

User Manual

Please read the user manual before using the Ovy App.

Note

The Ovy App is a stand-alone application designed for determining fertile and infertile days within the menstrual cycle based on data. The Ovy App and Ovy products are for women who want to have children, for women who want to prevent pregnancy naturally and for women who simply want to get to know their bodies.

The Ovy App is a Class I medical device. The Ovy App is not a certified method of birth control!

Intended Use

The Ovy App is for women of reproductive age (18–45 years) and can be used with the Ovy Bluetooth Basal Thermometer. The Ovy App algorithm is based on Natural Family Planning (NFP) or the symptothermal method when used in "Prevent pregnancy" mode.

The Ovy App is suitable for:

- Women of reproductive age.
- · Women who want to avoid hormonal birth control.
- Women with a desire to have children.
- Women who want to develop an awareness of their body.
- Women who want to learn more about the natural processes of the menstrual cycle.
- Women who are diligent in recording their data daily in order to calculate their fertile/infertile days as accurately as possible.
- · Women who want to calculate their ovulation, fertile window and next period.
- · Women who own and use the Ovy Bluetooth Basal Thermometer

The Ovy App is <u>not</u> suitable for:

- Women for whom pregnancy poses a health risk. Just like the pill and other methods of birth control, Ovy **cannot** prevent pregnancy with one hundred percent certainty.
- Women under 18 years of age.
- Women who have irregular cycles, since it is difficult to determine the fertile and infertile days in this case.
- Women who have an irregular lifestyle and therefore cannot guarantee that they will document their body signals daily.

Important Information

- When using "Prevent pregnancy" mode, you must use an additional method of birth control, such as a condom, on the fertile days, or avoid sexual intercourse entirely.
- Using the Ovy App does not protect you from STDs (sexually transmitted diseases).
 Use a condom in order to protect yourself.



- If you use emergency birth control (e.g. the morning after pill), this may cause irregularities in the cycle that affect the calculation of fertile and infertile days. You can record what you have taken under "medication" in the Ovy App.
- If your period is more than a week overdue after using emergency birth control, you should perform a pregnancy test or consult a doctor directly.
- The Ovy App is not a substitute for medical diagnosis and treatment, is provided for information purposes only and is not intended to encourage self-diagnosis or self-treatment. Please always consult a doctor if you have health problems.

Pricing Ovy App

Certain features of the Ovy App will become part of Ovy Premium. These functions will then be marked with a small lock and are available by signing up for an annual (34,99 €) or monthly (3,99) subscription. The annual or monthly subscriptions start with 30-day free trial period. In this period, the subscription can be cancelled at any time and no costs will be incurred.

A basic version of the Ovy App is still available for free. Customers of the Ovy Bluetooth Basal Thermometer get Ovy Premium free for 12 months.

Getting started with the Ovy App

To ensure you use the Ovy App safely, it is important to master the method used or learn it as you go. Learning the respective categories is especially important when observing body signals.

To use the Ovy App you need a basal thermometer that measures to two decimal places accurate to within 0.05°C. The measurement time should ideally be 3 minutes.

During the night, the core body temperature drops to its minimum level. This is known as the basal body temperature. The basal body temperature is an important indicator for calculating your ovulation. It is important to measure your basal body temperature orally, vaginally or rectally in the morning immediately before getting up. You should sleep for at least four hours before taking the measurement. Try to measure in the morning at the same time every day. Within each cycle we recommend using the same measurement location. Use the Ovy Bluetooth Basal Thermometer to transfer the temperature directly.

Ideally, you should start using the Ovy App on the first day of your period, which is the first day of your cycle. It can be started on any day of your cycle, however. Start by downloading the Ovy App from the Apple or Google Play Store After registration, the Ovy App will ask for relevant data in order to calculate your first cycle. Select "register" and start the setup process. You will be asked for the following information:

Email address and password:

It is not strictly necessary to enter an active email address. However, this is recommended in order to receive news from time to time or to reset your password. After you have agreed to the terms and conditions and the data protection declaration, you will see the "registration" section

1. Cycle objective

Select the mode based on your planned usage behavior and objective. The display within the app will change depending on the mode you select.



The following two modes are available:

<u>Prevent pregnancy</u> (in accordance with the NFP method)

Select this mode if you wish to evaluate your cycle according to the Natural Family Planning (NFP) method and prevent pregnancy without hormones. Depending on your data, the Ovy App will divide your cycle into fertile and infertile days. The NFP method assumes you are fertile until sufficient data is available to prove otherwise. In addition to your period and basal body temperature, your cervical mucus and cervix are relevant for the calculation. There is no forecast, but rather a daily calculation which is updated daily. There is no possibility to fall back on a different evaluation method, e.g. the temperature method, if insufficient data is available. Ovulation test results are not taken into account here.

<u>Get pregnant</u>

If you are trying to conceive, you should select Get pregnant. The Ovy App divides your chance of getting pregnant into three categories: low, medium and high. Your fertile window of six days is marked in green, and the expected day of ovulation will also lie within this window. This will allow you to know in advance when you should have sexual intercourse in order to fertilize your egg.

If there is not enough data about your cycle to use the symptothermal method, the Ovy algorithm will fall back on the temperature method to perform the calculation. If there are not enough temperature readings either, the calendar method will be used. Please note that the calculation may be adjusted retroactively based on the data you enter. Your cycle and day of ovulation are calculated based on a self-learning algorithm which takes other factors into account such as sperm survival time. If you have a positive ovulation test, enter the test result into the Ovy App. From then on, ovulation will be expected within the next 48 hours.

2. Hormonal Birth Control

This information is important because separate rules apply to the first cycle after stopping the pill. If you are using hormonal birth control, you can use the Ovy App as a period tracker and to document your body signals. Hormones suppress ovulation, which is why the app does not report a fertile phase in the app.

Start and end date of your last period:

The Ovy App needs this information to calculate the first day of your current cycle. If you don't know the date, you can click on "don't know" and add the data later. Please note that the view in the Ovy App will remain gray in accordance with this. In order to use the full functionality of the Ovy App, you need to enter the first and last day of your most recent period or document the first day of your next period as soon as it occurs. You always start a new cycle by entering a new period. If you stop taking hormone-based contraceptives, you may initially experience what is known as withdrawal bleeding. Documenting your cycle does not begin with withdrawal bleeding, however, but by adding weak, medium or heavy bleeding as a body signal listed under "period".

Average cycle length:

The average cycle length is relevant for women who want to have children, as the Ovy App calculates the end of the cycle. If you don't know the average length of your cycle, click on "don't know". In this case, a mean value of 28 days is assumed, which will later be adjusted based on your newly documented cycle lengths.



Pairing the Bluetooth Basal Thermometer:

If you own an Ovy or Beurer Bluetooth Basal Thermometer, you can start the pairing process here or do it later.

3. Starting a new cycle

The blue plus (+) below your cycle will take you to the body signals overview. Select "period" and whether it is strong, medium or weak. As soon as you have confirmed the entry, a new cycle begins. A minimum length of 16 days per cycle is required.

Use the Ovy App daily:

4. Daily data collection

Use the plus (+) to view the body signals overview. It is important that you measure and document your basal body temperature daily. Note that you have to exclude temperatures that occur after temperature interferences. To evaluate using the symptothermal method, the Ovy App needs another symptom: Cervical mucus or cervix. When calculating the cycle (NFP), missing data can mean that no evaluation can take place. On these days, fertility must be assumed.

5. Calculating the cycle using the Ovy App

The cycle calculations used in the Ovy App vary between the three modes. The cycle can be divided into the following four phases: The period, the infertile phase before ovulation (follicular phase), the fertile phase including possible ovulation (ovulation) and the infertile phase following ovulation (luteal phase).

In "Prevent pregnancy" mode, the Ovy App calculates according to the NFP method as follows:

- The first 5 days of a new cycle are considered infertile if a first high temperature (FHT) occurred in the previous cycle. As soon as mucus of category f, S or S+ is identified or the cervix (partially opened, fully opened, soft) is observed, the infertile period ends at the beginning of the cycle (see 5-day rule).
- As soon as 12 evaluable cycles are available, which all have a first high measurement (FHT), the Ovy App will use the earliest of all higher measurements as the basis for the calculation. Eight days are deducted from this value to determine the last infertile day at the beginning of the cycle (see minus-8 rule). This rule overrides the 5-day rule in cases of doubt. If the beginning of the fertile phase is earlier than day 6 due to the 8-day rule, and within the first 12 cycles, the 8-day rule is applied immediately and not after 12 months.
- If the Ovy App has 12 cycle lengths recorded, the shortest cycle is determined and 20 days are deducted from the shortest cycle to determine the last infertile day at the beginning of the cycle. Here too, as soon as cervical mucus or a "moist" sensation occurs, fertility must be assumed (see minus-20 rule). The minus-20 rule is also overridden by the minus-8 rule, which in turn is overridden by the 5-day rule.

The Ovy App applies the following rules to calculate the infertile phase at the end of the cycle, if sufficient data is available:



- The infertile phase in the second half of the cycle begins on the following day after all temperature rules and all cervical mucus or cervix rules have been applied. The individual body signals (temperature and cervical mucus / temperature and cervix) double-check each other. If, for example, the temperature is affected by temperature interferences once on several consecutive days, the infertile period nevertheless only begins once the cervical mucus or cervix rules are met.
- Rules for evaluating the basal body temperature: Ovulation has occurred as soon as three consecutive readings are higher than the highest reading of the previous six days. The third of the three higher measured values must be at least 0.2°C higher. The highest value of the six low temperatures is shown by a guide line in the cycle graphs.
- First exception rule for temperature: If the third elevated temperature value is less than 0.2°C higher than the highest value of the six previous temperatures before the elevation, you must wait until a fourth temperature has been recorded. This fourth value must be above the guideline, but it is no longer necessary for it to be higher by 0.2°C.
- Second exception rule for temperature: During the three higher measurements a value may fall on or below the guideline. This value is then excluded and not taken into consideration. In this case a total of four measurements are also necessary. The two exception rules may not be combined.
- Temperature interferences: Whether temperature values are excluded is decided based on the individual.

There are no fixed factors that must always be excluded by default. However, there is a list of factors in the app including alcohol, lack of sleep etc. that can potentially influence your temperature. Don't forget to select "exclude temperature" for the temperature in question, should you want to. The temperature appears in the graph and is depicted by an empty dot. If temperatures are missing, this is not serious provided there are sufficient values on the other days of the cycle to complete the NFP evaluation.

- Rules for evaluating cervical mucus: The infertile cervical mucus phase begins when one day with the best cervical mucus quality for the individual is followed by three days with poorer quality mucus. One of these days can be left empty.
- Special rule 1: If the quality of the cervical mucus improves again within the 3 days with poorer cervical mucus quality, the search for the cervical mucus quality peak must restart.
- Special rule 2: If the individual best cervical mucus quality f is found again after the rules for cervical mucus control have been applied, but before all temperature rules have been followed, then the cervical mucus must be analyzed again.
- Rule for evaluating the cervix: The cervix rule is fulfilled when a soft and open cervix is followed by three days on which it is hard and closed.

There is one more special case for evaluating both infertile phases. If you used hormonal birth control in the previous month (e.g. the pill), select "No, but in the last cycle" during the setup process or "No" in your profile. This activates "post-pill mode". The Ovy App needs an additional temperature value at this point, which must be above the guideline. It is not necessary for this temperature to be 0.2°C above the line. In Post-Pill Mode, the first 5 days are also assumed to be infertile. After no longer taking the pill, users will experience their first cycle with strong, medium or weak bleeding.

The symptothermal method has a Pearl index of 0.4–1.8. This means that for every 100 women who use this form of birth control for a year, one woman on average will unintentionally become

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pregnant. The Pearl index for the pill is 0.1–0.9, meaning that less than 1 person in 100 women can be expected to become pregnant unintentionally.

6. General Information

The Ovy App supports smartphones with Android 6.0/Lollipop (or above) or iOS 11.2 (or above) and requires a stable internet connection. We publish relevant updates at regular intervals to improve the user experience and calculations. The Ovy App is available in 7 languages: German, English, Spanish, French, Dutch, Italian and Turkish.

7. Data Protection

We use your health data to calculate your menstrual cycle and to provide you with personalized content relevant to your cycle phase in the Ovy Care area. We do not share your data, and are also distancing ourselves from even entertaining the possibility of health data from cycle apps being shared on social networks. All development and data storage for the Ovy App takes place in Germany. The way in which we use your data to calculate your cycle is described in detail in our privacy policy.

8. Deleting your account

If you want to stop using the Ovy App and delete your data, you can do so via your account. If you do not delete your data, it will be deleted automatically after 5 years (see deletion periods in Ovy GmbH's data protection concept) at <u>www.ovyapp.com</u>).

9. Relevant Literature

Concerning the temperature method, natural family planning and cycle calculation, the following clinical studies were evaluated:

- Baur, Siegfried: Scientific Principles of Natural Family Planning in: Imago Hominis, Volume 17, Issue 4, p. 275; Institute for Medical Anthropology and Bioethics, Vienna 2010
- Frank-Herrmann, Petra: Family Planning Individual, Global and Ethical Aspects. 2000 IEEF/EIFLE Conference "Natural Family Planning: Future Role and Developments" in cooperation with CAMEN and with the contribution of the University of Milan, 28th June-2nd July 2000, in: Abstracts, p. 47.
- Frank-Herrmann, Petra; Sottong, Ursula; Freundl, Günter; Strowitzky, Thomas: Natural Family Planning, Springer Verlag, Berlin/Heidelberg/New York 2010, Special Edition.
- Freundl, Günter; Sivin, Irving; Batár, István.: State-of-the-art of non-hormonal methods of contraception: IV. Natural Family Planning, in: The European Journal of Contraception and Reproductive Health Care, April 2010, 15:113-123.
- Freundl, Günter; Freundl-Schütt, T.: Family planning: Natural and without using hormones, in: Extracta gynaecologica (2009), Issue 2, p. 34-44.
- Freundl, Günter: Natural Methods of Family Planning. Fertility Control Update and Trends. T. Rabe, B. Runnebaum (published), Springer Verlag, Berlin/Heidelberg/New York 1999.
- Freundl, Günter; Frank-Herrmann, Petra; Raith-Paula, Elisabeth: Natural Family Planning, in: The Gynecologist (1998), Vol. 31, p. 398-409. Freundl, Günter: Natural Family Planning, in: Archives of Gynecology and Obstetrics (1995), Vol. 257, No. 1-4, p. 525-529.
- Freundl, Günter: Present stage of knowledge of reproductive biology concerning natural family planning, in: GENIUS (1998), Vol. LIV, n. 3-4, p. 57-74.
- Rabe, Thomas (published): Seminar Book of Gynecological Endocrinology Chapter on Natural Methods, published by Thomas Rabe, Heidelberg 2012.
- Sottong, Ursula; Schulze-Hobeling, Hubert: Family Planning Aspects of a Natural Method. Gaining Life. Central Pastoral Office of the German Bishops' Conference, Section. Marriage and Family (published), 1996, in: Working aids booklet 56, p. 26-30.
- Sottong, Ursula: NFP in Europe. Presentation at the Guangzhou Conference, Canton, China, 06/26/2005.
- Sottong, Ursula; Klann-Heinen, Petra: NFP Online Counselling. Fertility and Family life in a changing world, anthropological and medical aspects. 2004 European Conference 24-26 June 2004, VMU Kaunas, in: Kaunas Conference Report 2004, p. 12.
- Sottong, Ursula: "Natural family planning with Sensiplan" (The Midwife 2015; 28:288-293).
- Frank-Herrmann, Petra; Baur, S.; Freundl, Günter; Gnoth C.; Rabe, T.; Strowitzky, Thomas: "Natural Family Planning Current Status", (Springer Verlag, Gynäkologe 2015; 48:657-666).



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