



©SteadySense GmbH,

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Symbol description



Manufacturer



Medical Device



LOT Number



CE certified



Green Dot



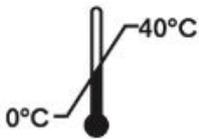
Single use product



Expiration date



Do not dispose in household waste



Storage temperature



NFC required



Information



Safety device



Observe electronic operating instructions

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 femSense app can be used as a period diary without a patch. The user can choose which app function they wish to use – Cycle Tracking 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.
- **Cycle Tracking 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.

Intended user group

The femSense user group are healthy women of fertile age. The Get Pregnant mode is recommended from the age of 18.

The user must be able to read and understand the instructions for use. The user must also be able to follow the instructions of the femSense app and act appropriately. In addition, the user shall be familiar with smartphone applications and able to operate an NFC-enabled smartphone. Existing experience with smartphone applications is recommended but not required to operate femSense properly.

The user should have regular menstrual cycle lengths between 21 and 35 days with a maximum deviation of +/- 3 days.

There are no limitations regarding nationality of the user.

In general, there are no restrictions regarding the weight of a user. However, extreme weight conditions can negatively impact the accuracy of femSense and further cause discomfort, skin irritations, non-detection of ovulation and damage of the sensor. As a guideline, a regular BMI (Body Mass Index) between 18,5 and 30 is recommended to ensure proper functionality.

Data protection

The app only collects data which is absolutely necessary for using the app. The legal data protection requirements are met. The content and the online program are subject to the Austrian Federal Data Protection Act and the General Data Protection Regulation (DSGVO). More detailed information on the processing of personal data can be found in our privacy policy at <https://www.femsense.com/en/data-protection/>.

Contact of the data protection officer:

gdpr@steadysense.at

Tel: +43 316 232 004



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- 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. In the event of reuse, the adhesive strength of the patch is no longer ensured and the patch may become detached. Furthermore, reuse may cause skin irritation due to contamination.
 - 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.
 - femSense does not interfere with other electronic devices. femSense is not affected in normal use.
 - For users with pacemakers: Wear the patch only on the side of the body away from the heart, as the smartphone may interact with the pacemaker. If you are unsure, ask your doctor.
 - femSense may react unpredictably in combination with strong magnetic fields. Please remove the patch before MR or CT examinations.
 - 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.

- A very high BMI (>30) may affect the accuracy of femSense. It may also cause discomfort, skin irritation, non-detection of ovulation and damage to the sensor.

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- 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 using 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.
 - Do not overstretch patch during application as this may cause skin irritation.
 - 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 everyday, 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.
 - After showering, make sure that you dry the patch carefully (dabbing is best) so that the patch does not come off unintentionally.
 - After contact with water (e.g. shower), make sure you pat the patch firmly and allow the patch to dry well.
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Product Shelf life & Package Contents

Sensor patch:

- GTIN (Global Trade Item Number):
 - 1 piece: 09120095900052
 - 3 pieces: 09120095900069
- The patch is supplied in product packs of 1 or 3 patches.
- The patch is a single use product and has a shelf life of 2 years.
- Batch number and expiration date can be found on the bottom of the product package.
- The patch is worn for a period of up to 7 days after application.
- The patch is a microelectronic device and should be disposed off according to local disposal regulations or returned to the manufacturer for recycling. See the **Disposal** section for more information.

femSense app:

- The femSense app is available in the App Store (Apple App Store & Google Play Store) and is updated regularly.
- The femSense app is compatible with all patches distributed in the EU (except Ireland).

Package Contents

- **Patch:** each product package includes one or three patches (for one or three cycles); patches are individually packaged
 - **Quick Guide:** each package contains a Quick Guide. This is to remind you how to use the patch. Using femSense for the first time? Then check out our **instructions** further down.
 - **femSense Fertility app:** the femSense app can be downloaded for free from the App Store. You need it to use the patch.
 - **femSense Instructions for Use:** the electronic instruction manual is available in paper form upon request. Please contact support at support@femsense.com. The instructions for use will be sent to you by mail free of charge within a maximum of seven calendar days.
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Measures for IT Safety

- Choose a secure password when you create an account in the femSense app.
- You can change your password at any time by logging out of the app and clicking "Forgot Password" on the login screen.
- Do not give your smartphone to anyone else if you do not want other people to insight on your femSense app.
- Once you have created your femSense account, all of your data and cycle information is stored in the femSense backend.
 - If you change your phone, you can log in with your existing account sign in and password to access your data.
- If necessary, you can delete your user account in the femSense app menu. This will anonymize your data and it can no longer be associated with you. If you would like to physically delete your data, please contact us via email: support@femsense.com
- Keep the femSense app up to date if possible.

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/en/faq for more support.



App for iPhone 7 and higher



Android smartphones with NFC

femSense offers two modes of operation:

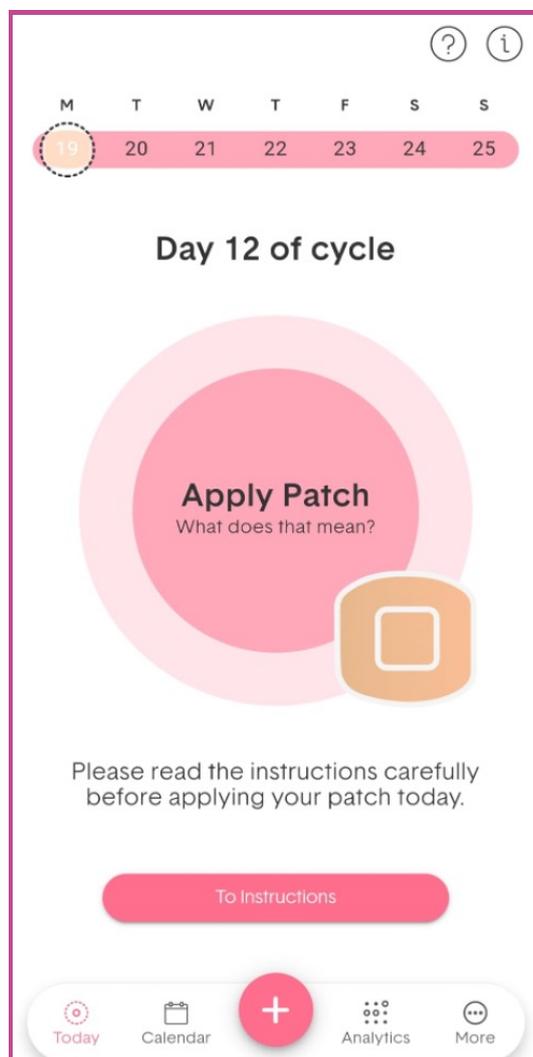
- **Get Pregnant mode:** for women who are planning a pregnancy.
- **Cycle Tracking mode:** for women who want to track their fertility.

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 and the calendar will differ slightly.

Once you have successfully registered and entered your cycle details, femSense can calculate your individual cycle profile and show you in the calendar when you are likely to be most fertile. The "Today" screen tells you when you can apply the patch.



Only apply the patch when the app instructs you to do so. Once you have reached your patch application day (which is marked by a patch symbol in your calendar), you have 48h to apply and activate your patch.



Disclaimer: this screen might vary slightly depending on the selected operating mode

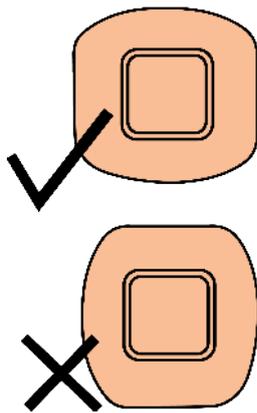
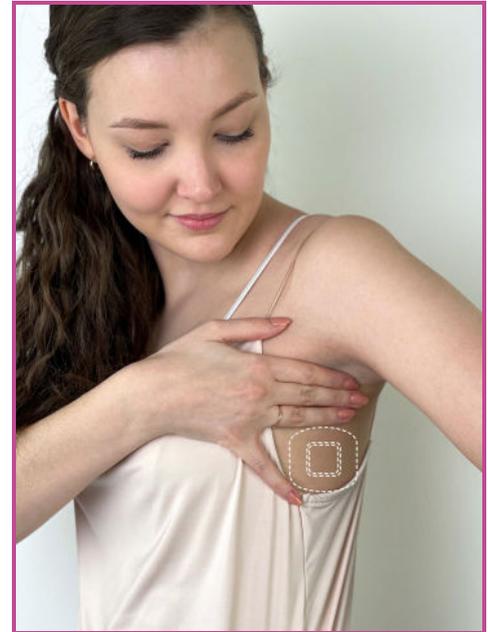
On the day you are instructed by the app to apply the patch, please follow the below steps:

1. Preparation

The patch must be applied on clean, dry skin (without cream/deodorant). It is recommended to apply the patch after showering. The adhesive area can also be cleaned with a suitable alcohol swab. However, make sure your skin is dry before applying. Apply the patch only on intact skin.

2. Find position

The correct position of the patch is important to achieve accurate measurements. Place your hand on your hip and relax your shoulder. The correct position of the patch is three finger widths under the armpit, centered between the back and chest.



Note: Place the patch so that the rounded sides face up and down.

3. Attach patch

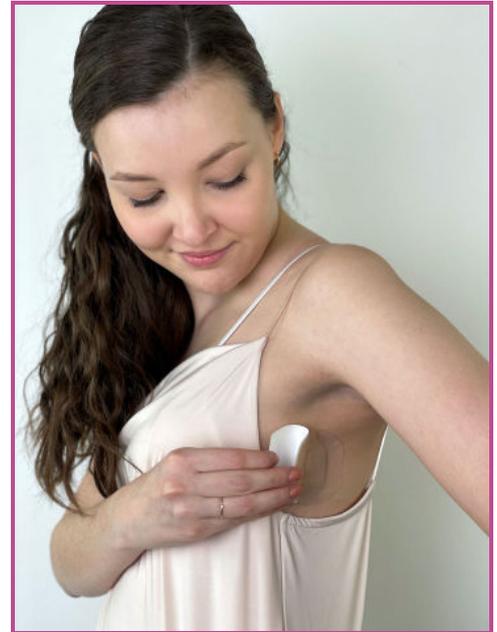
Remove the small part of the backing, make sure you are relaxed, and apply the patch to the previously determined location. Once again, make sure that your shoulder is relaxed and that your skin does not have strong wrinkles here. Then remove the rest of the backing and press the patch firmly on all sides.

4. Activate patch

After you have applied the patch correctly, it can be activated. To do so, tap on "Read patch" in the femSense app and hold the back of your smartphone calmly on the center of the patch for a few seconds to activate it. A vibration will confirm successful activation. Once activated, the patch will continuously measure your temperature.

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.



5. Read out patch

After startup, you should read the patch at least once a day. Twice a day is recommended to get regular updates on whether ovulation has been detected. To do this, go to the "Cycle" screen of the femSense app. Tap on "Read patch" and hold the smartphone on the patch as described in point 4 (Activate patch). Your temperature data will be read from the patch and you will see if ovulation has been detected. You can also read out the patch several times a day.

6. Remove patch

The maximum wearing time of the femSense patch is 7 days. The app will inform you when it is time to remove the patch.

To remove the patch, it is helpful to moisten the patch with warm water to soften the adhesive (e.g. when showering or using a washcloth). Then you can carefully remove the patch.

If the patch feels uncomfortable to wear, or if you feel itching or a burning sensation, please remove the patch.

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.

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.

Change/ delete entry

To change or delete an entry, select the corresponding day in the calendar and then select the specific entry you want to change or delete. Click on the three dots on the right. Here you can select whether you want to change or delete the entry.

If you want to delete all entries for a day, you can do this for all individual entries as described above. Or scroll down to the bottom of the respective day and click on "Delete all entries".

Please be aware that changing or deleting entries is permanent, they cannot be restored.



Explanation of symbols



Period (predicted) – For these days your period is predicted.



Periode (entered) – You had your period on these days.



Ovulation – The femSense patch detected your ovulation on this day.



Next Patch – Day, on which you can apply your next patch.



Applied Patch – You have applied a patch on this day.



Missed Patch – You have not applied a patch within the application window of this cycle.

D Low Fertility – Your fertility is low.



High Fertility – Your fertility is high. Unprotected intercourse might lead to a pregnancy.



Fertility uncertain – Your fertility is uncertain, when no patch was used or no ovulation could be detected.



Today – This cycle represents today.



Entry – On this day you have entered additional entries.

In the analytics screen 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.

Exclude cycle

In the "Analytics" screen, you also have the option to exclude cycles from the cycle calculation. Exceptionally long or short cycles can, for example, distort the cycle calculation and thus the calculation of your patch application day. If such cycles are "outliers", you can exclude them from the cycle calculation. The reasons for such atypical cycles can be different: illness, pregnancy, miscarriage, emergency contraception or abortion, for example.

To do this, select the relevant cycle under "Analytics" and open it (by clicking on the arrow on the right). At the bottom you will find the option "Exclude cycle from analysis". If you have inadvertently excluded a cycle, you can easily undo this in the same way.

Under "More" you will find the menu of the femSense app. This is divided into several areas where you can manage your account and find additional functions and information.

At the top under "**Mode selection** " you can choose between the two operating modes.

Under "**My account** " you can view your account data, log out, change your password or delete your account.

Under "**My Body**" you can view and edit your user data. You also have the option of activating the app's pregnancy mode. In this mode, the "Today" screen changes and you receive information about your pregnancy progress.

Under "**Settings** " you can switch between the metric and Anglo-American measurement systems, change your region and activate or deactivate notifications.

Under "**Help & Support** " you will find the instructions for use as well as explanatory videos and tutorials for the femSense app. The "FAQs" button takes you to the frequently asked questions. By tapping on "Support team", you can contact technical support if you have any problems.

Under "**Legal matters** " you will find the privacy policy, the terms and conditions and the legal notice. You can also view the version of your femSense app here.

If the femSense app displays an error message, please take a screenshot. If you are not able to solve the problem on your own, please contact our support team with the screenshot directly in the app via "Contact support" or via email to support@femsense.com.

In order to be able to correct errors as quickly as possible, you can find the most common error messages here:

- "**READ_FAILED** Read failed, please try again. If this issue persists, please contact support."
- "**ACTIVATION_FAILED** The activation process failed, please try again. If this issue persists, please contact support."
- "**NFC_NOT_ENABLED_ANDROID** The NFC function on this device is disabled. Click OK to activate NFC in the settings."
- "**NFC_NOT_AVAILABLE_ANDROID** Your device does not support NFC. You cannot read femSense patches with this device."
- "**NFC_TAG_UNSUPPORTED** This patch is not compatible with the femSense app. Please contact support. Do not throw away your patch or its packaging."
- "**DID_INVALIDATE_WITH_ERROR** The read-out failed, please try again. Try holding your phone at a different angle or closer to the patch. If this issue persists, please contact support."
- "**PatchSwError** A unexpected software error occurred on your patch, please take off the patch but do not dispose of it. Contact support. Do not use another patch."
- "**PatchBatteryLow** The battery of your patch is empty, please take off the patch but do not dispose of it. Contact support. Do not use another patch."

Further information

- Terms and Conditions: <https://www.femsense.com/en/agb/>
- Privacy policy: <https://www.femsense.com/en/data-protection/>
- Revocation: <https://www.femsense.com/en/right-of-cancellation/>
- Imprint: <https://www.femsense.com/en/imprint/>

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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 +40°C (+86 to +104°F)
 - Humidity: 15 to 95%
 - Air pressure: 86 to 106 kPa
- Transport- und storage conditions:
 - Environmental temperature: 0 to +40°C (32 to 104°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 x 0.12 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
- UDI-DI App Store (iOS): 09120095900137
- UDI-DI Play Store (Android): 09120095900144



Guidance and manufacturer's declaration - electromagnetic emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Emission test	Frequency Range	Compliance	Compliance Level
EN 55011B/ EN 55032B RF Interference field	30-1000 MHz	Class B	PASS

Guidance and manufacturer's declaration - electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity Test	IEC 60601-1 test level	Compliance level	NOTE
EN 61000-4-2: Electrostatic discharge	Contact discharge: ± 8 kV	not applicable	Contact discharge is to be applied according to EN 61000-4-2 due to conducting surfaces of the DUT
	Coupler plate: ± 8 kV	PASS	-
	Air discharge: ± 2 kV ± 4 kV ± 8 kV ± 15 kV	PASS	-
EN 61000-4-3: Electromagnetic fields	10 V/m 80MHz to 2,7 GHz	PASS	-
EN 61000-4-8: Magnetic fields	-	not applicable	Device is not sensitive against power frequency magnetic fields. It has no magnetic field sensitive components.