

ENGLISH (EN)

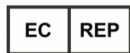
This Instructions for Use is applicable only to the following regions: United States, EU/EEA, Switzerland, United Kingdom.

Cycle Tracking Version 4.X

Instructions for Use



Apple Inc.
One Apple Park Way
Cupertino, CA 95014
www.apple.com



Apple Distribution International
Hollyhill Industrial Estate,
Hollyhill, Cork,
Ireland
Contact: medicalcompliance@group.apple.com



SWITZERLAND COUNTRY SPECIFIC INFORMATION:

CH-REP:

QUNIQUE GmbH
Bahnhofweg 17
5610 Wohlen
Switzerland

INDICATIONS FOR USE/INTENDED USE (US & EU REGIONS)

Cycle Tracking is a software-only application intended to track and predict menstrual cycles, including ovulation, in order to inform users about their menstrual health and to facilitate conception (not to be used for contraception). Cycle Tracking analyzes user inputs including typical cycle length, typical period length, menstrual flow, and ovulation test results, along with aggregates of sedentary heart rate and wrist temperature.

CONTRAINDICATION

Cycle Tracking is not indicated for contraceptive use.

USING CYCLE TRACKING

Set-Up/Onboarding

- For region availability and device compatibility for Cycle Tracking, please visit <https://support.apple.com/en-us/HT210407>
- Update Apple Watch and iPhone to the latest OS.
- On your iPhone, open the Health app and tap the Browse tab.
- Navigate to “Cycle Tracking.”
- Tap “Get Started” and follow the onscreen instructions.
- You may exit onboarding at any time by tapping “Cancel.”
- Once onboarding is completed, you can start tracking your cycle.

How to track your cycle

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Swipe to the correct date, then tap the oval to log your period.
- To add more information, scroll down and tap a category, make a change, then tap Done. You can track symptoms, spotting, basal body temperature, and more.

To track your cycle from your Apple Watch, open Cycle Tracking, swipe to the correct date, then tap the oval to log your period.

How to check the date for your next and last period

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Scroll to Highlights to see when your next period is likely to start. If you don't see the estimate, tap Show All next to Highlights.
- Scroll to Summary to see the date your last menstrual period started and your typical cycle length.

To check the dates from your Apple Watch, open Cycle Tracking, then scroll down to Period Prediction or Last Menstrual Period.

How to set up notifications for period tracking and fertility tracking

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Scroll down and tap Options.
- Select Period Predictions and Period Notifications. These notifications can let you know when your period is about to start and ask if your period has ended.
- Select Cycle Deviation Detection. These notifications can let you know when your cycle history shows a pattern that's not clinically expected.
- Select Fertile Window Estimates and Fertility Notifications. These notifications can let you know when your fertile window is likely to start or has been updated based on new information, as well as provide a retrospective estimate of when you ovulated.

Period predictions can begin after you have entered at least two periods in Cycle Tracking and are based on logged data. If you log a period before it's predicted to begin, you won't get a notification that your period is about to start for that cycle. Notifications appear on your Apple Watch and iPhone.

How to delete Cycle Tracking on Apple Watch

You can remove Cycle Tracking directly from the Home screen of your Apple Watch:

- On your Apple Watch, go to the Home Screen.
- If you are in Grid View, touch and hold Cycle Tracking lightly until it jiggles.
- Tap on the app, then tap the "x" icon.
- If you are in List View, swipe left on Cycle Tracking and tap the Trash icon.
- Tap Delete.
- Press the Digital Crown to finish.

SAFETY AND PERFORMANCE

The performance of Cycle Tracking was tested in statistically powered pre-specified analyses to predict upcoming period starts (n = 1,238 cycles from 260 users) and estimate ovulation day (n = 934 cycles from 226 users). The results of the analysis demonstrate that the Cycle Tracking feature meets pre-specified clinical endpoints. Period start predictions are within the limits of the equivalence bounds of +/- 3 days from the actual period start. Additionally, Ovulation Day Estimations are within the limits of the equivalence bounds of +/- 2 days from the ovulation day determined via the reference luteinizing hormone (LH) ovulation test.

TROUBLESHOOTING

If you experience difficulties in operating Cycle Tracking, refer to the troubleshooting guide below. Access to certain functionalities within this application are based on regional availability and hardware compatibility.

Problem: User not receiving predictions for period start.

Solution: The cycle tracking feature requires at least two period logs to provide enough data for period start predictions. Ensure that any Pregnancy Cycle Factors have an end date logged.

Problem: User not receiving fertile window predictions.

Solution: The cycle tracking feature requires at least two period logs to provide enough data for fertile window predictions. Review user settings. Ensure that any Pregnancy or Contraception Cycle Factors have an end date logged.

Problem: User not receiving ovulation date estimates.

Solution: The cycle tracking feature requires sufficient overnight wrist temperature data from a compatible Apple Watch to estimate ovulation date. Set up Sleep on Watch and wear your Apple Watch to sleep each night in order to receive ovulation date estimates after it occurs.

CAUTIONS

DO NOT use the predicted fertile windows or ovulation estimates as a form of birth control.

DO NOT use data from the Health app and Cycle Tracking to diagnose health conditions.

Third-party apps that work with the Health app can also be used with Cycle Tracking.

If you believe you're having a medical emergency, call emergency services.

DO NOT take clinical action including making changes to your medication without consultation with a qualified health care professional.

This is a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: You should notify your physician if you detect possible changes in your health.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID, or Touch ID (fingerprint) to your iPhone and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure the iPhone since you will be storing personal health information. Users will also receive additional iOS and watchOS update notifications on the device, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. See “iOS and watchOS Security Guide” which describes Apple’s security practices and is available to all of our users. For the iOS and watchOS Security guide please visit <https://support.apple.com/guide/security/welcome/web>.

Cycle Tracking Version 3.X

Instructions for Use



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SWITZERLAND COUNTRY SPECIFIC INFORMATION:

CH-REP:

QUNIQUE GmbH
Bahnhofweg 17
5610 Wohlen
Switzerland

INTENDED USE (EU REGION)

Cycle Tracking is a software-only application intended to track, predict, and inform the user about their menstrual health. Cycle Tracking analyzes user inputs including typical cycle length, typical period length, menstrual flow, and ovulation test results, along with an aggregate of sedentary heart rate from HealthKit. Users are also able to manually log the following information for reference, but these inputs have no impact on predictions: spotting (intermenstrual bleeding), symptoms, progesterone test result, pregnancy test result, cervical mucus quality, basal body temperature, and sexual activity. User input data can be entered manually or can be imported from third-party apps. The predictions displayed are for informational use only.

CONTRAINDICATION

Cycle Tracking is not indicated for contraceptive use, nor is it intended to cure, mitigate, treat, or prevent any disease.

USING CYCLE TRACKING

Set-Up/Onboarding

- For region availability and device compatibility for Cycle Tracking, please visit <https://support.apple.com/en-us/HT210407>
- Update Apple Watch and iPhone to latest OS.
- On your iPhone, open the Health app and tap the Browse tab.
- Navigate to “Cycle Tracking.”
- Tap “Get Started” and follow the onscreen instructions.
- You may exit onboarding at any time by tapping “Cancel.”
- Once on-boarding is completed, you can start tracking your cycle.

How to track your cycle

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Swipe to the correct date, then tap the oval to log your period.
- To add more information, scroll down and tap a category, make a change, then tap Done. You can track symptoms, spotting, basal body temperature, and more.

To track your cycle from your Apple Watch, open Cycle Tracking, swipe to the correct date, then tap the oval to log your period.

How to check the date for your next and last period

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Scroll to Predictions to see when your next period is likely to start. If you don't see the estimate, tap Show All next to Predictions.

- Scroll to Summary to see the date your last menstrual period started and your typical cycle length.

To check the dates from your Apple Watch, open Cycle Tracking, then scroll down to Period Prediction or Last Menstrual Period.

How to set notifications for period tracking and fertility tracking

- On your iPhone, open the Health app and tap the Browse tab.
- Tap Cycle Tracking.
- Scroll down and tap Options.
- Select Period Predictions and Period Notifications. These notifications can let you know when your period is about to start and ask if your period has ended.
- Select Fertility Prediction and Fertility Notification. These notifications can let you know when your fertile window is likely to start or has been updated based on new information.

Predictions will begin after you have entered at least two periods in Cycle Tracking and are based on logged data. If you log a period before it's predicted to begin, you won't get a period prediction notification for that cycle. Notifications appear on your Apple Watch and iPhone.

How to delete Cycle Tracking on Apple Watch

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- Tap Delete.
- Press Digital Crown to finish.

SAFETY AND PERFORMANCE

The ability of Cycle Tracking to predict upcoming period starts and fertile windows was tested in a study with 210 subjects. It relies on a heart rate based deep learning algorithm (when heart rate data are available) to provide period start and fertile

window predictions. Cycle Tracking includes the period start in displayed predictions 80% of the time. At a population level: 83.4% predicted fertile windows will have at least one fertile day (defined as within 5 days before ovulation or on the ovulation day).

TROUBLESHOOTING

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

Problem: User not receiving predictions for period start.

Solution: The cycle tracking feature requires at least two period logs to provide enough data for period start predictions. Ensure that any Pregnancy Cycle Factors have an end date logged.

Problem: User not receiving fertile window predictions.

Solution: The cycle tracking feature requires at least two period logs to provide enough data for fertile window predictions. Review user settings. Ensure that any Pregnancy or Contraception Cycle Factors have an end date logged.

CAUTIONS

DO NOT use Cycle Tracking to facilitate conception.

DO NOT use the predicted fertile windows as a form of birth control.

DO NOT use data from the Health and Cycle Tracking to diagnose health conditions.

Third-party apps that work with the Health app can also be used with Cycle Tracking.

If you believe you're having a medical emergency, call emergency services.

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

This is a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: You should notify your physician if you detect possible changes in your health.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iPhone and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security.

It is important to secure the iPhone since you will be storing personal health information. Users will also receive additional iOS and watchOS update notifications on the device, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. See “iOS and watchOS Security Guide” which describes Apple’s security practices and is available to all of our users. For the iOS and watchOS Security guide please visit <https://support.apple.com/guide/security/welcome/web>.

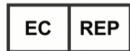
EQUIPMENT SYMBOLS



Manufacturer



Consult instructions for use



European Authorized Representative



Medical Device

099-35727 Revision A, July 2022