# Fertile Window User Manual

### **About This User Manual**

This user manual is applicable for Fertile Window version 1.1 or greater.

This user manual is available in the following languages: Danish, English, Finnish, French, German, Italian, Japanese, Latvian, Norwe gian, Polish, Spanish, and Swedish.

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#### Warning

**Do not use as contraception.** The Fertile Window feature has been designed and developed specifically as an aid in conceiving a pregnancy, and not as a tool to help prevent pregnancy. Using the Fertile Window feature counter to its indications can result in pregnancy. Subtle shifts in your data can change your fertility status, and conception is possible outside of your predicted Fertile Window.

If you are interested in contraception options, see Oura's website for information about our partnership with Natural Cycles, which offers FDA-cleared digital contraception powered by the Oura Ring.

### Precautions

Only limited data are available for cycles that are shorter than 21 days or longer than 35 days. Data are also limited for cycles that vary by more than 7 days in length. This might result in incomplete or inaccurate predictions for users with shorter or longer cycle lengths, or cycles with higher variation in length over time.

Only limited data are available for use in cases of diagnosed or clinical infertility. This might result in incomplete or inaccurate predictions for users with these conditions.

The following circumstances may affect your physiology, and could result in an inaccurate fertility status: irregular cycles, breastfeeding, irregular sleep, working night shifts, insomnia, use of temperature-affecting medications, use of alcohol, extensive smoking, recreational drug use, sickness, infections, extreme physical or mental stress, and traveling through different time zones.

# **Product Description**

Fertile Window is for Oura Ring users with menstrual cycles. It helps users estimate the days in their cycle when they're most likely to conceive, so they can plan ahead. Fertile Window also helps users follow and understand their menstrual cycles by providing future predictions and historical data.

## **Indications For Use**

The Fertile Window is intended to interpret physiological parameters as an aid in ovulation prediction to facilitate conception.

The Fertile Window is intended for use as a personal fertility monitoring tool. It has been developed to aid individuals in understanding and tracking their fertility patterns to help them plan to conceive a pregnancy.

The Fertile Window is not intended for use as contraception.

# Intended Purpose (EU Region)

The Fertile Window is intended to interpret physiological parameters as an aid in ovulation prediction to facilitate conception (not to be used for contraception).

## **Target Population And Intended Users**

The intended user group is adults with menstrual cycles. The Fertile Window is not intended for the pediatric population (<18 years of age).

#### Contraindications

- Do not use Fertile Window as contraception. Fertile Window can only be used as an aid in conceiving a pregnancy and cannot be used to prevent pregnancy.
- The Fertile Window is not intended:
  - for the pediatric population (<18 years of age)
  - for people who don't have a natural temperature variance in their menstrual cycle due to conditions like fertility treatments, hormonal contraception, hormone replacement therapy, or any drugs, medication, or hormones that impact natural temperature variation

#### Side Effects

Fertile Window has no known direct side effects.

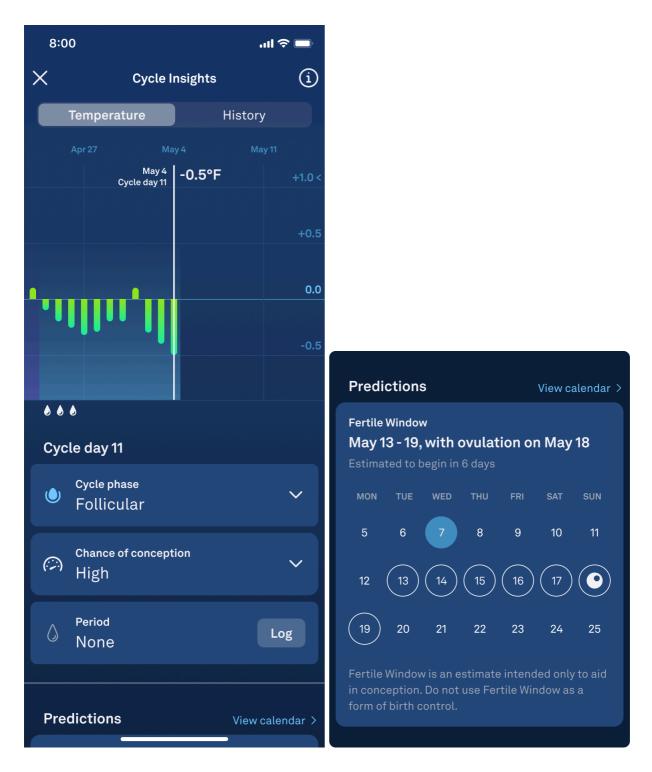
#### **Using The Fertile Window**

Fertile Window is available to Oura members with an Oura Ring Generation 3 or later. For region availability, please visit Feature Availability.

Please follow these steps to use the Fertile Window software:

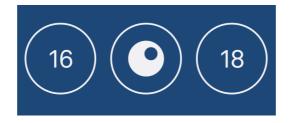
- 1. Update your Oura App to the latest available version.
  - This will help keep your app safe from cybersecurity threats and vulnerabilities. Oura recommends that you set your smartphone to update the Oura App automatically
  - For iOS, open "App Store" from your phone, search for the Oura App and select to update, if an update is available

- For Android, open "Play Store" from your phone, search for the Oura App and select to update, if an update is available
- 2. Enter Cycle Insights
  - Upon launching the Oura App, navigate to the Cycle Insights feature
  - From there, scroll to the "Predictions" section



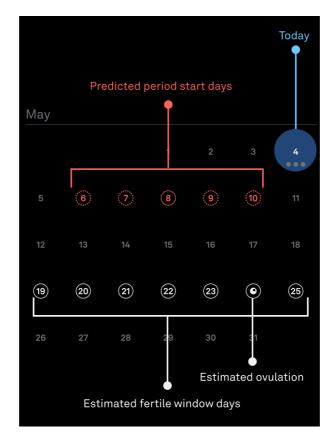
3. Determining Your Fertile Window:

- In the Predictions section, you will notice certain days circled in white, indicating your estimated Fertile Window
- The Fertile Window spans from 5 days before ovulation, to 1 day after ovulation. It represents the days in which you're most likely to conceive during your current cycle
- Your Fertile Window estimate is based on physiological data captured by the software, and information you provide about your cycle. Remember to log each day of your period to keep your predictions accurate and up-to-date. If you don't have a period during a cycle, wait until the end of your luteal phase when your temperature drops, and log a period with "no flow." The ovulation and Fertile Window cannot be predicted if periods are not logged accurately
- In the Predictions section, you will also see one day highlighted in light blue. This indicates today's date
- 4. Your Estimated Ovulation Day
  - Within your estimated fertile window, one day will be marked with a solid, white icon of an egg. This is your estimated ovulation day



# Seeing All Future Predictions In Your Calendar

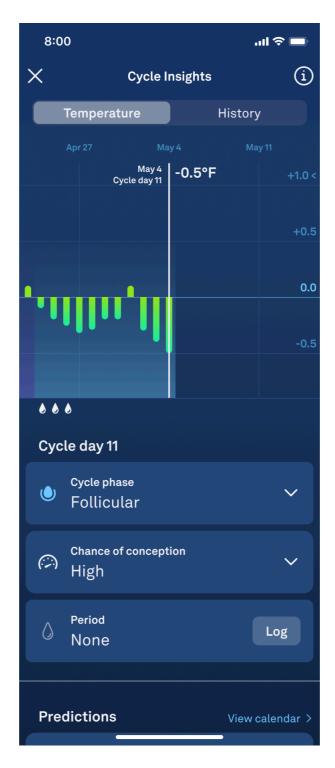
- The Predictions section will only show one predicted cycle event at a time—either your estimated Fertile Window or your next expected period
- If you'd like to see all your upcoming predictions at once, tap the blue "View calendar" button
- Once in your Calendar, you can see your estimated Fertile Window, ovulation day, and upcoming period all in the same place
- The days within your estimated Fertile Window will be marked with white circles. Your estimated ovulation day will be marked with a solid white icon of an egg
- The days circled in red represent the range of days in which your period is estimated to begin
- The day highlighted in light blue indicates today's date



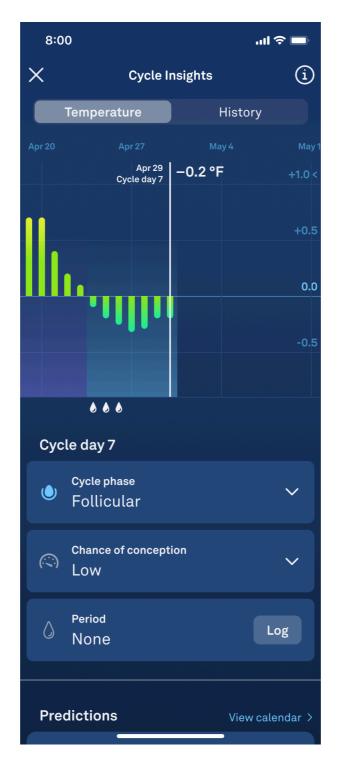
# Your Fertile Window And The Daily Temperature Graph

Before Ovulation Is Detected:

- Before ovulation is detected, Oura creates estimates for your ovulation day and Fertile Window. Your Fertile Window spans from 5 days before you ovulate to 1 day after
- Your Daily Temperature graph shows you how your temperature rises and falls each day compared to your baseline throughout your cycle
- On days when you're in your Estimated Fertile Window, your "Chance of conception" will be marked as "High," accompanied by an icon of a meter with a high reading

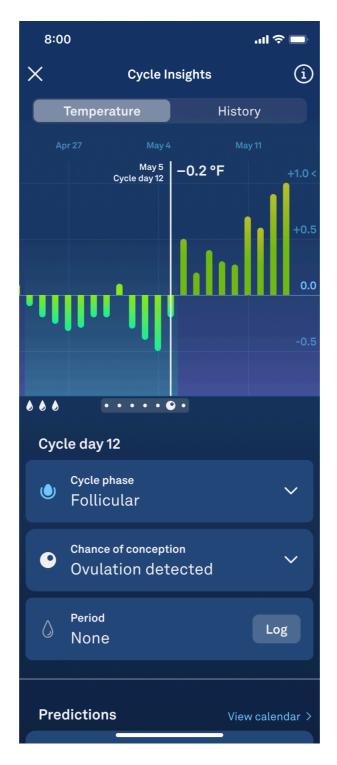


- When you're outside your estimated Fertile Window, your "Chance of conception" will be marked as "Low," next to an icon of a meter with a low reading
- Please note that your estimates can change. Cycle Insights will update to reflect these changes, but your estimates should not be used as a form of birth control.



After Ovulation Is Detected:

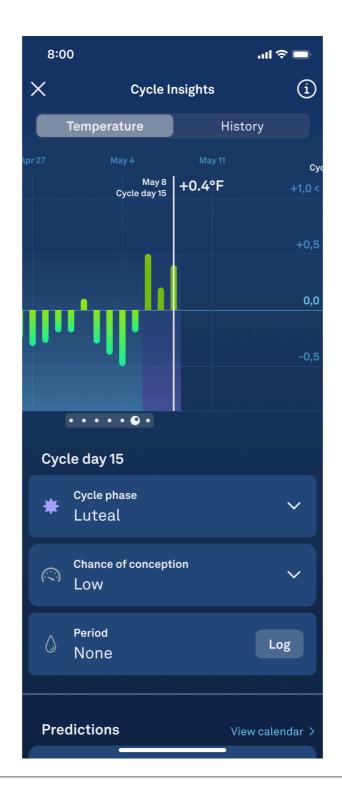
- Oura observes your physiology for at least two days before confirming ovulation, as many factors can cause a rise in basal body temperature
- Once ovulation has been detected, your confirmed ovulation day will be marked on the bottom of your temperature graph with a solid white icon of an egg
- In addition, your "Chance of conception" will be marked as "Ovulation detected."



- After ovulation has been detected, your Fertile Window will shift from "estimated" to "confirmed," and the dates of your Fertile Window will be set for the remainder of your cycle
- When you scroll back through previous days in your cycle, your confirmed Fertile Window days will be represented by a dot icon beneath the temperature line on your Daily Temperature graph, and the span of your fertile window will be highlighted with a white background
- In addition, you will find "Chance of conception" marked as "High" for these days, next to an icon of a meter with a high reading

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- After ovulation has been detected, days outside of your Fertile Window will have no accompanying icon on your Daily Temperature graph.
- In addition, your "Chance of conception" will be marked as "Low," next to an icon of a meter with a low reading



## Support

If you cannot access the Fertile Window feature or if you suspect a malfunction, please follow the steps below:

- Familiarize yourself with the instructions in this manual
- Contact the Oura Member Care Team

#### **Incident Reporting**

Serious incidents involving Fertile Window should be reported both to Oura and to the competent authority in your country. A "serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat

# Accessing The Instructions For Use

For comprehensive instructions and information about Fertile Window, you can access this manual through the Education View at any time.

Navigate to the Education View by tapping the ① icon in the top right corner of the software interface. Then select "User Manual."

If you would like a paper copy of the User Manual, Oura will send you one, free of charge. Contact the Oura Member Care team. Paper instructions for use are provided within seven calendar days of receiving the request.

# Performance specifications

Fertile Window can predict fertile days in a regular cycle with an accuracy of 70% or higher. The software can forecast ovulation up to 6 days in advance, with a Mean Absolute Error of up to 3 days.

# Symbols

CE CE Mark

Manufacturer

Release date





MD Medical Device

UDI Unique Device Identifier

LOT SW version

# **Manufacturer**



**Oura Health Oy** Elektroniikkatie 10 90590 Oulu Finland

# Version and date of this manual

FD-LDS2 version 6 12/2024

# **Unique Device Identifier**

The Unique Device Identifier (UDI) of Fertile Window is comprised of the UDI-DI (Global Trade Item Number) and the UDI-PI (software version).

UDI-DI for Fertile Window iOS: (01)06430060159990

UDI-DI for Fertile Window Android: (01)06430060159983

# **Historical Versions**