Instructions for Use
femSense Fertility

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NFC required

Symbol description

LOT Lot number

Manufacturer

Expiration date

MD Medical Device

Single use product

Do not dispose in household waste

40°C 0°C Storage temperature

Follow electronic instructions for use

Green dot

Safety device

Information

Instructions for use

Please read the instructions for Use and the safety instructions carefully before using femSense and adhere to them.

What is femSense?

femSense is a medical device used to determine a woman's fertility on a given day. femSense Fertility consists of a wearable temperature measurement patch, the femSense sensor patch, and the supporting smartphone app for iOS and Android.

The femSense Patch is a disposable product that is worn under the arm for a period of up to 7 days when a woman is most fertile. During this time it continuously measures, records and analyzes body temperature data to determine the current fertility status.

femSense can be used to determine the fertile and infertile phases of a woman's menstrual cycle, either to support natural family planning methods or to plan a pregnancy. The femSense app communicates with the sensor patch, guides the user through the system and shows the user a calendar view of her fertility during her menstrual cycle. The user can choose which app function they wish to use – Fertility Awareness or Get Pregnant.

- **Get Pregnant mode**: the app gives you information about your cycle, your most fertile days (when you are most likely to get pregnant) and if and when ovulation could be detected.
- **Fertility Awareness mode**: the app gives you a calendar overview of your daily fertility status, shows you the days of high fertility and if and when ovulation could be detected.

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

Intended Use

femSense is intended for fertile women from 16 to 49 years of age who want to track their fertility or plan a pregnancy.

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

Contraindications

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

- Serious, acute or chronic diseases
- Nicotine or alcohol abuse
- Amenorrhea
- Oligomenorrhea (too infrequent menstrual bleeding)
- Polycystic ovary syndrome (PCOS)
- Obesity (BMI > 30)
- Hirsutism
- Known allergy to components of plasters or adhesive
- Medication that can influence your body temperature
- Hormone treatments (e.g. pill, hormone injections, hormon spiral etc.) may affect body temperature

Extreme weight conditions can affect the reliability of femSense. If you are not sure whether femSense is suitable for you, please consult your doctor before beginning use.

Safety Instructions

- The patch should only be worn by those in the specific femSense user group (fertile women between 16 to 49 years of age).
- The patch is a disposable product, use it only once and not longer than 7 days.
- Do not use the patch if you are sick.
- Do not apply the patch on injured skin.
- Do not use the patch if you are allergic to adhesives.
- Do not use the patch if it has been damaged or contaminated.
- Do not attempt to disassemble or open the patch. Do not fold or twist the patch.
- Do not apply successive patches on the same body side.
- Do not use the patch when undergoing an MR or CT examination.
- The patch is a small electronic device and should not be disposed in regular household waste.
- Do not throw the patch into the fire, the battery could explode.
- Keep the patch out of the reach of people with disabilities, children and animals.
- Store the patch in a dry place and protect it from sunlight.
- Do not take extended baths or go swimming while wearing the patch.
- If the patch becomes uncomfortable, please remove it immediately.
- Use the patch only under the specified environmental conditions.
- The patch should not be permanently exposed to an NFC field.
- When applied, the patch can cause local and temporary skin irritations.
- Increased immune system activity (for example due to a vaccination) can promote temporary skin reactions in the patch application areas. Remove the patch immediately if the patch feels uncomfortable.

Usage Informations

- femSense is designed for ovulation detection and does not show temperature curves.
- The patch can only be read via NFC.
- You need the femSense app to be able to use a patch.
- The patch should only be worn as instructed in the app.
- Only one patch can be used per cycle.
- Large cycle length variations can reduce the reliability of femSense.
- The patch must be worn in the correct position under the arm to ensure reliable ovulation determination.
- Do not apply the patch until the app instructs 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. The area can also be cleaned unsing a suitable alcohol pad.
- Do not use deodorants or lotions beforehand.
- When applying the patch, remove the small part of the carrier foil first.
- Do not touch the adhesive side of the patch, this could reduce the overall adhesiveness.
- After applying the patch, smooth it out gently on all sides to fix it in place.
- Do not wear tight bras while wearing the patch as this can cause pressure points and can also affect the reliability of femSense.
- The patch should be read via NFC at least once a day. For best results, it is recommended to read the patch twice everday, once in the morning and once in evening.
- Hold your smartphone as still as possible while activating and reading the patch.
- Remove the patch immediately if it feels uncomfortable or causes skin irritation.
- Avoid high intensity sports or other activities that cause excessive perspiring (sauna/steam/ bath) while wearing the patch.
- Prolonged sunbathing and environments that can significantly affect your surface temperature during use should be avoided.
- Everyday activities such as personal hygiene, work or light physical activity will not affect the patch.

Help

If questions or problems with the product occur, please contact our support:
support@femsense.com or tap "Contact Support" in the femSense app menu.
Go to www.femsense.com/de/faq for more support information.

Download the femSense app

Download on the App Store

App for iPhone 7 and higher

ANDROID APP ON Google Play

Android smartphones with NFC

femSense operating modes

femSense offers two modes of operation,

- **Get Pregnant mode**: for women who are planning a pregnancy.
- **Fertility Awareness mode**: for women who want to track their fertility.

When you register in the femSense app, you must choose one of the two functions. You can change the function in the femSense app menu if you want to use the other mode. Depending on the selected mode of operation, the display of the "Today" screen will differ slightly.

Quick Use Guide

After registering and entering your personal cycle information, femSense will calculate your individual cycle profile and will display your predicted fertile days in the calendar . The "Today" screen will tell you when to apply the femSense patch.

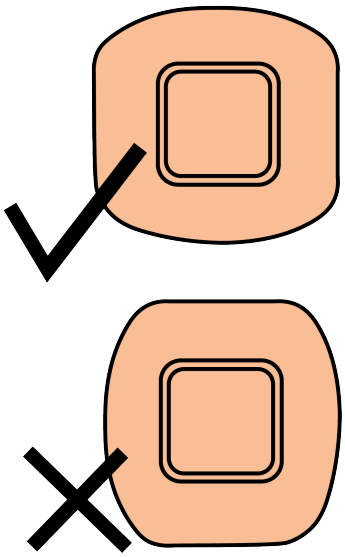
On the day you are instructed by the app to apply the patch, please follow the below steps.

1. Apply Patch

When the femSense app tells you to apply the patch, clean the patch application area. The patch should be applied to clean dry skin, free from any cream or deodorant. The applicaiton area can also be cleaned using an alcohol wipe.

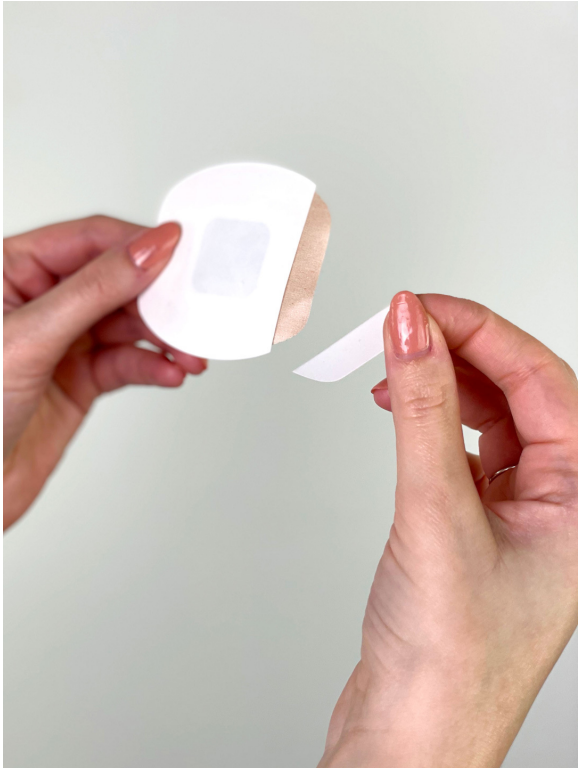
In the femSense product packaging you will find a quick guide on how to apply the patch.

Hint: Please stick the patch so, that the rounded sides point up and down.



Step 1: Find position: Relax your shoulder, place your hand on your hip and place three fingers under your armpit. This will determine the position of the patch, please remember it.

Step 2: Remove small carrier foil: Remove the small part of the carrier foil, so that you can apply the patch in the next steps.



Step 3: Patch-application posture: Now put your hand on your hip and relax your shoulder once again.

Step 4: Attach Patch: Now attach the patch in the previously determined position using the small adhesive side. Make sure that the upper edge of the patch is three fingers below your armpit, between back and breast. Your shoulder should be relaxed and your hand should be on your hip. Then fold the patch over the edge and pull off the remaining part of the carrier fold. Gently smooth out the patch on all sides.

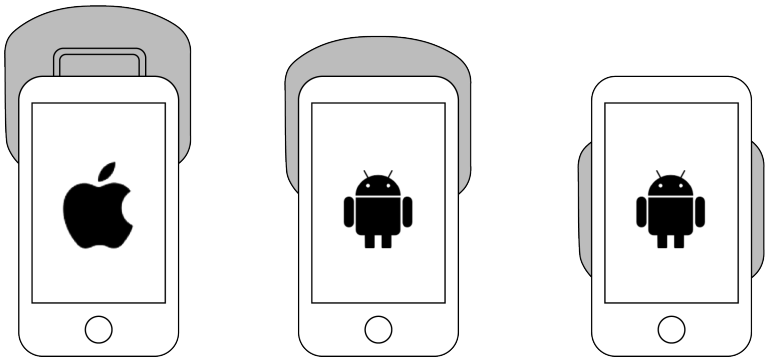
2. Activate Patch

Once you have stuck the patch under your arm, you are ready to activate 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 device manufacturer and operating system (Apple iOS or Android) the smartphone has to be held differently against the patch in order to read it correctly.

- **iPhone:** Hold the top edge of the backside of your phone, at an slight angle, to 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.



3. Read Patch

After the successful activation of the patch, you should read it twice a day to get regular updates on your fertility status and ovulation. To do this, tap on “Today” in the femSense app quick menu at the bottom of the screen, tap on “Read Patch” and hold your phone against the patch as you did when activating the patch. 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 multiple times a day.

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.

In the **Get Pregnant mode**, fertile days are marked with hearts and your predicted and actual period days are highlighted in light and dark pink. Dark pink indicates your entered periods, light pink shows your next period as predicted by the app.

In the **Fertility Awareness mode**, days of high fertility are displayed in pink, if your fertility status cannot be clearly determined by femSense, the days are marked in gray in the calendar. The display of your period days in this mode is identical to the Get Pregnant mode.

If femSense has measured and confirmed your ovulation, the ovulation day is marked with a pink ring. If you tap on a date in the calendar, you will get to the detailed view of that day. By tapping on the (+) button you can enter more details like period, illness or sporting activities. All data entered by you will be treated confidentially and will not be passed on to 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 two 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 "Mode Selection" you can change the operating mode of the app. In addition, under "My Body" there is the option to activate the Pregnancy Mode. In this mode the "Today" screen changes and you get weekly information about how your pregnancy is progressing.

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 installed 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 and Play Store.

Further information

- Terms and Conditions: https://www.femsense.com/de/agb/
- Privacy policy:https://www.femsense.com/de/datenschutz/
- Revocation: https://www.femsense.com/de/widerruf/
- Imprint: https://www.femsense.com/de/impressum

Follow us on social media

Disposal

The patch is powered by a button cell battery. Therefore, it should not be thrown out in the regular household waste but disposed according to the local waste regulations for batteries and electrical goods. The femSense packaging is recyclable and can be disposed in the paper bin.

Technical Specifications

- Type of measuring device: temperature sensor for ovulation detection
- Measurement site: Axilla
- Type of use: Single use product
- Typical application duration: 7 days
- Operating conditions:
    - Environmental temperature: +15 to +42°C (+86 to +107.6°F)
    - Humidity: 15 to 95%
    - Air pressure: 86 to 106 kPA
- Transport- und storage conditions:
    - Environmental temperature: 0 to +40°C (32 to 107.6°F)
    - Humidity: 15 to 95%, non-condensing
    - Air pressure: 86 to 106 kPa
- System requirements:
    - iPhone: iOS 13 or higher on iPhone 7 or newer models
    - Android: Android OS 6.0 Marshmallow or later on an NFC-enabled smartphone
- Internet connection at least 3G or WIFI
- Warranty: 2 years after production
- Dimensions patch: 65 x 60 x 3 mm (2.56 x 2.36 x0.12 in)
- Weight: 3 g (0.11 oz)
- Power source: 3 V lithium button cell battery (not replaceable)
- IP-classification: IPX5: Protection against waterjets from any direction