

User manual PedesHome

Contact information!

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Comments on the functionality, performance or service of the product can be sent by email. You can also contact VistaFeet by phone.

Area of use

PedesHome is a device that works as a complement to the self-care program patients with diabetes or other neurological diagnosis are recommended by their healthcare provider. The purpose is to help the user to see signs of inflammation with the help of temperature differences, i.e. that something is happening inside the foot, so that the user can take preventive measures and avoid the occurrence of complications. PedesHome does not make a diagnosis.

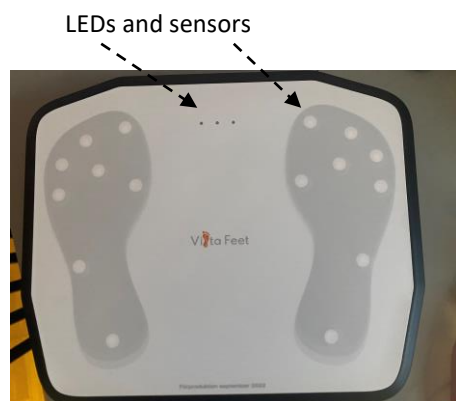
PedesHome is not recommended to be used by people with ongoing foot ulcers or instead of the self-care program recommended by the healthcare provider.

About PedesHome

The PedesHome plate contains electronics that indicate the temperature differences between the user's feet at eight points on the plantar side of the foot. Data is transferred from the plate when synchronized with the application in a user's phone or tablet.

The top of the plate consists of a cover that can be wiped with a slightly damp cloth. On the underside of the plate, you will find the battery cover and an on/off button.

Data from each measurement made with the tablet is transmitted via Bluetooth/wireless, when the tablet is synchronized with the application. In order not to lose data, it is important to synchronize the tablet with the app at least once a week.



The box of PedesHome includes: One (1) plate including battery, a start-up guide, a user manual (this document) and a return form.

Risks and Benefits

Risks

The plate does not cause any pain or discomfort during use. If the footplate is used incorrectly, the measurement results can be misleading, which can lead to indications not being detected correctly.

Benefits

It can be a challenge for people at risk for foot complications to spot early signs of foot complication when examining their feet. PedesHome helps the user in a simple way to identify signs of temperature differences (inflammation) between the feet. With the help of this information, the user can initiate measures to avoid foot injuries or seek professional help in time.

General warnings and precautions

PedesHome is a complement to self-care programs. Do not use the product if it is broken or damaged. The plate should only be used by one (1) and the same person to get the correct history.

When the plate indicates signs of temperature difference, a yellow or red light appears. Then it is important to act by taking measures to reduce the temperature difference. The user can do this, for example, by resting, changing shoes or relieving the foot. If the temperature difference does not disappear from the same spot within two days, you should contact your health care provider. By looking at your history and writing memories, the VistaFeet Home app helps you get to know your feet, so you know how different choices (shoes, activities etc) affect you. It allows you to take care of your feet and make them feel good.

If all or several dots are red at once, you may need help understanding the cause. Wait a few minutes and repeat the measurement. If the result is the same, it is important that you contact your healthcare provider immediately.

If you notice changes in the performance of the plate, or if it flashes yellow at startup (not the first time you start the device), please contact VistaFeet AB for instructions on how to handle this.

WARNING: Do not open or modify the equipment. Also, do not place other objects on the plate when it is used, there is a risk that the measurements will not be correct.

Start instruction!

1. Unpack the PedesHome (plate) from the box and place it on the floor. In the box you will also find instructions and information on what to do if you need to send the product back to VistaFeet AB. Do not use the plate if it is broken.
2. Download the VistaFeet Home application on your phone or tablet and set up your profile as instructed in the application.



3. The you turn on the plate using the ON/OFF button on the back
4. To connect the tablet with the application for the first time, you need to use the "connect" function in the application. You **MUST** take a measurement before connecting the plate for the first time.



You can start the measurement when the green light flashes. The measurement is complete when a lamp lights up with a steady light.

Remember that the tablet must be running (one lamp light with a steady light) for the application to find the device.

5. Place the plate on a flat floor near your bed, where it is free of other objects, and where you can comfortably stand for up to 60 seconds.

For correct results, you need to test your feet without socks, preferably when you have rested.

WARNING: Do not place the plate where you risk tripping on it. Also, do not place the device in a place where it can get wet, in direct sunlight or next to a radiator.

User instruction

For proper results, follow this process every morning and evening. Test your feet, without socks.

1. Examine your feet every day, according to your care plan.

WARNING: If you have developed wounds that have not healed, you can get misleading results using the plate. Contact your health care provider immediately.

2. Check the plate before using it to make sure it is not damp or damaged. If the plate is damaged, do not use it and contact VistaFeet AB for support.
3. Stand barefoot on the plate (or sit and lean forward). To start the plate, turn on the on/off button (or press it lightly with your foot) and wait for the green light to flashe. Place your feet according to the markings and make sure you cover the rings. The measurement lasts as long as the lights are flashing in different colors.

WARNING: Do not use the plate if your foot is wet or smeared with ointment.

4. The measurement lasts for 20–60 seconds. It is important that you remain standing throughout the measurement to get a correct result. The three lights flash while the measurement is in

progress. When the measurement is complete, one of the lights on the plate will light up to indicate a result. To see details from the measurement, the device must be synchronized with the application.

If the red-light flashes, it means that the measurement has not been correct and must be repeated. Get off and restart the plate and repeat from step two.

5. When the measurement is complete and users synchronize the device with the application, the device must be turned on (some light must be on). The application provides information on whether the transfer was successful.

For information

- Data is stored by VistaFeet AB.
 - No data will be shared with third parties without the consent of the user.
 - Data that is shared will be decoded so that it cannot be traced back to a specific user.
6. Monitoring. The user of PedesHome is responsible for performing their measurements and synchronizing data from the device with the application.
 7. Detailed information. The user sees details from the measurement in the application after synchronizing. Data shows if the user has signs of temperature difference as well as a picture of two feet to clearly show where on the foot the increased temperature was measured. Based on the results, users act.

Care and maintenance

Care: Wipe your PedesHome plate regularly with a slightly damp cloth to reduce the risk of deposits. However, be careful about using soap as it can make the plate slippery. Remember to let the plate dry thoroughly before use.

Battery: The PedesHome plate is powered by 1st CR2032 battery. When replacing the battery, it is important to first turn off the plate using the ON/OFF button.

To replace the battery:

1. Unscrew the screw.
2. Lift the lid.
3. Pull out the battery holder (DO NOT reinsert it without a battery).
4. Insert a new battery.
5. Reinsert the battery holder.
6. Attach the lid and screw in the screw.



Recycling

PedesHome plate: electronics recycling and battery. Plastic parts are recyclable.

Packaging: carton

Bubble wrap: plastic

Technical information

- Operating temperature: 15-40 °C
- Storage and transport: 5-40 °C 15-90% relative humidity and 700- 1060 hPa ambient pressure
- Accuracy: ± 0.2°C
- Normal time for measurement: max 60 seconds
- Size: 37 x 31 x 2 cm
- Weight: 1,8kg
- Max weight of users: 150kg
- Protection class IP21
- Warranty: 2 years when used as instructed
- Battery: Lithium battery, CR2032, 6 months
- Product certification: Medical device - CE marking according to MDR class 1, rule 13

Symbol explanation



Company Address



Electronics recycling



Includes a CR2032 3V battery



Keep dry



The plastic material is recyclable



Medical device class 1



Meets current requirements



Product name



Serial number



Caution, read the manual