

# Natural Cycles

## Instructions for use

### What is Natural Cycles?

Natural Cycles is a stand-alone software intended to be used for contraception and fertility monitoring. It informs a woman whether and when she can become pregnant.

Women who are using Natural Cycles for contraception must either abstain from intercourse or use another form of protection (e.g. barrier contraceptive such as condom) on days that are indicated as red (fertile).

### Precautions

Please read this manual before you start using Natural Cycles. Additional information can be found on [www.naturalcycles.com](http://www.naturalcycles.com).

- You must be over 18 years old to use Natural Cycles
- Natural Cycles does not protect against sexually transmitted infections (STIs) in any way.
- Natural Cycles informs you whether and when you can become pregnant. Abstention or protection (e.g. condoms) are required on red days to prevent pregnancies.
- As a contraceptive, Natural Cycles may be less suitable if you experience irregular menstrual cycles as predicting your fertile days becomes more difficult and you will get an increased number of red days. For contraception, it is ideally used by women with fairly regular and ovulatory menstrual cycles.

### Checklist

To get started with Natural Cycles you will need the following:

#### **1. A Natural Cycles account**

You can access Natural Cycles via your web browser, by visiting [www.naturalcycles.com](http://www.naturalcycles.com). For access via the app, download the app on your Android, iPhone or iPad on Google Play or the App Store. Follow the registration steps to create your personal account. Make sure to be connected to the internet on the device that you use for accessing Natural Cycles. Your account on Natural Cycles is personal and should not be used by anyone except you.

#### **2. A Basal thermometer**

To get started you will need a basal thermometer, it is more sensitive than a regular fever thermometer as it shows two decimals. The range of how much your temperature changes is quite small, so for you to get the most out of Natural Cycles and receive more green days you will need the correct thermometer. If you sign up to the Natural Cycles Annual subscription a thermometer is included or visit our webshop at [shop.naturalcycles.com](http://shop.naturalcycles.com) to purchase one.

### 3. Ovulation tests (optional)

Ovulation (LH) tests are optional but can help detect ovulation. These are simple urine tests you only need to take on a few days of your cycle. Results may increase the number of green days if you are preventing a pregnancy, but they are not critical for the app to work. We particularly recommend taking the when you are planning a pregnancy as they will help pinpoint your ovulation Purchase ovulation (LH) tests in our Webshop under [shop.naturalcycles.com](http://shop.naturalcycles.com).

## How it works

Your daily morning routine:

- Measure your temperature first thing in the morning after you wake up, before getting up and out of bed.
- Add your reading and additional data to your account
- Check your status for the day. You will get a green or a red day depending on whether you need to use protection. Read more about your status for the day, fertility and whether to use protection (condom) on the next pages.

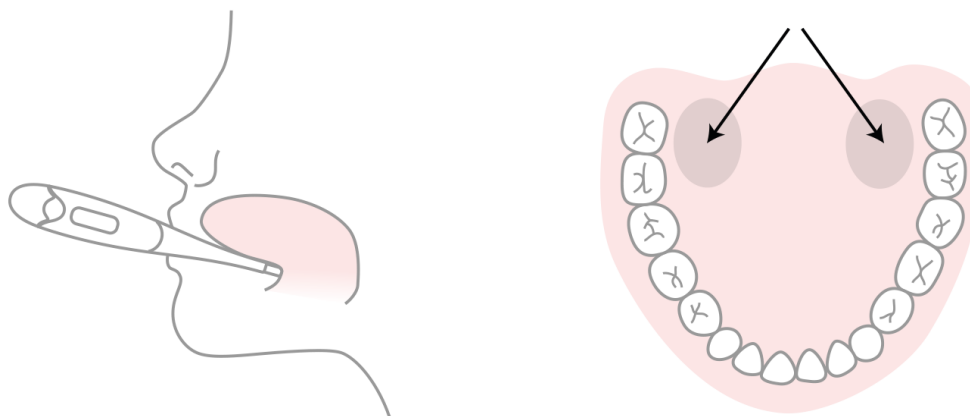
⚠ When you start using Natural Cycles, it will take Natural Cycles a couple of weeks to get to know your unique cycle. Which can result in an increased amount of red days in the beginning (1-3 cycles). It is to ensure effectiveness, but once the app has detected your ovulation you are likely to receive more green days.

## Measuring your temperature

### How to measure

Follow these steps when measuring your temperature:

1. Place the thermometer in your mouth and under your tongue, as far back as possible, next to the tongue root as depicted in the diagrams below.



2. Only press the on button once the thermometer is in your mouth and in place.
3. Try to keep still when measuring, close your mouth to keep any cool air out and breath through your nose.
4. Wait until it beeps (approx. 30 seconds).
5. Once you have your reading, add the temperature into the app.

You can use the calibration tool in your 'Profile' page of the app to check if you are measuring correctly. The thermometer will save your reading, so you can check your reading once again later. To do this press the on button once, the saved reading will appear for a few seconds before the temperature resets. A tip to remember to measure; place the thermometer on top of your phone before going to bed.

## **When to measure**

Measure your temperature once a day only, but as many days as possible - it will lead to better results. Aim for at least 5 times per week.

- ⚠ Measure first thing in the morning when you wake up, before you get up and out of bed. Measure at roughly the same time and after a similar amount of sleep (+/- 2 hours). Only measure your temperature on the days these requirements are met.
- ⚠ If you are not using the thermometer provided by Natural Cycles, please make sure to record your temperature with a commercially available basal thermometer that displays the temperature with  $\pm 0.01$  degrees (i.e. displays 2 decimal places) and has a sensitivity and accuracy of  $\pm 0.10$  degrees.
- ⚠ Check your fertility status each day after you have measured your basal temperature directly when waking up and entered it into Natural Cycles. Do not enter measurements of your temperature that you have taken later during the day.

## **When not to measure**

Certain circumstances may affect your basal temperature and could result in inaccurate detection of ovulation and false display of green days. Under these circumstances either do not measure your temperature that day - then tap 'Skip today' - or mark the entry as a 'Deviating temp' in the add data view. This way the measurement will not be used in the algorithm's calculation.

- ⚠ If you are subject to the following conditions, please do not record your temperature for the day by either not measuring your temperature that day - then tap 'Skip today' - or mark the entry as a 'Deviating temp' in the add data view:

irregular sleep (+/- 2 hours than normal), insomnia, use of medication that may affect your body temperature, extensively consumed alcohol and feel hungover, are taking drugs, have already had sex that morning, did extensive amounts of sport the evening before, have an infection or feel sick, are experiencing extreme stress, work under excessive strain or pressure, are traveling or have shifted sleeping hours in the previous 24 hours.

## Application overview

Your fertility status for the day is shown through different views within the app.

### Today's view

On this screen you will get all of the info you need at one glance. A screen to enter your temperature pops up automatically when you open up your app in the morning and once you've entered your reading you receive a green or a red day. On a red day, you should use protection. Tap the '+' to add data such as your temperature, period or LH tests. You can go into the app and update your temperature or data at any time.

### Calendar view

Tap the "Month" tab in the calendar view to access the monthly view. Here you can see your predicted red and green days for the month, these may change over time and should not be used as the end result. You can see when your ovulation and period is coming up and easily access your past data by tapping on any given day. The days on which you have entered data are marked with a 'tick'.

### History view

The "History" tab is a log of all the data that you've previously entered. Scroll up and down to view your temperature readings and cycle days as well as an extraction of your notes displayed in grey below.

### Graph view

Access the view by tapping the graph icon in 'Today's view'. The graph is a visualisation of your temperature curve. Watch it develop as you continue to measure throughout your cycle. Swipe left or right to view graphs of your past cycle and tap '3 cycles' or '9 cycles' to compare them to each other. You can see logged sex on top of the graph and your period, fertile days and ovulation are indicated by colours.

### Statistics view

This view will give you an overview of how you're your cycle statistics and how your average cycle looks as a graph. You will see your cycle length, regularity and a detailed analysis of the three phases of your menstrual cycle - the follicular, luteal and ovulatory phases. The average statistics of all women using Natural Cycles is displayed below yours for comparison. Your Cycle begins on cycle Day 1 (CD1) with the first day of your period and ends when your next period begins.

### Profile page

This page allows you to see and change your personal settings and subscription plan as well as see the achievements that you have received. Achievements help you keep track on your journey as a Cyclor.

### Messages

These are gentle reminders and useful info we send you, so you can get the very most out of your Natural Cycles experience. Messages are tailored to your unique cycle and are only sent if they are relevant for you. Learn more about your body, enjoy knowing when your period is coming up and more. You can also contribute to research in women's health by answering one of our research questions. This just takes just a couple of seconds and with your support we can continue to drive studies within the fields of contraception, reproduction and fertility.

## Reminders

You can optionally set 'Reminders' in Natural Cycles, to guide you in your usage. Do so by pressing the bell icon in the top left hand corner within the app. Note that you must enable Natural Cycles to send you push notifications in your device settings to receive these.

Examples of possible reminders:

- Reminder to measure: set a reminder for the night before or in the morning to remember to measure your temperature.
- Period: A reminder to indicate that your next cycle is about to begin.
- First red day: indicates the first day in your cycle you need to 'use protection'.
- Take an LH test: indicates to take an ovulation (LH) test, which is optional.
- PMS: informs you when you can expect PMS symptoms.
- Breast self-exam: suggests to do a breast self-examination at the best point of your cycle.

## Add data to your account

Once you have your reading, add the temperature into the app. The view to add data will automatically open up or press the '+' icon in top right hand corner. You can also add additional data, such as your period or the result from an ovulation (LH) test. Once you save today's data, the app will calculate your status for the day. A 'green day' means that you cannot get pregnant as you are not fertile. A 'red day' means that you should use protection in order to prevent a pregnancy. You can go into the app and update your temperature or data at any time.

⚠ Make sure to always enter the temperature with the two decimals indicated by your basal thermometer, in order to get an accurate result.

## Contraception: Prevent a pregnancy

Your status for the day is displayed in red or green colours.



### Not fertile

On green days, you cannot get pregnant as you are not fertile. Green days are indicated by a green outlined circle.



### Use protection

On red days, you are very likely to be fertile and at risk of becoming pregnant. Use protection (condom) or abstain in order to prevent a pregnancy. Red days are indicated by a red outlined circle.

The app will pinpoint and indicate your ovulation (symbol of an egg) as well as when you have entered and are expected to have your period (symbol of a blood drop). The application also shows predictions for upcoming days in the Calendar View. The predictions may change and should not be used as the final result, which is why you should check your status for the day - every day.

⚠ The predictions for upcoming days are only a prediction and may change in the future. Make sure to always check the colour of today.

- ⚠ Always make sure to update your software app, so that you have the latest version.  
The default setting on phones is that apps will be updated automatically.

## When to use protection

You can have sex without protection on a green day. You cannot get pregnant as you are not fertile. On red days, you will need to use protection in order to prevent a pregnancy (e.g. condom). The app will indicate when you need to use protection by displaying a red day. What type of protection you choose to use on red days, influences the relative effectiveness and depends on the method's Pearl Index.

- ⚠ The risk of getting pregnant is significantly higher on red days as you are very likely to be fertile.

## Effectiveness

Data on the use of Natural Cycles has been collected from 22,785 women who used the app for an average of 9.8 months. This data was analysed to determine how often Natural Cycles failed as a contraceptive method, meaning that users got pregnant when they were not planning to become pregnant. There are three commonly used ways to calculate the effectiveness of contraceptive methods:

The app has a method failure rate of 0.5%, which is a measurement of how often the app incorrectly displays a green day when the woman is actually fertile, and she gets pregnant after having unprotected intercourse on this green day. This means that 5 out of 1,000 women who use the app for one year will become pregnant due to this type of failure.

The app has a perfect use failure rate of 1.0, which means that 10 out of 1000 women who use the app for one year and who become pregnant will do so either because:

- a. They had unprotected intercourse on a green day that was falsely attributed as non-fertile (i.e., method failure); or
- b. They had protected intercourse on a red day, but the chosen method of contraception failed.

The app has a typical use failure rate of 6.8, which means that in total 68 women out of 1000 get pregnant during one year of use due to all possible reasons (e.g. wrong attributed green days, having unprotected intercourse on red days and failure of the contraceptive method used on red days).

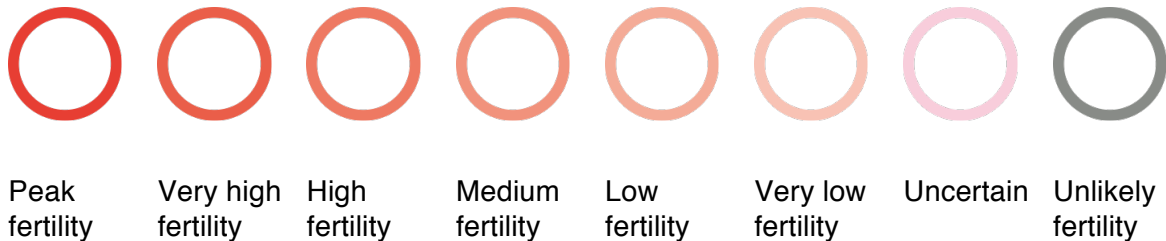
These failure rates are within the range for other contraceptive methods, which have been reported as 1.4% for long-acting contraceptives such as the IUD and implanted hormone release devices, 4% for injected hormones, 7.2% for the oral contraceptive (the "pill"), 12.6% for condoms, and 20% for the withdrawal method.<sup>1</sup>

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<sup>1</sup> Sundaram A, Vaughan B, Kost K, Bantolo A, Finer L, Singh S. Contraceptive Failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth. Perspectives on Sexual and Reproductive Health 2017; 49(1):7-16.

## Planning a pregnancy

If you use the application for planning a pregnancy—you select this either when setting up your personal experience or in the settings—you will see more detailed information on your fertility. In this mode your fertility is displayed as a scale so you easily can identify the days you are most likely to become pregnant.



If your period is overdue and your temperature does not seem to drop, we will encourage to take a pregnancy test to confirm the pregnancy.

## Monitor your pregnancy

Once pregnant, the app will turn into a pregnancy monitor and follow the development of you and your baby. Make sure to continue measuring your temperature throughout your pregnancy as it may provide you and your healthcare professional(s) with useful information.

## Taking an LH test

On some days, Natural Cycles will ask you to take a LH test (ovulation test) to increase the accuracy of detecting ovulation. These are optional to take. When you're planning a pregnancy, we strongly recommend taking ovulation tests since the occurrence of LH coincides with your most fertile days.

## Platform description

**App Version:** 2.9.x and onwards

**Medical Device version:** A

**Intended use:** Natural Cycles is a stand-alone software intended to be used for contraception and fertility monitoring. It informs a woman whether and when she can become pregnant.

**Significant performance characteristics:** Estimation of fertility status, display of fertility status.

## Indications / Contraindications

**Indications:** For healthy women from 18-45 years old to monitor their fertility to plan or prevent a pregnancy.

**Contraindications:** Natural Cycles is not recommended to use by you if:

- You have a medical condition that implies that becoming pregnant could be dangerous (such as problems related to high blood pressure or heart disease).

- There could be a potential health risk to the foetus if you become pregnant (such as addiction problems or intake of medication known to cause birth defects).
- You are experiencing symptoms of menopause or taking hormonal treatments or hormonal contraception that affects ovulation. If you are using Natural Cycles for contraception, you may only get red days. You can however use Natural Cycles for fertility monitoring purposes.

## Additional Warnings

- ⚠ If you chose to have sexual intercourse, Natural Cycles can in no way physically prevent a pregnancy, or protect against sexually transmitted diseases or infections. Natural Cycles informs you whether and when you can become pregnant.
- ⚠ If you are breastfeeding, you will only get red days until you ovulate again. You may use Natural Cycles while breastfeeding to keep track of when you start ovulating again.
- ⚠ You may experience irregular cycles after discontinuing hormonal contraception, which can lead to an increased amount of red days. If you are currently on hormonal contraception, Natural Cycles will not work as it inhibits ovulation. You can however use the app in demo mode and switch to the normal mode once you have come off it.
- ⚠ If using emergency contraception, you should refrain from measuring until your regular period has shown up, as the additional hormones will affect your body temperature. You shall also protect yourself with a barrier method until your next period starts before continuing with the Natural Cycles. Note that the bleeding you experience after taking emergency contraceptives is not the equivalent to your regular period.
- ⚠ Any other medical conditions such as multiple ovulations, PCOS or thyroid-related conditions can lead to irregular cycles and/or fluctuating temperatures which result in an increased amount of red days.

## Alarms

- If you enter a temperature that is biologically unreasonable high or low, a message will inform you immediately to correct the entered temperature.
- When the predicted ovulation day is approaching, you can be recommended you to take an ovulation test.
- If the Natural Cycles application cannot access the internet, thereby being unable to edit or access data, a message will be displayed.
- If the Natural Cycles application predicts that you have become pregnant, a message will inform you and recommend you to take a pregnancy test to confirm this prediction.
- If you enter sex without protection on a red day in the Natural Cycles application, it displays a cautionary message.



## Accessories

For official accessories from Natural Cycles, please visit [shop.naturalcycles.com](https://shop.naturalcycles.com).

- **Basal Thermometer:** Required. Natural Cycles can be used with any Basal Thermometer. If you are not using the thermometer provided by Natural Cycles, please make sure to record your temperature with a commercially available basal thermometer that displays the temperature with  $\pm 0.01$  degrees resolution (i.e. displays 2 decimal places) and has a sensitivity and accuracy of  $\pm 0.10$  degrees.
- **LH-Test:** Optional but recommended if you are planning a pregnancy. Ovulation test, which detects Luteinizing Hormone (LH) surges in urine, which can predict ovulation. If you are not using an LH test that is provided by Natural Cycles, use a clinically approved test and only enter Ovulation when the test is indicating a surge in LH.
- **Pregnancy tests:** Optional test, which detects hCG (Human Chorionic Gonadotropin) in urine, which can be detected after conception. If you are not using a pregnancy test that is provided by Natural Cycles, use a CE marked test.

Devices to access the Natural Cycles App, at least one of the following two is required:

**Mobile phone:** Android OS (4.4+) or iOS (iOS7+)

**Computer / Internet browser:** Microsoft Edge (12 and higher) or later versions of Firefox, Google Chrome or Apple Safari.

## General information

### Explanation of symbols



Manufacturer

CE 0123 CE Mark



Caution



Consult Instructions for Use



You must be above the age of 18 years

### EC DECLARATION OF CONFORMITY

**Name of the Manufacturer:**

NaturalCycles Nordic AB

**Address of the Manufacturer:**

Luntmakargatan 26,  
111 37 Stockholm,  
Sweden

**Customer support:**

[support@naturalcycles.com](mailto:support@naturalcycles.com)

**Device type:**

Internet based standalone software intended to monitor woman's fertility

**Name:**

Natural Cycles

We declare that this product meets all applicable requirements of the Directive 93/42/EEC for medical devices (MDD) and bears the mark CE0123.

**Date of publication:**

November 2017

**Document version:**

2.5

CE 0123