Natural Cycles - Cycle Tracking

User Manual / Instructions for Use

Please read this manual before you start using the Cycle Tracking.

Indications for Use

The Cycle Tracking in Samsung Health is an over-the-counter (OTC) software-only, mobile software application intended to be used for period and cycle tracking.

Intended Target Population

The intended target group is women of reproductive age. The pediatric population <18 years of age is excluded from the target group. The user shall be capable of reading the IFU document and operating the Samsung Health application.

Intended Use Environment

The device is intended for use in non-medical settings.

Contraindications

The Cycle Tracking is not intended to be used for contraception.

Side-Effects

The product has no known direct side effects on the human body.

Warnings

⚠ Do not use fertility information given in the app as a form of birth control.

⚠ Do not use data from the Cycle Tracking to diagnose health conditions, including using the skin temperature data to diagnose fever.

⚠ The user is not intended to interpret or take clinical action based on the app output without consultation of a qualified healthcare professional.

Precautions

● If you are currently taking hormonal birth control or undergoing hormonal treatment that inhibits ovulation, this product will not be useful for tracking ovulation.

Checklist

To get started with the Cycle Tracking, you will need the following:

1. **An Android smartphone (Android O (8.0) or later) with latest Samsung Health app**

You can access Cycle Tracking via Samsung Health app on Android smartphone. The Samsung Health app can be downloaded through the Google Play Store or Samsung Galaxy Store. To use Samsung Health, a Samsung account is required.

2. **Samsung Galaxy Watch5 (optional)**

The Cycle Tracking is available on Galaxy Watch5 and above for skin temperature measurement.

Platform description

Cycle Tracking Version: 1.0.0.002 and above

Devices that may be used to access the Cycle Tracking via the Samsung Health Application (version 6.23.5 and above):
- Android Smartphones: Android OS version 8.0 and above, 250 kbps or faster internet
- Samsung Galaxy Watch 5: Wear OS 3.5 and above

Using Cycle Tracking

Onboarding

1. Select Samsung Health app.
2. Select Cycle Tracking from the home tab.
3. Enter necessary data (last period date, average period duration, average cycle length).

Check your cycle status
1. You can check your cycle status and predictions on both smartphone and watch.
2. You can manually enter cycle-related information via both smartphone and watch.
3. You can delete your cycle-related data via smartphone only.

Skin temperature measurement
1. Make sure that your Watch is connected to your smartphone.
2. Turn on the skin temperature function from the Cycle Tracking.
3. Wear the watch overnight.
   - Suggested wearing guide:
     - 4 hours during sleep
     - 5 times per week

Safety and Performance

The ability to detect ovulation and predict the upcoming period with the Samsung Watch was evaluated in a clinical study involving 56 subjects recording 98 cycles. Study subjects were instructed to wear the Samsung Watch during the night, measure their temperature orally with a thermometer in the morning and take urine-based ovulation (LH) tests prior to the predicted ovulation day. The ovulation day determined by the Watch data was compared with that by the LH test. It showed that the mean absolute difference was within 3 days. The mean absolute difference between the period start predictions and the actual period start was found to be less than 3 days.

Problems/Troubleshooting

If you experience difficulties in operating the Cycle Tracking, refer to the troubleshooting guide below.

Problem: You are unable to find the 'skin temperature during sleep' function in the Cycle Tracking App on Galaxy Watch.
Solution : Check that your Galaxy Watch is a Galaxy Watch5 model that supports the skin temperature during sleep. If your Galaxy Watch is a Watch5 model, make sure it is upgraded to the latest Maintenance Release using the Galaxy Wearable application. Also make sure the Samsung Health app is the latest version.

Problem: You are wearing the watch at night but do not see the skin temperature measurement in the app.
Solution: If the quality of the measured temperature data is too low, or there are less than 3 hours of data available, the data will be discarded and will not be visible in the app. Make sure your watch fits snugly on your wrist while you sleep. Also make sure your battery is charged before you sleep, and keep your watch on for at least 4 hours.

Problem: You are measuring according to the instruction but your ovulation was not confirmed
Solution: Ovulation is detected based on your temperature data. If your temperatures fluctuate significantly along the cycle, it becomes more difficult to detect ovulation. Make sure you wear the Watch correctly and measure according to our guidelines. Temperatures can also be affected by factors such as illness, traveling, medications, and disruptions to your daily routine.

Problem: Your predicted and confirmed ovulation dates don't match.
Solution: The prediction for your upcoming ovulation day is based on your historical data, such as when your ovulation usually occurs and how much this varies from cycle to cycle. Since every cycle is unique, you may ovulate on a day that is different from the predicted one. Once ovulation has actually occurred, your most likely ovulation day will be determined based on your temperature data.

For other problems and questions, please contact the Samsung Customer Support team and our trained support agents will assist you.

Accessing the Instructions for Use

The Instructions for Use can be found within the Cycle Tracking under the 'About cycle tracking' page or online on the Natural Cycles website.
If you would like a paper copy of the Instructions for Use we will send you one at no cost. Contact customer support with your request.

Security

It is strongly recommended that you choose a strong password for your phone to protect your account from unauthorized use. While not recommended, if you choose to share your login with somebody, you do so at your own risk. Keep in mind that you can always revoke access by changing the password to your account.

If you would like to delete your account, please contact Samsung customer support at https://help.content.samsung.com/ .

Please refer to the Samsung Privacy policy for further information on security and data privacy.

General information

Explanation of symbols

	Manufacturer
	CE Mark
	Caution
	User Manual/Instructions for Use
MD	Medical Device

EC Declaration of Conformity

Name of the Manufacturer:
NaturalCycles Nordic AB

Address of the Manufacturer:
St Eriksgatan 63b
112 34 Stockholm
Sweden

Customer support:
https://help.content.samsung.com/

Device Name:
Cycle Tracking

We declare that this product meets all applicable requirements of the Regulation (EU) 2017/745 for medical devices (MDR) and bears the mark CE.

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V1.1

Version History

VER.	DATE	DESCRIPTION	
1.0	2022-11-28	Initial Release	-
1.1	2022-02-20	Minor updates to Platform Description section- Cycle Tracker, Samsung Health, Samsung Galaxy Watch 5 OS supported versions	The IFU is being updated to align with updates to the minimum version of Cycle Tracker, Samsung Health, Samsung Galaxy Watch 5 OS. The changes in the IFU will have no added impact on the product or on the QMS as a whole. No changes to indications for use, warnings or precautions.

Document Approval

	NAME	FUNCTION	DATE	SIGNATURE
AUTHOR	Megan Callanan	Regulatory & Compliance Manager		
REVIEW & APPROVAL	Raoul Scherwitzl	CEO		
REVIEW & APPROVAL	Jack Pearson	Head of Medical Affairs		
REVIEW & APPROVAL	Eleonora Benhar Noccioli	Head of Science and Data		
RELEASE	Megan Callanan	Regulatory & Compliance Manager		