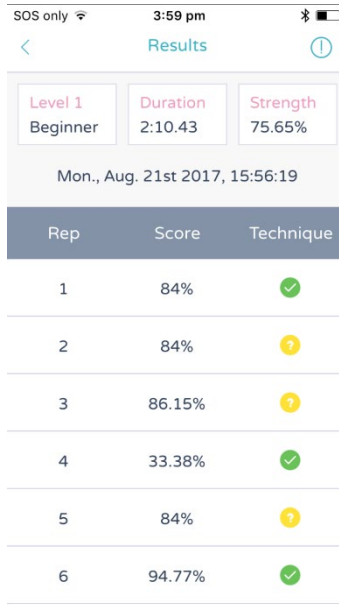


Figure 35: Results summary

- b. Tap Back to return to the previous window.
- 5. To replay the graphical representation of the session:
- 6. Tap Review.
You can swipe right or left to move forwards or backwards through the graph of the session.
- 7. Tap Done to return to the previous window.
- 8. To close the session, click Done. You are returned to the home page of the app.

The details of the exercise are uploaded to a secure website and you can access this website and review a history of all the exercises that have been uploaded (as explained in the next section).

Turning off the probe

The probe will power off after it has been disconnected from the app by pressing the phone's back button or selecting Disconnect on the app home screen. After two minutes of inactivity the probe will automatically turn off. Placing it in the charging case will also turn it off.

Your exercise history

Logging into your PeriCoach system enables the system to store the results of your exercises in secure cloud hostage and for you to be able to retrieve them anywhere and at any time. (You might, for example, want to show your doctor or clinician the results from following a particular exercise regime.)

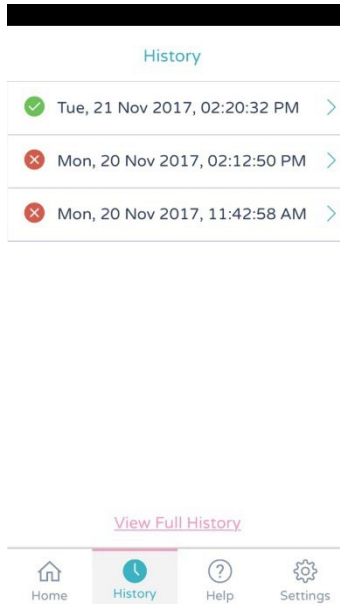


Figure 36: Session history summary

To retrieve the results of previous exercise sessions:

1. Tap **History** on the home page of the PeriCoach app.
A list of the current day's sessions appears along with the time each one ended.
2. To retrieve one of these sessions, tap on it.
The information that appears is the same as when you tap **Details** at the end of a session (see Figure 36 on page 61). Tap **Back** to return to the **History** screen.
3. To retrieve the results of earlier exercise sessions, tap **View Full History** at the bottom of the screen.
You are taken to the PeriCoach website.
4. Log in using the same username and password you used to log in to the PeriCoach app.
5. Tap **Exercise History** and explore your details as you wish.

NOTE

You can access the PeriCoach website from any computer. Just enter the following URL, click on **Users > User Portal Login** and log in using the same username and password you use to log in to the PeriCoach app: <https://my.pericoach.com/>

6. MAINTENANCE AND TROUBLESHOOTING

Maintaining power

The PeriCoach probe is powered by a rechargeable battery. As the battery may have lost some power since the probe left the factory, you may need to recharge it before using the probe for the first time. You should also recharge the battery whenever the battery level reading falls below 20%. (Note that the time between recharges will vary with the frequency and duration of use.)

You can charge the battery from a PC (providing that the PC has a spare USB port and is turned on). Alternatively, you can charge the battery from mains power using a USB power adapter (not supplied with the kit).

The battery is not replaceable. If your battery fails to recharge, contact the manufacturer (see "Getting help" on page 68).

Checking the level of battery power

If you charge the battery after every exercise session, you will not have to worry about the power failing during a session. However, if you don't regularly charge the battery, you can see if it needs to be recharged by checking the battery level. If the level is below 20%, you should charge it before your next exercise session.

To check the battery level:

1. Turn on the probe.
2. Open the PeriCoach app on your smartphone. Probe should connect.
3. Tap Settings on the main window of the app. The Settings window appears (Figure 37).
4. Tap on Device

5. Device information box should appear (Figure 38).

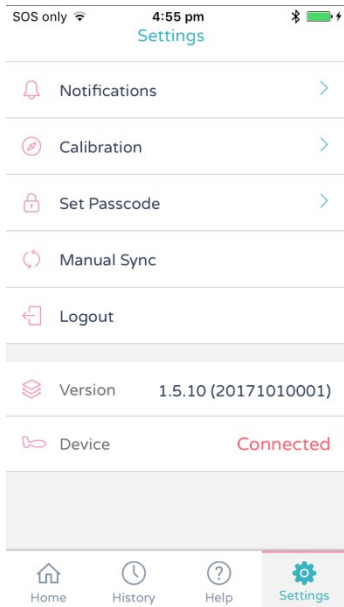


Figure 37: Settings screen

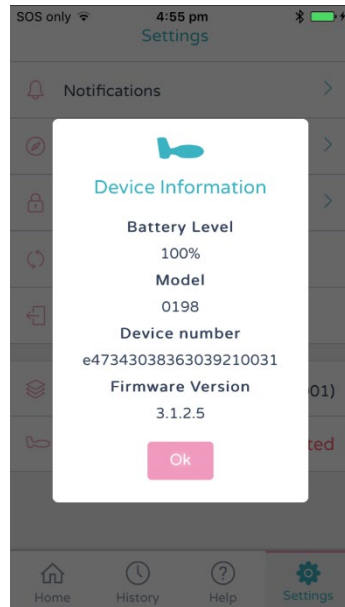


Figure 38: Device Information box

Note the Battery Level reading towards the top of the box. This is also where you'll find the Device number, Model and Firmware Version.

6. Tap Back to return to the main window of the app.

If the battery needs recharging, continue with the next section.

Charging the battery

To charge the battery:

- 1. Place the probe in PeriCoach charging case. Make sure it fits snugly into the moulded recess.**
- 2. Plug the USB cable that came with the kit into the port on the side of the case.**

3. If you are charging the probe from a PC, plug the other end of the USB cable into a spare USB port on the PC. (The PC needs to be turned on for charging to occur.) Continue with step 5.



Figure 39: Place the probe in the charging case recess

4. If you are charging the probe from mains power, plug the other end of the USB cable into the USB socket on the power adapter, plug the adapter into a regular mains power outlet and turn on the power.
5. The end of the probe will glow purple while charging is occurring. When the probe no longer glows purple, the battery is fully charged. Disconnect the cable and remove the probe from the case. The probe is now ready for use.

NOTE

If the probe doesn't glow purple during charging, see "Troubleshooting" below.



Do not attempt to insert or use the probe while it is being charged.

Troubleshooting

Consult the table below for advice when your PeriCoach system is not working as described in this instruction manual (or by an authorised representative of the manufacturer). If your system still fails to work as expected, contact the manufacturer (see "Getting help" on page 68).


No part of the PeriCoach system has been designed to be repairable or serviceable. Hence under no circumstances should any attempt be made to dismantle or modify any item in the PeriCoach system. Doing so will render your warranty null and void. It might also lead to injury to yourself or damage to the equipment.

Software updates

To ensure proper operation of the PeriCoach app you will need to keep your Smartphone software up-to-date (consult your Smartphone manual for updating the software).

From time to time the PeriCoach app may be updated to introduce new features or fix bugs. It is important that you have the most up-to-date app version, so it is recommended that you have Auto-update Apps turned on.

How to update all Android apps automatically

1. Open the Google Play Store app .
2. At the top right, tap the profile icon.
3. Tap Settings > Network Preferences > Auto-update apps.
4. Select an option:
 - Over any network to update apps using either Wi-Fi or mobile data.
 - Over Wi-Fi only to update apps only when connected to Wi-Fi.

How to turn on automatic updates, iOS

1. Go to phone Settings.
2. Tap App Store.
3. Turn on App Updates.

Table 3: Troubleshooting

Problem:	Probable cause and/or solution:
The probe doesn't glow purple when the battery is being charged.	<ul style="list-style-type: none">• Is the PC or mains power switch turned on?• Is the USB cable firmly connected between the case and the PC or power adapter?• Is the probe sitting snugly in the moulded recess?• Is the battery already fully charged? (See "Checking the level of battery power" on page 63)
I get a "Connection failed" message.	You have tried to connect to the probe, but the probe is either not turned on or not in discoverable mode. See "Registering for PeriCoach" on page 21.
I get a "Device not connected" message.	The probe will turn off automatically if not used for 2 minutes. Turn it on. When it glows green at the base, tap Connect to Device on your phone. The base of the probe will turn blue and the PeriCoach: Connected message appears on the screen.

Cleaning the probe

You should wash the probe before its first use, after each use and again before each subsequent use.



Do not use harsh cleansing agents (such as those containing bleach, benzene or alcohol). Only use agents that are designed to clean hands and lightly soiled kitchen items (e.g., mild household soap/detergent).



Use only a soft cloth to clean the probe. Abrasive materials such as scouring pads and steel wool can damage the covering of the probe, reducing its reliability and adding to the risk of contamination and subsequent infection.



Do not clean the probe in an autoclave or dishwasher.



Do not submerge the charging case in water.

To clean the probe:

1. In a clean bowl or wash basin dilute a mild household soap/detergent with water.
2. Soak a soft cloth in the soapy water and wring out the excess moisture.
3. Wipe the probe all over.
4. Rinse the cloth in water until it is free of all detergent.
5. Wring out the excess moisture and wipe the probe all over.
6. Let the probe dry before replacing it in the charging case.

Getting help

In addition to this instruction manual, online help is available inside the app. Just tap Help on the home screen of the app and navigate to the topic of interest.

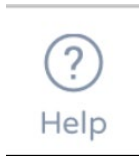


Figure 40: Help icon

The PeriCoach website will also be updated from time to time with useful information on using the PeriCoach system. This information will be available from: <http://pericoach.com/faqs/>

If, after reading this manual, consulting the online help, and visiting the PeriCoach website, you still need help setting up, using or maintaining the PeriCoach system, or if the system does not operate as described, contact the customer helpline for assistance:

Australia & New Zealand

Email: help@pericoach.com

UK

Email: help-uk@pericoach.com

USA

Email: help-us@pericoach.com

Other Countries

Outside of these areas, refer to website: pericoach.com

Reporting a serious incident

If any serious incident occurs in relation to your use of the PeriCoach, you must report this incident to Stratos MedTech (manufacturer), and the medical device regulatory authority in your region.

A serious incident is one that results in death or a serious injury.

7. LEGAL NOTICES

Electromagnetic compatibility (EMC)

The PeriCoach system complies with the Electromagnetic Compatibility requirements of CISPR 11:2015/AMD2:2019 and 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.

Refer to the electromagnetic compatibility (EMC) information provided in Section 8 of these instructions for use and operate the PeriCoach in accordance with the information provided there.

Contact the manufacturer for further information (see "Getting help" on page 68).

Disposing of the PeriCoach kit



The PeriCoach probe and charging case must not be disposed of with your general household waste. It is your responsibility to dispose of these items by taking them to an authorised collection point for the recycling of unwanted electrical and electronic equipment. Consult your local authorities for advice on the location of such facilities. Note that the lithium battery in the probe poses a fire hazard and may explode if incinerated.

European Authorised Representative



MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert/Germany

Phone: +49 6894 581020

Fax: +49 6894 581021

Email: info@mt-procons.com

www.mt-procons.com

Other Information

You may continue to use the probe while it is within its warranty period, you have an active subscription to the PeriCoach service, and the probe is not damaged or compromised in any way (always check for surface damage/contamination before use.)

Intellectual Property

PeriCoach trademarks and registered trademarks owned by Stratos MedTech: PeriCoach, Peelates, Leak When You, Kegelface, PeriTrack.

The PeriCoach system may be covered by one or more of the following Patents: AU 2012245056, CN ZL201280018210.2, JP 6069297, AU 2015380288, US 10966654, IN 384850, EP 2699321, Patents Pending: BR 112013027117-5, US 14/112855, CA 2964183, EU 15879275.4, Design Registrations AU 349010, CN ZL201330410966.9, EU 002326462-0001, UK 90023264620001, IN 256028, JP 1499657, US D710007.

8. TECHNICAL SPECIFICATIONS

Equipment type



Internally powered medical electrical (ME) equipment. Type BF Applied part (IEC 60601-1)

The PeriCoach probe is rated to IP27.

Expected Service Life

The expected service life of the PeriCoach probe and charging case is 2 years.

Stratos MedTech does not guarantee that the PeriCoach device and software (including security updates) will continue to be supported outside of this service life.

Battery

Type: Lithium-polymer Voltage: 3.7 VDC

Typical service life of the battery: 3 years

Charging Case

 Power input: Voltage: 5 VDC, Current: 200 mA

5V 200mA

Safety approval requirement for charger or PC providing power to charging case: IEC 60950-1.

Environmental limits



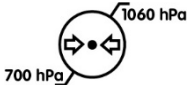
Only store and transport this device in places where the temperature ranges between -25°C (-13°F) and 70°C (158°F).



Only use this device when the room temperature is between 5°C (41 F) and 40°C (104 F).



Only store and use this device with relative humidity up to 93% and non-condensing (that is, no water is forming on the device due to condensation).



Only use this device in when the atmospheric pressure is between 700 hPa and 1060 hPa. Except in extraordinary circumstances, the weather in most parts of the world have atmospheric pressure well within the 700-1060 hPa range.

Refer to the Symbols Glossary on page 82 of this manual for the meaning of all symbols and indicators used in the PeriCoach system.

Physical attributes

Probe dimensions

12 cm (L) × 3 cm (w) × 4 cm (h) (4.7" (L) × 1.18" (w) × 1.57" (h))

Probe weight: 50 gm (1.76 oz.)

Cable

Type-A USB-to-mini-Type-A USB cable

Smartphone Requirements

Android 2.3 or later, or iPhone 4s or later required.

Bluetooth interface

Internet connection (e.g., 5G, LTE or WIFI)

Electromagnetic Compatibility (EMC) information

The PeriCoach system has been tested to, and complies with, the EMC requirements of IEC 60601-1-2:2014.

The PeriCoach is suitable for use in the home environment and in general clinical environment.

The PeriCoach system is designed to be used in proximity to the mobile phone used to operate the PeriCoach App.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



WARNING: 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 PeriCoach system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The PeriCoach probe complies with the following levels specified in IEC 60601-2:2014:

- The Home Healthcare Environment limits apply.
- **RF Emissions:** Radiated RF emissions: CISPR 11 RF emissions, Class B limit and CISPR 32 RF emissions, Class B limit.
- **RF Immunity:**

- **Electrostatic Discharge:** $\pm 8\text{kV}$ contact, $\pm 15\text{kV}$ air discharge.
- **Radiated RF EM fields:** 10V/m , 80 MHz - 2.7GHz . 3V/m , 2.7GHz - 6GHz .
- **Rated power frequency magnetic fields:** 30A/m 50Hz , 60Hz
- **Proximity Fields from RF wireless equipment:** Limits as per section 8.10 of IEC 60601-1-2:20-14.

The PeriCoach system intentionally receives and transmits RF electromagnetic energy for the purpose of its operation. (Bluetooth connection)

Frequency band of transmission and reception: $2400 - 2483.5\text{ MHz}$

Modulation: Bluetooth BLE (GFSK) or Bluetooth Classic GFSK/ $\pi/4$ -DQPSK/8-DPSK

Effective Radiated Power: $<10\text{dBm}$

US FCC Information

FCC Label and Compliance Statement (FCC Part 15.19)

FCC ID: 2AXG8-PC4

Model Number: PeriCoach V4

FCC 15.19 Compliance Statement

This device complies with Part 15 of the FCC Rules. 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.

Information to the user (FCC Part 15.105)

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, or
- Consult the dealer or an experienced radio/TV technician for help.

Modification Warning (FCC Part 15.21)

Warning: Do not modify this equipment. Any changes or modifications not expressly approved by Stratos MedTech Pty Ltd could void the user's authority to operate this equipment.

Manufacturer Details

Manufactured by:

Stratos MedTech Pty Ltd

98 Ellena Street,

Maryborough, QLD, 4650 Australia

Telephone: +61 (7) 3278 1950

9. WARRANTY INFORMATION

Australia

This notice applies to all PeriCoach devices sold to end customers ("You"). Recent legal changes in Australia affect the warranty terms applicable to Covered Devices. This notice clarifies the relationship between the PeriCoach warranty included in the packaging of Covered Devices ("*PeriCoach Warranty*") and the Australian Consumer Law. It also provides information needed to make a warranty claim.

Your Consumer Rights

The benefits given to You in the PeriCoach Warranty are additional to, and do not detract from, any rights and remedies that You may have under Australian laws, including the Australian Consumer Law.

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure ("*Your Consumer Rights*").

Claiming under our PeriCoach Warranty

Once Stratos MedTech is notified of any defect in your Covered Device, unless we decide to replace the product immediately, we will arrange for the device to be collected from your premises, at our expense, and returned to our headquarters to be analysed and to determine what action will be taken under the PeriCoach Warranty. Any Covered Devices repaired or replaced under the PeriCoach Warranty will be delivered again to your premises, at our expense.

Stratos MedTech will also reimburse any other reasonable expenses you incur in making your claim under the PeriCoach Warranty.

To claim any entitlement under the PeriCoach Warranty (including any reasonable expenses incurred in making a claim under the PeriCoach Warranty) please contact PeriCoach Customer Service:

Email: help@pericoach.com

Exclusions and Limitations in the PeriCoach Warranty

The PeriCoach Warranty applies to new devices sold and not to any used devices or replacement devices supplied under warranty or provided on loan during a period of service and repair of an original device, although you may have some consumer rights in respect of such products.

Any exclusions of direct, incidental, consequential, or other damages and other warranties (including express or implied warranties of merchantability, fitness for a particular purpose, etc), referred to in the PeriCoach Warranty apply only to your rights under that PeriCoach Warranty, and do not affect Your Consumer Rights.

Stratos MedTech stands by the quality of its products but also supports these legislative changes as beneficial for consumers. We thank you for your ongoing support of Stratos MedTech devices.

Limited Warranty - USA

What is covered by this warranty

Stratos MedTech Pty Ltd warrants the PeriCoach® device and case (the "Product") contained in the original packaging against defects in materials and workmanship when used normally in accordance with Stratos MedTech's published guidelines for a period of ONE (1) YEAR from the date that you purchase the Product. Stratos MedTech's published guidelines include but are not limited to specifications, user manuals, instructions for use, and service communications.

What Stratos MedTech will do

Stratos MedTech will replace the Product provided that you (a) have contacted the Stratos MedTech Help Desk, and (b) after talking with the Help Desk, have returned the Product to Stratos MedTech as instructed by the Help Desk.

Refer “Getting help” on page 68.

What Stratos MedTech will not do

This warranty does not apply to any usage or treatment of Product outside of those set out by Stratos MedTech published guidelines.

How state law applies

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

Limitation of liability

Except as provided in this warranty and to the maximum extent permitted by law, Stratos MedTech 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.





Other Jurisdictions




Refer to the product website www.pericoach.com or contact the distributor in your region.





10. SYMBOLS GLOSSARY





The meanings of all symbols and indicators used in the PeriCoach system, including packaging, are shown in the table below



Symbol	Symbol Title	Symbol Meaning	Labelling Standard and symbol reference
	Follow Instructions for Use	Consult the Instructions for Use. The eIFU identifier is placed beneath this symbol.	IEC 60601-1:2005/AMD2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Ref Table D.2. #10.
	General Prohibition	This symbol is used to indicate a mandatory prohibition - you must not do this.	ISO 9010:2019 – Graphical Symbols – Safety colours and safety signs – Registered safety signs. Ref P001
	Catalogue Number	Indicates the manufacturers catalogue number so that the medical device can be identified.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.1.6.



	Batch Code	Indicates the manufacturers batch (or lot) code so that the batch or lot can be identified.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.1.5.
	Caution	Caution is necessary when operating the device of control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.4.4.
	Manufacturer	Indicates the name and address of the medical device manufacturer.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.1.1.
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.1.3.

	<p>Authorized representative in the European Community/ European Union</p>	<p>Authorised representative in the European Community / European Union.</p>	<p>EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.1.2.</p>
	<p>CE Mark</p>	<p>Signifies European conformity (CE) mark. Indicates manufacturer declaration that the product complies with applicable European regulations.</p>	<p>N/A</p>
	<p>Do not open/use if packaging is damaged in transport and consult Instructions for Use.</p>	<p>The device should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.</p>	<p>EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.2.8.</p>

	Fragile, handle with care.	The device may be broken or damaged if not handled carefully.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.1.
	Keep dry.	Protect from moisture	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.4.
	Keep away from sunlight.	Protect device from light sources.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.2.
	Temperature limits (upper and lower)	Temperature limits to which the medical device can be safely exposed.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.7.

	Humidity limitation	The humidity range to which the medical device can be safely exposed.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.8.
	Atmospheric pressure limitation	The range of atmospheric pressure to which the medical device can be safely exposed	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.3.8.
	Single patient multiple use	The device may be used multiple times on a single patient.	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.4.12.
	Medical Device	This item is a medical device	EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements. Ref 5.7.7.

	Type BF applied part	Electrical classification of the device part that contacts the patient.	IEC 60601-1:2005/AMD2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Ref Table D.1. #20.
	Direct Current	Provides the power input information for the device.	IEC 60601-1:2005/AMD2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Ref Table D.1. #4.
IPN₁N₂ e.g. IP27	Ingress Protection.	The degree of protection provided by electro-medical device enclosures against the ingress of dirt or water. In the format IPN₁N₂, N₁ is the degree of protection against dirt, N₂ is the degree of protection against water. N₁ = 2 Protected against solid foreign objects of 12,5 mm Ø and greater N₂ = 7 Protected against the effects of temporary immersion in water	IEC 60601-1:2005/AMD2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Ref Table D.3. #2.

	<p>Probe Only</p>	<p>This symbol indicates that the associated information applies to the PeriCoach probe only, it does not apply to the charging case.</p>	<p>N/A</p>
	<p>Waste stream disposal status</p>	<p>Product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.</p>	<p>Annex IX of Directive 2002/96/EC (WEEE)</p>