

Instructions for Use: Cycle Tracking

Cycle Tracking : ENGLISH (EN-GB)

These Instructions for Use are applicable only to the following regions: United States, EU/EEA, Switzerland, United Kingdom and the Republic of Korea.

Cycle Tracking

Instructions for Use



Apple Inc.
One Apple Park Way
Cupertino, CA 95014, USA

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

MOLDOVA COUNTRY-SPECIFIC INFORMATION:

Registration Number: DM000322299, DM000322300

AUTHORISED REPRESENTATIVE:

JERELO S.R.L.
MD-2024, str. Pietrăriei, nr 19A, of. 3.
mun. Chişinău, Republica Moldova
+37378538295

UKRAINE COUNTRY-SPECIFIC INFORMATION:

Registration Number: DM000322299, DM000322300

ТОВ «ДЖЕРЕЛО-УКРАЇНА»

01033, Україна, м. Київ, вулиця Шота Руставелі 33-Б, офіс 27
email: uarep@jerelo.eu

тел. +38 (044) 360 30 11



REPUBLIC OF KOREA COUNTRY-SPECIFIC INFORMATION:

본 앱은 “의료기기” 임.

수입업자: 이머고코리아 (유)

06236) 서울특별시 강남구 테헤란로 152 강남파이낸스센터 26층

제조원: Apple Inc.

(본사) One Apple Park Way, Cupertino, CA 95014, USA

(공장) 20450 Stevens Creek Blvd., Cupertino, CA 95014, USA

허가번호: 보류중

명칭 (제품명, 품목명, 모델명): ‘생리 주기 추적’ (Cycle Tracking)

소프트웨어 버전: 4.X

출시연월: 2022년 12월

포장단위: 1ea

사용목적 :

본 ‘생리 주기 추적’ 소프트웨어는 여성의 생리 및 가임기간, 후향적 배란일에 대한 추정정보를 제공하여, 여성 스스로 생리 등 일상적인 건강관리에 사용됩니다. 참고로, 동 소프트웨어는 의료 또는 피임 등의 목적으로 사용될 수 없습니다.

사용 시 주의사항:

‘생리 주기 추적’은 의료 또는 피임을 목적으로 사용할 수 없습니다.

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 analyses 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

Setup/Onboarding

- For region availability and device compatibility for Cycle Tracking, please visit <https://support.apple.com/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 onboarding is complete, 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 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 the app, then tap the "x" icon.
- If you are in List View, swipe left on Cycle Tracking and tap the Bin icon.
- Tap Delete.
- Press 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 luteinising 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 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 doctor if you detect possible changes in your health.

SECURITY: Apple recommends 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 your iPhone since you will be storing personal health information on it. 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 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 Authorised Representative



Medical Device

099-35727 Revision B, February 2023
