

# Instruction manual femSense Fertility



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## Symbol description

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Lot number



Manufacturer



Can be used until



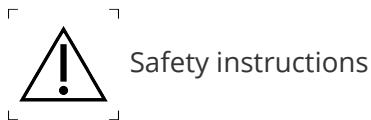
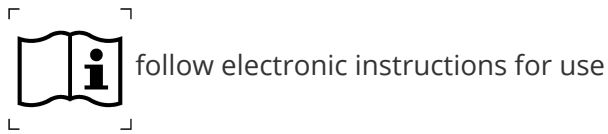
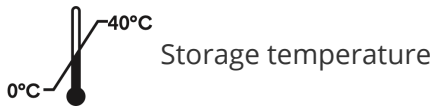
Medical Device



Disposable product



Dispose of in battery compartment



## Instructions for use

Please read the instructions for use and the safety instructions carefully and follow them exactly. Improper use or disposal of the sensor patch may be harmful to health and may post a risk for third parties.

### 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 analysis body temperature data to determine her 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 the menstrual cycle. The user can choose which app function they wish to use – Fertility Awareness or Get Pregnant.

- In the 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.
- In the 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 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?

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femSense is intended for women over 18 and in childbearing age who want to track their fertility or plan a pregnancy



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

## Restrictions

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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 the skin patches
- Medication that can influence your body temperature
- Hormone treatments may affect body temperature

Being very underweight as well as very overweight 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 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 people with disabilities, children and animals.
- 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 use the patch if it has been damaged.
- Do not take long baths or go swimming while wearing the patch.
- Do not apply the patch if the adhesive surface has been contaminated.
- 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.
- Wearing the patch can cause localized skin irritations which should disappear within 24 to 48 hours once the patch has been removed.
- The patch should not be worn by those not in the specific femSense user group (women over 18 of childbearing age)
- The patch should not be permanently exposed to an NFC field.



## How to use femSense

- 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.
- 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 patch should not be worn for more than 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.
- 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 you experience a problem with femSense, a technical defect or side effects, please contact our support: [support@femsense.com](mailto:support@femsense.com) or tap "Contact Support" in the femSense app menu.

Go to [www.femsense.com/de/faq](http://www.femsense.com/de/faq) for more support information.

## Download the femSense app



App for iPhone 7 and higher



Android smartphones with NFC

# femSense operating modes

femSense offers two modes of operation,

- Get Pregnant for women who are planning a pregnancy.
- Fertility Awareness 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.

## Using the patch

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 stick the patch, please follow these steps.



### 1. 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.



On the inside of the femSense product packaging you will find a quick guide showing how to stick the patch correctly.

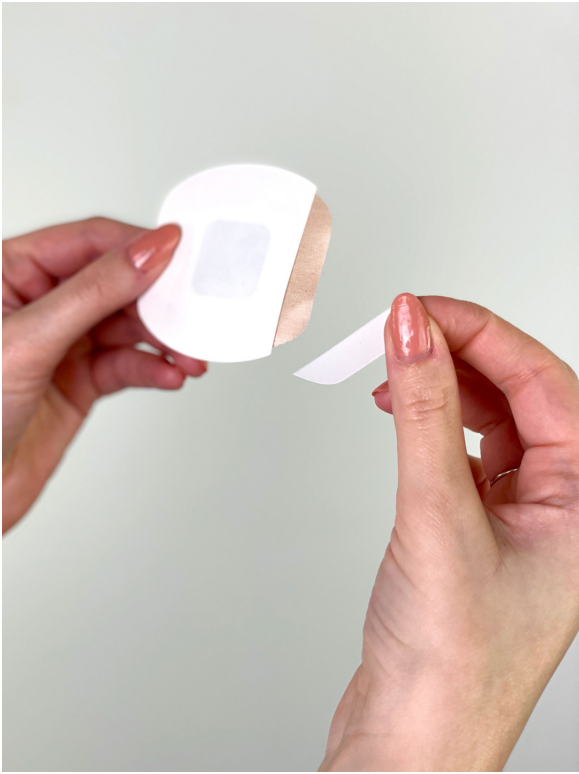


## 2. Applying the patch

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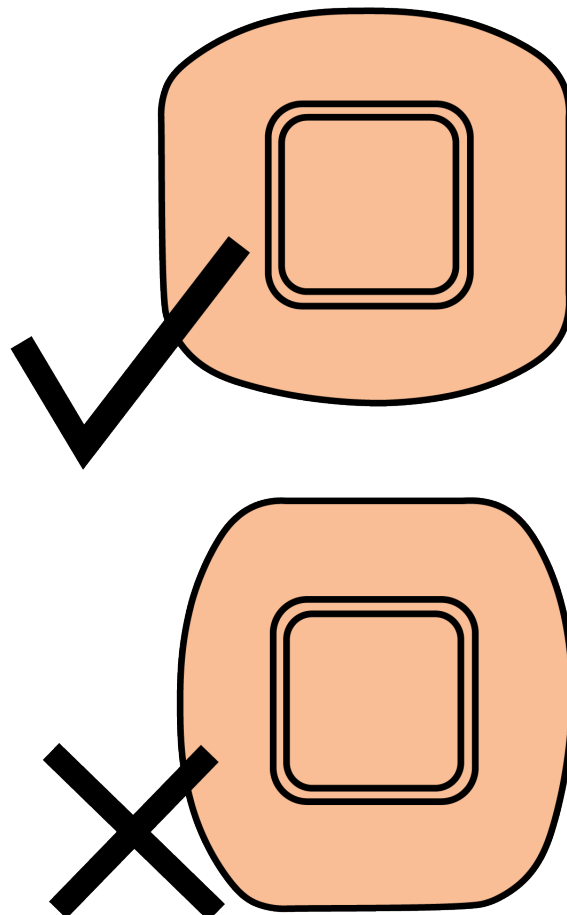
To apply the patch, relax your shoulder, put your hand on your hip and place 3 fingers under your arm to determine the correct position to stick the patch. Then remove the larger part of the adhesive protection foil and hold the patch on the smaller end of the foil. Before attaching the patch put your 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, between back and breast. Please stick the patch so that the rounded edges point up and down. Then pull off the remaining part of the adhesive foil and smooth the patch down gently on all sides.





### 3. Activate Patch

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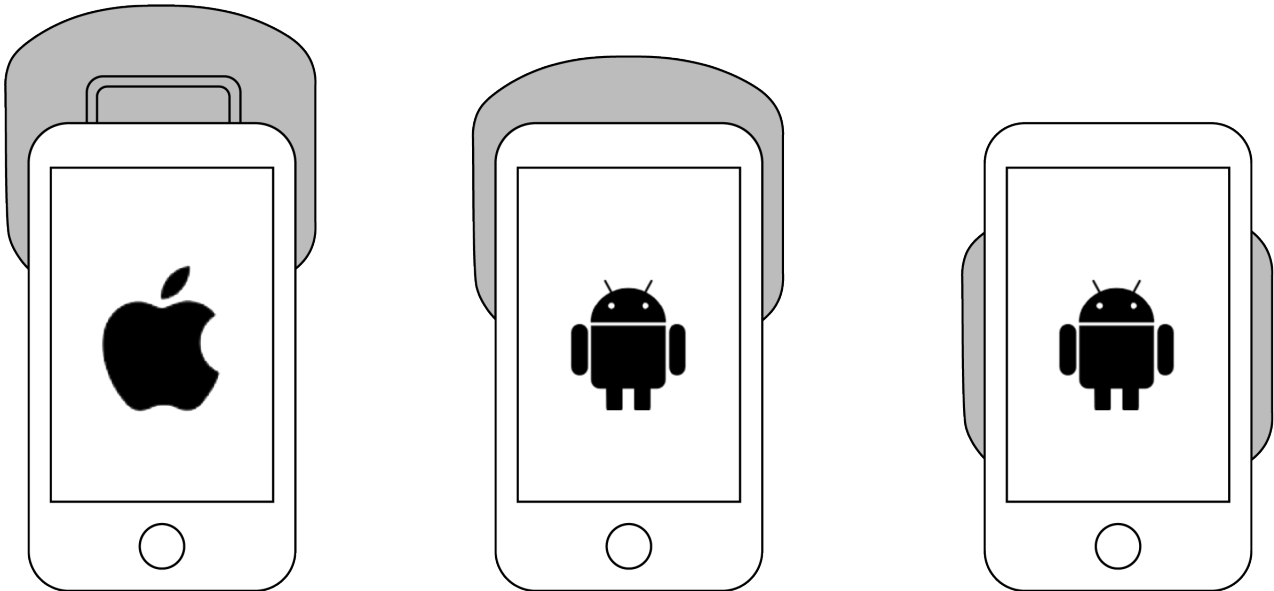
Once you have stuck the patch under your arm, you are ready to start it. Tap on “Read Patch” in the femSense app and hold the back of your smartphone for a few seconds on the center of the patch to activate it. A vibration confirms the successful activation.



#### Position for NFC communication

Depending on your 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 a slight angle, 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.



## 4. Reading the patch

Once you have started 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 starting 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. 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. Your predicted and actual period days are highlighted in light and dark pink.

If femSense has measured and confirmed your ovulation, then 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 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 "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 week by week 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.

## Further information

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- 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

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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.



## Technical Specifications

- Type of measuring device: temperature sensor for ovulation detection
- Measurement location: on the side of the breast under the arm
- Type of use: Single use product
- Typical duration of use: 7 days
- Operating conditions:
  - Environmental temperature: +15 to +42°C
  - Humidity: 15 to 95%, non-condensing
  - Air pressure: 86 to 106 kPa
- Transport- und storage conditions:
  - Environmental temperature: 0 to +40°C
  - Humidity: 15 to 95%, non-condensing
  - Air pressure: 86 to 106 kPa
- System compatibility:
  - iPhone: iOS13 or later 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: 66.3 x 61.2 x 3 mm
- Weight: 3 g
- Power source: 3 V lithium button cell battery
- IP-classification: IPX5 - protection against water jets from any direction