

Label Details

The User manual (containing FCC compliance label details (FCC ID, 15.19 compliance statement) is available on the device website via link provided with the device smartphone app.

E-labelling requirements are therefore applied in accordance with [KDB 784748](#) D02 e labeling v02r01 section 4.

(Section 4.5) FCC ID supplied on a label on the device packaging – see label below

Label Sticker for device packaging



Label location:

Label sticker (with FCC ID) will be located on EUT packaging as indicated below



([KDB 784748](#) D02 Section 4.1) Insert provided with instructions to access User manual with FCC compliance information.

“Quick Guide” package insert

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.

- 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/washbasin 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.

Using the PeriCoach

Installing the PeriCoach App on your smartphone:

7. Download the App from the Google Play Store or Apple store.
 8. Tap install and follow the instructions for download and installation.
- Once the App is installed open it to pair the sensor and login to your account. The Startup Wizard will guide you through the following required steps:
9. Logging in to the app
 10. Turning on and connecting to the probe
 11. Setting up the device to suit your body
 12. Beginning to exercise

Doing your exercises

Wash your hands and the probe thoroughly before each use to minimise the risk of infection.

Use of a water-based lubricant is recommended for ease of insertion.

Only the body of the probe should be inserted. Do not attempt to insert the device past the neck (refer to Figure 10 in the IFU).

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.

Getting Help: Refer to website: pericoach.com

Manufacturer: Analytica Ltd 320 Adelaide St, Brisbane, QLD, 4000, AUSTRALIA

PeriCoach® - Quick Guide

V1.8

PeriCoach® - Quick Guide

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.

Indications for Use – Others

The PeriCoach 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.

Before you begin

It is essential for your own safety – and for those who could come into contact with the PeriCoach system – that you read the Instructions for Use (IFU) before using the system.

When you completed your registration you should have received the Instructions for Use by email. You can also access it here: my.pericoach.com/Account/Login If you have any questions or doubts about the PeriCoach system that are not answered in the IFU, consult your doctor before using the system.

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.
- you are experiencing back pain severe enough for you to need pain-killers, as doing so may affect an underlying condition.
- you have recently undergone surgery, as doing so may affect an underlying condition.
- symptoms of bladder infection are present, as doing so may affect an underlying condition.
- symptoms of a vaginal infection are present, as doing so may affect an underlying condition.
- you have a history of urinary retention or symptoms thereof, as doing so may affect an underlying condition.
- 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 of the above Contraindications.

FCC Information

All FCC labelling, information and warnings can be found in Section 8 of the online user manual at: <https://www.pericoach.com/PeriCoachInstructionsForUse.pdf>

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Details for access to User Manual (FCC ID, warning and compliance statements) as per [KDB 784748](#) D02 section 4.3.