

femSense®

Ovulation Detection



Requires NFC- and internet connection

SYMBOL DESCRIPTION



Lot number



Manufacturer



Usable until



Medical device



Disposable product



Dispose of in battery recycling



Storage temperature



Follow the electronic instructions for use (eIFU)



Green dot



Safety instructions



Information



SteadySense GmbH
Kärntnerstraße 518, A-8054
Seiersberg-Pirka

Version: 20_09; date of issue: 01.09.2020

INSTRUCTION MANUAL

Please read the instructions for use and the safety instructions carefully and follow them exactly. Improper use or disposal may be harmful to health and may involve risks for third parties.

What is femSense Ovulation Detection

femSense Ovulation Detection is a medical device which can determine a woman's most fertile days based on a rise in basal body temperature. femSense consists of a temperature sensor embedded in an adhesive patch and the supporting smartphone app.

The femSense patch is a disposable device which is applied under the arm and worn for up to 7 days, during which time it continuously measures and records the body temperature.

The femSense app is a cycle tracker with an additional ovulation detection function. The patch is started and read using the femSense app. The app provides you with information about your cycle, your fertile days and if and when ovulation has been detected.

The femSense patch is a non-invasive product that can only be applied to healthy skin and which, based on body temperature measurements, provides information about a woman's fertile days. It is not intended for diagnostic or therapeutic use. femSense does not display temperature values.

Who can use femSense?

femSense is intended for women of childbearing age with regular menstrual cycles and a cycle length variation of maximum +/- 3 days, who wish to have children and want to learn more about their menstrual cycle.

femSense is not a form of contraception and does not protect against sexually transmitted diseases

Restrictions

Certain medical conditions do not allow femSense to reliably determine ovulation. These include:

- ▶ Serious, acute or chronic diseases
- ▶ nicotine or alcohol abuse
- ▶ amenorrhoea
- ▶ oligomenorrhoea (too infrequent menstrual bleeding)
- ▶ polycystic ovary syndrome (PCOS)
- ▶ obesity (BMI > 30)
- ▶ hirsutism
- ▶ known allergy to ingredients of skin patches
- ▶ medication that can influence your body temperature

If you are not sure whether femSense is suitable for you, please consult your doctor before using femSense.



SAFETY INSTRUCTIONS

- ⚠ The patch is a disposable product, use it only once and not for more than for 7 days.
- ⚠ Do not use the patch if you are sick.
- ⚠ Keep the patch out of the reach of children, animals and people with disabilities.
- ⚠ Do not apply the patch over wounds or abrasions.
- ⚠ Do not use the patch if you are allergic to adhesives.
- ⚠ Do not fold or bend the patch.
- ⚠ Do not take long baths or go swimming while wearing the patch.
- ⚠ Do not use the patch if it has been damaged.
- ⚠ Do not attempt to disassemble or open the patch.
- ⚠ If you remove a patch and apply a new patch for the next cycle, place it under the other arm.
- ⚠ Remove the patch before an MRI or CT scan.
- ⚠ The patch is a small electronic device and should not be disposed of in normal household waste.
- ⚠ Do not throw the patch into a fire, the battery could explode.
- ⚠ Do not wear the patch longer than instructed by the app.
- ⚠ If the patch feels uncomfortable on the skin, remove it immediately.
- ⚠ Use the patch only under the specified environmental conditions.
- ⚠ Store the patch in a dry place and protect it from sunlight.



HOW TO USE

- ▶ femSense is designed for ovulation detection and does not show temperature curves.
- ▶ Before you can use a patch you must enable the Ovulation Detection function in the app.
- ▶ The patch should only be applied as instructed in the app.
- ▶ The patch must be worn in the correct position under the arm to ensure reliable ovulation detection.
- ▶ Do not apply the patch until the app advises you to do so.
- ▶ Only apply the patch as described in the instructions for use.
- ▶ Wash and thoroughly dry the skin under the arm before applying the patch.
- ▶ Do not use deodorants or creams before applying the patch.
- ▶ Do not touch the sticky side of the patch as this may affect its adhesive power.
- ▶ Smooth out the patch well on all sides after application.
- ▶ The patch should be read via NFC at least once a day.
- ▶ The maximum application time for the patch is 7 days.
- ▶ Remove the patch immediately if it feels uncomfortable.
- ▶ Avoid high intensity sports or other activities that cause excessive sweating (sauna/steam bath) while using the patch.
- ▶ Everyday activities such as personal hygiene, work or light physical activity will not affect the patch.

HELP

If you experience a problem with femSense, a technical defect or side effects, please contact our support: support@femsense.com or tap on "Contact Support" in the femSense app menu

At www.femsense.com/faq you will find further useful information.

Download femSense app:



PATCH APPLICATION

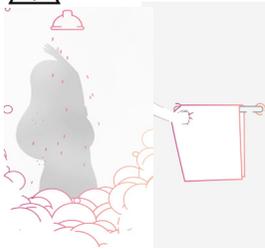
1. Activate the Ovulation Detection function

In order to detect your ovulation with femSense, you first need to enable the Ovulation Detection function in the app by tapping on "Ovulation Detection". After that you will see a countdown until the day you can apply the patch.



2. Preparation

When the femSense app tells you to apply the patch, take a shower with non-greasy soap or shower gel and dry the area under your arm thoroughly. Please make sure not to use deodorant or body lotion before applying the patch as this can reduce the adhesive power.



3. Apply patch

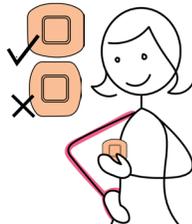
To apply the patch, relax your shoulder, put your hand on your hip and place 3 fingers under your arm to determine the correct position to stick the patch.



Then remove the larger part of the adhesive foil and hold the patch on the smaller end of the foil.

Before attaching the patch put your hand on your hip and relax your shoulder once again.

The patch should be applied in such a way that the upper edge of the patch is 3 fingers width beneath your armpit, on your side. Please stick the patch so that the rounded sides point up and down. Then pull off the remaining part of the adhesive foil and smooth the patch down gently on all sides.



4. Start Patch

Once you have stuck the patch under your arm, you are ready to start it. Tap on "Read Patch" in the femSense app and hold the back of your smartphone for a few seconds on the center of the patch to activate it. A vibration confirms the successful activation.



Position for NFC communication



Depending on your operating system (Apple iOS or Android) the smartphone has to be held differently against the patch in order to read it correctly.

Apple:

Hold the top edge of the backside of your phone, slightly slanted, on the middle of the patch.

Android:

On an Android phone the NFC antenna can be located in different positions. Hold either the area around the camera or the back of the smartphone against the middle of the patch. Please make sure that NFC is switched on. NFC can be switched on in the quick menu or in the settings.



5. Reading the patch

Once you have started the patch you should read it daily. To do this tap on "Ovulation Detection" in the femSense app quick menu at the bottom of the screen, tap on "Read Patch" and hold your Smartphone against the patch as described in point 4. The recorded temperature data will be transferred to the app and you will be informed whether ovulation has been detected or not. You can read the patch up to three times a day. You should however wait several hours between readings, so that there is enough new temperature data available.

THE CALENDAR

The calendar function in the femSense app is a cycle tracker (period diary) which predicts future periods and fertile days. You can also enter personal data and dates relevant to your cycle.

The calendar also shows the date you will be advised to apply the patch and the date on which you can do a pregnancy test.

Predicted period days are marked in light pink, actual period days with dark pink. Fertile days (the perfect days to get pregnant) are marked with hearts. Once femSense has detected ovulation that day will be marked with a golden circle.

If you tap on a date in the calendar, you will be taken to a more detailed view of that day. By tapping on the + button you can add further entries such as period, illness, sports activities.

All data entered will be treated confidentially and will not be shared with third parties.

THE STATISTICS

In the statistics you will find a summary of all your cycles tracked with femSense, average cycle lengths and period days as well as an overview of the data entered in the cycle.

THE MENU

The femSense app menu is divided into 2 areas where you can manage your account and find additional functions and information.

Under "My body and Me" you can view and edit your account and user data.

Under "femSense" you will find the Instructions for Use, Terms and Conditions, Privacy Policy and instructional videos for the femSense app. You can also see which version of the femSense app you have in "About femSense". If you have a technical problem you can contact our technical support team directly by tapping on "Contact Support!". The FAQs button takes you to the frequently asked questions.

You can also access the femSense Webshop and the femSense Blog via the menu and you can rate femSense in the App Store.

Disposal

The patch is powered by a battery and is therefore considered an electronic device, it should not be thrown in the normal household waste, but disposed of in accordance with local waste regulations for batteries and electrical appliances.



The femSense box and transport packaging is made of recyclable paper or cardboard and should be disposed of in paper waste. The individual packaging can be separated and disposed of in plastic or paper waste.

Further Information

GT&C: <https://www.femsense.com/conditions/>
Data protection: <https://www.femsense.com/dataprotection/>
Cancellation: <https://www.femsense.com/cancellation/>
Legal Notice: <https://www.femsense.com/legal-notice/>

Follow us on social media



Technical data

Type of Device: Temperature sensor for ovulation detection
Measurement location: On your side, 3 fingers width under your armpit
Type of use: Disposable product
Typical application period: 7 days
Operating conditions: Ambient temperature +15 ... +40°C,
15 to 95% RH, air pressure: 86 - 106 kPa
System compatibility:
Apple: iOS13 or higher on iPhone 7 or newer models
Android: Android OS 6.0 Marshmallow or newer on an NFC-enabled smartphone
Internet connection minimum 3G or WIFI
Warranty: 2 years after production
Dimensions: 66.3 x 61.2 x 3 mm
Weight: 3 g
Power source: 3 V lithium button cell battery
IP classification: IPX5 - Protection against low pressure water jet spray from any direction.