

Flo Digital Contraception

Instructions for Use (User Manual)

Thank you for joining our clinical study of the Flo Digital Contraceptive (FDC). This manual provides instructions on how to use FDC. Please read this manual in full before you start using FDC.

Should you have any questions, please contact the study team on flo_birth_control_study@lindushealth.com

1. Indications for Use

Flo Digital Contraceptive (FDC) is a stand-alone software application that is being investigated for use by women 18 years and older to monitor their fertility for the purpose of preventing pregnancy (contraception).

CAUTION: Investigational device limited by federal (or United States) law to investigational use.

2. Warnings

What to watch out for while participating in this clinical study

⚠ No method of contraception is 100% effective. The effectiveness of FDC as a digital contraceptive is being evaluated in this study and is not yet known. Like any form of contraception, your use of FDC will not guarantee that you cannot get pregnant, it only informs you of the days in which you have a higher or lower risk of pregnancy based on the information that you enter into the app. **Even when the app is used exactly as intended, pregnancy can still happen.**

⚠ On "Use protection" days, you must either avoid sex or use protection. If you choose to have protected sex, we recommend you use male condoms to prevent pregnancy as the most effective form of barrier contraception. Make sure to have these on hand to use during "Use protection" days and log this as "vaginal sex - condoms" in the app. If you use a condom and it breaks/slips off, please log this as "no protection".

⚠ Flo Digital Contraceptive does not protect against sexually transmitted infections (STIs). Use a male condom to protect against STIs.

⚠️ If you have irregular cycles: Women with irregular cycles have less predictable ovulation timing, which can increase the risk of unintended pregnancy when using fertility awareness methods. The FDC device is designed to manage this risk by several mechanisms including automatically expanding the number of days when you should avoid unprotected sex when it detects your cycles becoming more irregular.

⚠️ Always check your daily pregnancy risk for the day. Be aware that fertility predictions for upcoming days are only predictions and may change. If you are unsure of your fertility status and can't access the app, don't have sex, or use protection in the meantime.

⚠️ If you take an emergency contraceptive pill, please log it in the app as soon as possible. Flo Digital Contraceptive will then guide you to either abstain from sex or use a male condom until your next cycle, to help reduce the chance of pregnancy.

It's normal to experience some bleeding after taking emergency contraception, and this bleeding is not the same as your regular period. If the bleeding worries you or feels unusual in any way, we recommend contacting a healthcare provider for advice.

If your period does not arrive within 7 days of when you expect it, or if it has been about 3 weeks since you took the emergency contraceptive pill, it's a good idea to take a pregnancy test.

If you use a copper IUD for emergency contraception, please log this in the Flo app. To log the use of the copper IUD for emergency contraception, navigate to the Symptoms panel from the Flo app Home Screen by tapping the plus ("+") button. Scroll down within the panel to the "Emergency contraception" section, select the "Copper IUD" option, and then tap "Apply."

The copper IUD is both an emergency and longer term contraceptive. If used, you will be withdrawn from the study and Flo Digital Contraceptive will be deactivated in your app. Even if this happens, you will continue to receive free access to Flo Premium for the full 2-year period from your enrollment date, whether you complete or exit the study early.

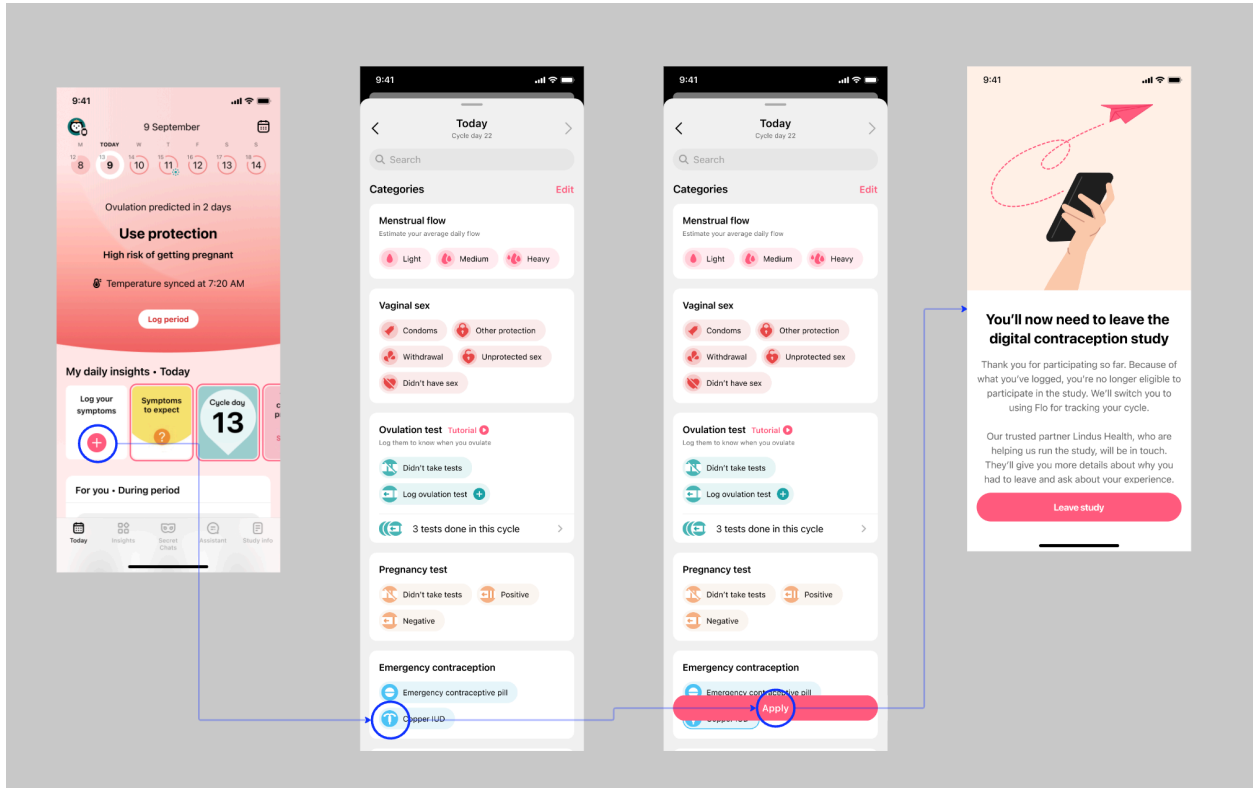


Figure 1. Screenshot of how to log emergency contraception use in the Flo app

⚠️ If you become pregnant while using FDC, you must inform the study team immediately. There are three ways in which you can do this:

1. Logging a positive pregnancy test in the Flo app
2. Monthly survey pregnancy status question
3. Direct communication to study personnel (phone: [833-930-8220](tel:833-930-8220) (available Mon–Fri, 9am–8pm EST), email: flo_birth_control_study@lindushealth.com)

Whichever method you choose to report a pregnancy, you will be asked to complete a pregnancy confirmation survey and will be withdrawn from the study.

3. Precautions

Things to remember

- **Keep your Flo app updated**, so that you have the latest version. Using the latest version will help keep your app safe from cybersecurity threats and vulnerabilities. Your app is updated via your app store. Flo recommends that you set your smartphone to update the app automatically.

- **Make sure your Apple Watch® wrist-wearable device is charged before going to sleep**, so that it has enough battery to record your temperature at night. This is important for Flo Digital Contraceptive to perform as intended.

If you have more questions, see the dedicated Digital Contraceptive information in the Flo app, or contact the study team on flo_birth_control_study@lindushealth.com

4. Checklist

To get started with Flo Digital Contraceptive you will need the following:

1. Have a Flo account

If you are a new user of the Flo App, you first need to download the Flo app from the App Store to your iPhone. Your phone must run on iOS, minimum version 16, with an internet connection. Follow the registration steps to create your personal account. Make sure the phone you use to access Flo is connected to the internet. Your Flo account is personal, and should not be used by anyone except you. You need to be comfortable reading and understanding English well enough to use the app and your phone correctly.

Existing Flo users do not need to create a new account to start using Flo Digital Contraceptive once they have completed the eligibility checks with Lindus Health, a contract research organization that helps investigate how effective the technology is.

2. An Apple Watch® wrist-wearable device (Series 8 or later, Ultra)

To track your daily temperature, you will need an Apple Watch® with temperature sensors capable of sensing sleep wrist-skin temperature. Compatible models include:

- Apple Watch® Series 8
- Apple Watch® Series 9
- Apple Watch® Series 10
- Apple Watch® Series 11
- Apple Watch® Ultra
- Apple Watch® Ultra 2

The Apple Watch® must be functional and connected to your iPhone, sharing wrist temperature data to the Flo application through Apple Health. Section 7 below provides instructions for this.

Important: While sleeping, Apple Watch® samples your wrist temperature every 5 seconds and provides an aggregate of the measurements taken over the sleeping period. You must set your sleeping schedule in Apple Health to inform Apple Watch® what period of time an aggregate of your wrist temperature should be measured over. You must make sure you have

charged your Apple Watch ® before going to sleep. We recommend you charge it while cooking dinner, watching TV, or during some downtime before bed when you don't need to use your watch.

3. Pregnancy tests

We recommend keeping a few home pregnancy tests (urine hCG tests) on hand before you start using Digital Contraception. This way, if your period is late and pregnancy is a possibility, you can check right away.

Pregnancy tests are easy to find at pharmacies, grocery stores, and dollar stores, and they're usually low-cost. You can also request pregnancy tests from the study team at any point during the study by emailing flo_birth_control_study@lindushealth.com. If requested, tests will be shipped to you with expedited overnight delivery.

4. Ovulation tests (optional)

Ovulation (LH) tests are urine test strips which detect the surge of luteinizing hormone that occurs 1-2 days before ovulation. It is optional to use LH tests with Flo Digital Contraceptive, but they can help to increase the accuracy of detecting ovulation and can, therefore, increase the number of "Not fertile" days you will see.

The Flo app helps users identify the time for an LH test. It provides an LH-test logging shortcut on the Home Screen and in the Calendar, which opens the Symptoms panel to record the result for that day. Users can also log an LH-test on any cycle day via the Symptoms panel by tapping the "+" (plus) button on the Flo Home Screen. Once a positive or negative LH-test result is logged, the shortcut is removed, and a grey dot appears beneath that date on the calendar.

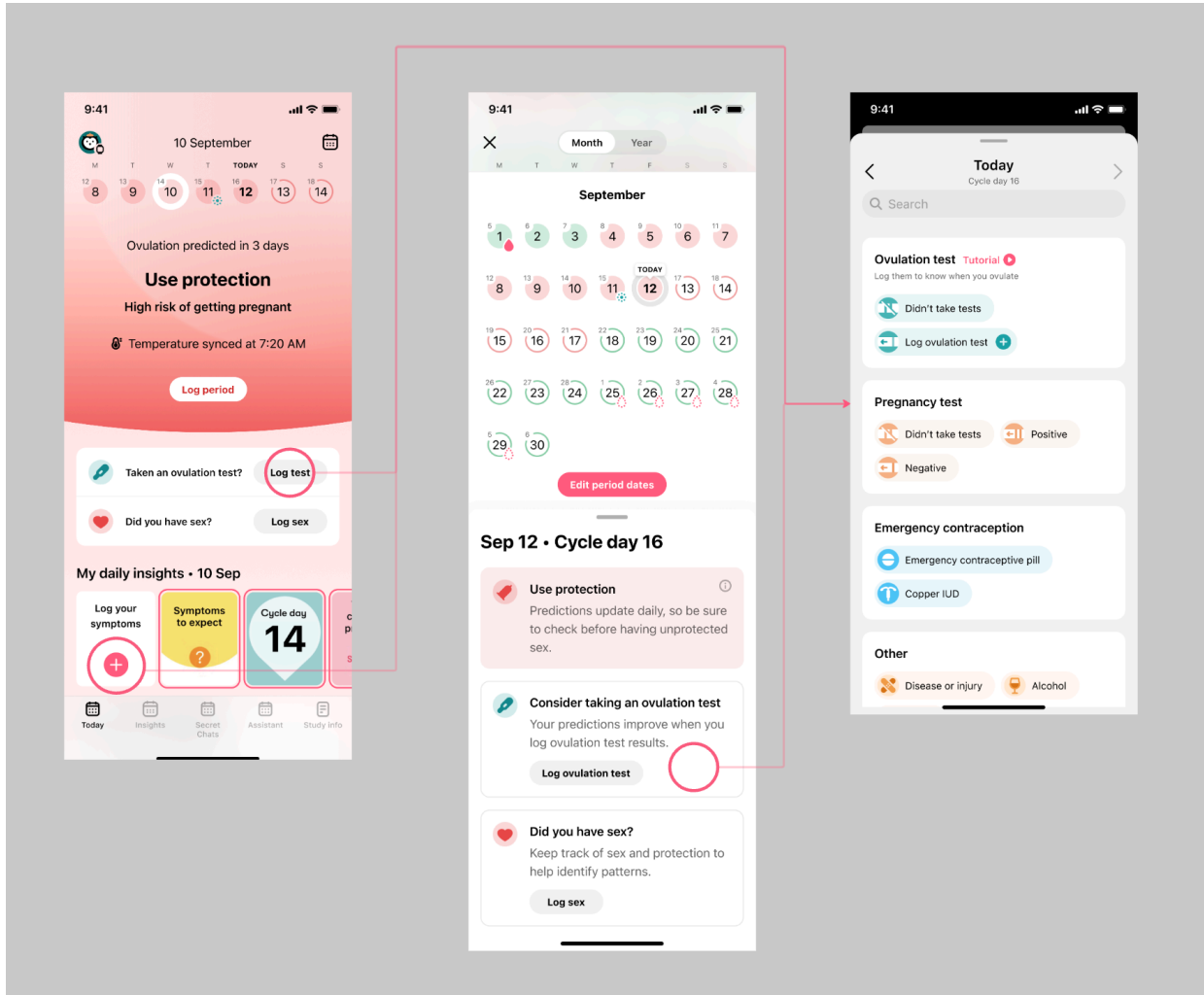


Figure 2. Screenshot of how to log an Ovulation (LH) test in the Flo app

5. Flo Digital Contraceptive and Apple Watch ®

How to set up

After logging in to the Flo app for the first time, you will be guided through the connection flow to set up syncing between Flo and Apple Health. Make sure your Apple Watch ® is paired with your iPhone and that you have enabled wrist temperature tracking in your Apple Health app.

Setting up Apple Health:

1. Open Apple Health
2. Open your profile (top right icon)
3. Go to "Apps" in the "Privacy" section

4. Select Flo in the list of apps
5. Make sure that "Wrist Temperature" is turned on

Setting your Apple Health Sleep Schedule:

1. In your Apple Health app, go to "Search"
2. Under "Sleep," select "Full Schedule & Options"
3. Set your Sleep Schedule
4. Enable "Use Schedule for Sleep Focus"
5. Return to the Flo app

How to use

Follow the user manual provided by Apple to measure temperature during the night with your Apple Watch ®. The temperature will be automatically transferred to Flo through Apple Health.

Your daily morning routine:

1. **Sync your data:** Your Apple Watch ® automatically syncs temperature data to Flo through Apple Health
2. **Add data:** Period, Sex events or LH tests can be logged using shortcuts from Main screen or Calendar view, as well as in Symptom Panel
3. **Check your fertility status:** The app will provide your fertility status directly after your first set of period data is entered. Your status for the day is displayed throughout the app.

Important Notes:

- **Do not use the temperature values provided by Apple Watch ® to make medical decisions** (e.g., diagnose fever).
 - **If you need to change your Apple Watch ® for any reason**, you should start using your new watch at the start of your period.
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6. How Flo Digital Contraceptive works

Understanding your daily pregnancy risk

The app shows when ovulation is predicted, when your period has started, and when your next period is expected. It also provides predictions for upcoming days and months. Because these predictions can change as new information is added, it's important to check your pregnancy risk in the app each day and follow the guidance.

Not fertile

"Not fertile" days indicate you are at "lower risk" (less likely to conceive) and can have sex without protection.

Use protection

"Use protection" days indicate you are at "higher risk" (more likely to conceive) and at risk of becoming pregnant. If you choose to have sex on these days, make sure you use protection (such as male condoms) to prevent pregnancy.

How Flo Digital Contraceptive determines pregnancy risk

With each menstrual cycle, you have a fertile window that is typically around 6-7 days, covering the days before, during, and after ovulation (when your ovary releases an egg).

FDC has been developed to help prevent pregnancy by predicting your "use protection" days based on the information that you enter into the Flo App. This includes your fertile window along with extra days to accommodate potential ovulation shifts. By estimating ovulation timing based on the data you log, it highlights the days you should use barrier protection (such as a male condom) or avoid sex to reduce your chance of pregnancy.

FDC uses overnight/sleeping wrist-skin temperature measured by Apple Watch® (Series 8 or later, Ultra) as a proxy for basal body temperature (BBT). Basal body temperature increases due to the rise in progesterone that follows ovulation. FDC monitors wrist-skin temperature as a method of detecting ovulation to determine whether you have entered the luteal phase and are no longer in the fertile window, and will adjust its prediction of non-fertile and fertile days accordingly.

Your participation in this clinical study will contribute data to validate the effectiveness of FDC as a contraceptive to prevent pregnancy.

7. If you become pregnant

If your period is late, you may be pregnant and the app will encourage you to take a pregnancy test to confirm the pregnancy. **If the test is positive, seek advice from a healthcare professional.**

It is best to have pregnancy tests to hand before you start using Digital Contraception. Pregnancy tests can easily be obtained from a pharmacy or grocery store. You may also request pregnancy tests from the study team at any time during the study by contacting flo_birth_control_study@lindushealth.com. Upon request, tests will be shipped via expedited overnight delivery.

As a study requirement, you must inform the study team immediately if you become pregnant. There are three ways in which you can do this:

1. Logging a positive pregnancy test in the Flo app
2. Monthly survey pregnancy status question
3. Direct communication to study personnel (phone: 833-930-8220 (available Mon–Fri, 9am–8pm EST), email: flo_birth_control_study@lindushealth.com)

You will be asked to complete a pregnancy confirmation survey, which will ask:

- Whether you adhered to the contraceptive guidance in the cycle you became pregnant
- Whether your intention was still to prevent pregnancy or if you had changed your fertility goal
- Other questions about your experience using FDC
- Confirmation of the pregnancy (photo of positive pregnancy test, ultrasound scan, or other confirmation) will be requested

After completing the pregnancy survey, you will be withdrawn from the study, and FDC will be deactivated in your app. Free access to Flo Premium will continue for the full 2-year period from your enrollment date, even if you complete or exit the study early.

8. Study participation information

Study procedures

During the study, you need to:

- Log your period every cycle (this is the most important data to log)

You can do this by clicking the “Log period” or “Edit period dates” button on the Flo Home Screen or in the calendar. This opens an editable calendar where you can mark your period days. Based on your cycle phase, Flo will also recommend logging your period via a shortcut on the Home Screen or in the calendar; this usually appears toward the end of your cycle.

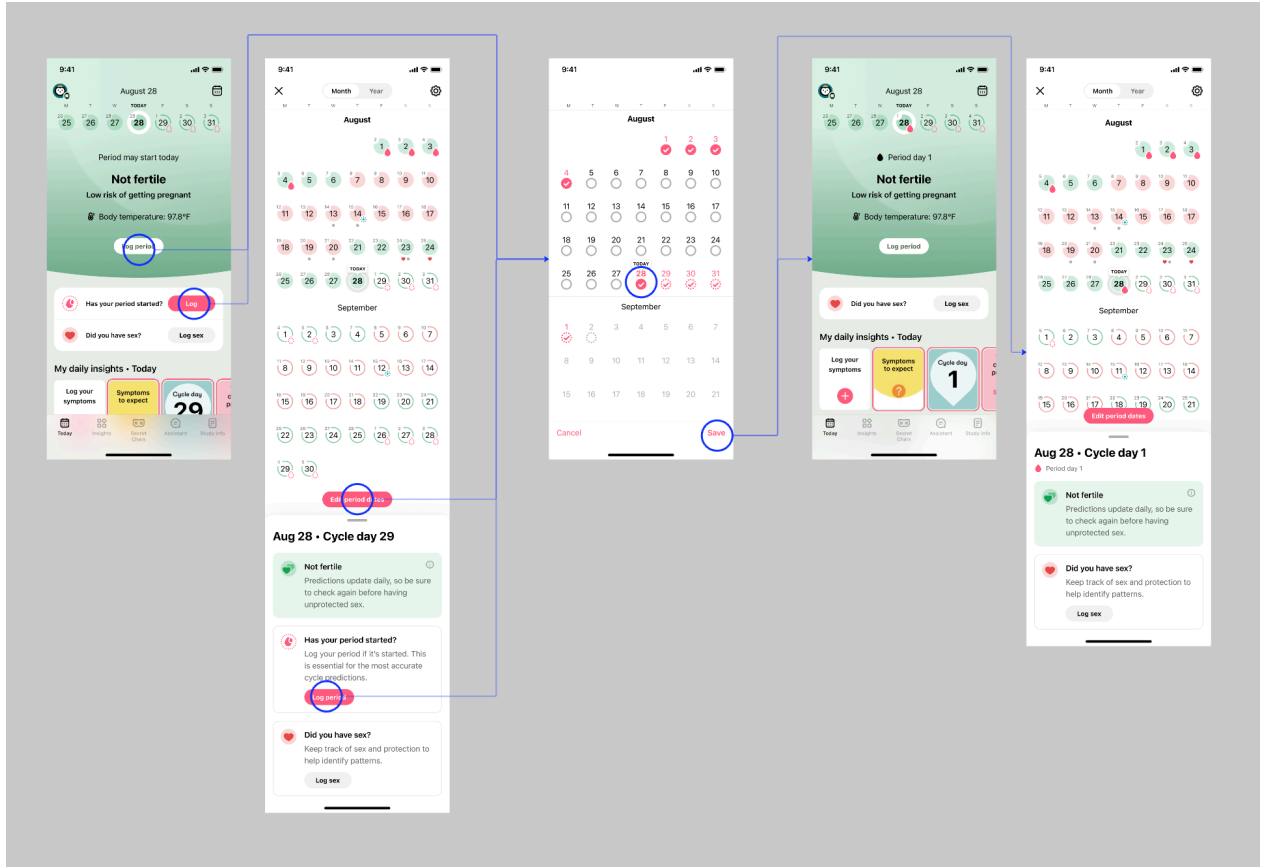


Figure 3. Screenshot of how to log your period in the Flo app

- Wear your Apple Watch® every night to track temperature. Ensure it is consistently charged, reaching a minimum of 30% before bedtime to enable accurate wrist temperature collection.
- Try to get at least 4 hours of sleep at roughly the same time each night
- Log partnered sex every time, including whether it was protected or not

Sex can be logged in two ways:

1. **Home Screen Shortcut or Calendar:** Use the shortcut on the Home Screen or select a date in the calendar. This opens the Symptoms panel, where you can log the type of sex for the chosen date. A heart icon will then appear below that date in the calendar.
2. **Symptoms Panel:** Alternatively, click the "+" (plus) button on the Home Screen to directly access the Symptoms panel and log sex.

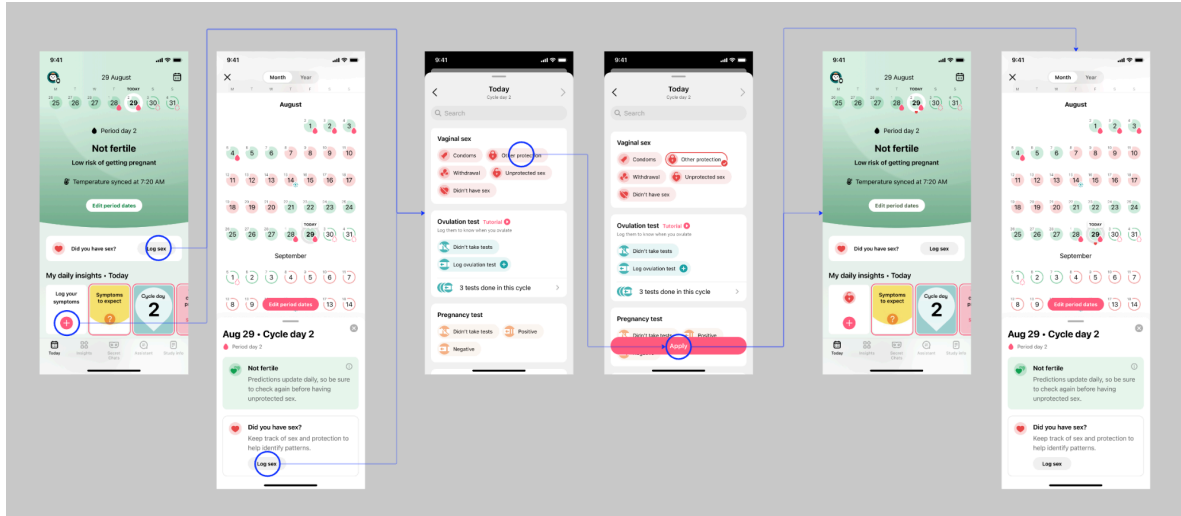


Figure 4. Screenshot of how to log sex in the Flo app

- Check your predictions daily and use barrier protection (such as male condoms) or abstain from sex on days that are labelled as “use protection.”
- Optionally log ovulation (LH) tests for more accurate predictions. See section 4.4 of this document, "Checklist: Ovulation test (optional)" for details.
- Complete monthly surveys administered by the research team (Lindus Health)

Every month you will be sent a survey via email on behalf of Flo Health from our research partner, Lindus Health. This survey will ask you a series of questions related to:

- Your sexual history from the previous cycle
- If you have encountered any safety issues related to your use of the FDC
- Your pregnancy status

For each month you complete all of your surveys , we will compensate you for your time in the form of a token compensation of \$5.00 for each month you complete all your surveys.

Leaving the study

You can leave the study at any time. If you wish to leave, you can do so through the study information page in the app (found in the bottom navbar or by going to your settings). Once you leave, you cannot restart the study. You can also leave by indicating you no longer wish to participate in the monthly surveys administered by the research team (Lindus Health), or directly contact the study team at flo_birth_control_study@lindushealth.com.

Reasons you may be withdrawn from the study

- Withdrawal of consent to study participation

- Inability to comply with study procedures
- Commencement of contraindicated medication or treatment that may interfere with the device's intended use
- Starting hormonal contraception (such as the pill, implant, injection, hormonal IUD) or copper IUD
- Change in pregnancy risk status requiring mandatory contraceptive use
- Medical advice that reliable contraception is necessary
- Pregnancy
- Other medical or safety events/complications
- Loss to follow-up (if you are inactive in the Flo app for over 60 days and do not complete 3 consecutive monthly surveys; the study team will attempt to contact you via phone/email if you are unresponsive to surveys)
- The study's lead investigator determines a condition or circumstance compromises your ability to comply with the study protocol, or poses an unacceptable risk to your safety, well-being, or interference with the study's objectives.

Data collected from you up to the point of withdrawal will be retained and included in the final analysis.

Study participation: What you receive

No Cost for Study Participation

There is no charge to participate in this clinical study or to use Flo Digital Contraceptive during the study.

As a study participant, you will receive:

1. **Free access to Flo Digital Contraceptive** for the duration of your study participation (up to 13 menstrual cycles or 18 months)
2. **Free Flo Premium membership** for 2 years from enrollment
 - Valued at \$120 for paying subscribers
 - This free access is provided as compensation for your time and participation in the study, not as a commercial sale of the investigational device
 - Both current Flo users (free or Premium) and new users are eligible to participate
3. **Survey compensation:** \$5 for each monthly survey you complete through Lindus Health + \$30 for completing the final exit survey

What Happens When the Study Ends

- When you complete the study or exit early, FDC will be deactivated in your Flo app but you can continue to use the Flo app in 'track your cycle' mode.
- Free access to Flo Premium will continue for the full 2-year period from your enrollment date, even if you complete or exit the study early

- At the end of the two years, billing will start automatically unless you cancel via Apple Subscriptions.
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9. Common Questions

What if my temperature didn't get recorded?

Missing a day or two isn't a problem—the app can still predict your “use protection” days. However, you'll likely see more days when unprotected sex isn't recommended. For the best experience, we recommend wearing your Apple Watch ® (Series 8 or later, Ultra) every night and keep it charged. See the dedicated troubleshooting advice in Section 6 of this document and in the Common Questions section of the Flo app.

Why do all my predictions say "Use protection"?

This usually means the algorithm can't confidently predict ovulation. Reasons may include:

- Your period is delayed
- You logged an emergency contraceptive pill in this cycle
- You haven't provided enough temperature data
- You're in your first few cycles using the app
- You logged positive LH-test(s) that can't be interpreted by the algorithm

It's important to note that the algorithm will only start showing you fertility predictions once you have logged your first period.

Can I use other contraception?

On days labelled as ‘Use protection’, we recommend you use male condoms as they are the most effective form of barrier contraception. However, if you start using hormonal birth control (like the contraceptive pill, implant, or injection), get an IUD, or have a procedure that prevents your ability to get pregnant, you must discontinue use of Flo Digital Contraceptive and inform the study team.

What if I have unprotected sex during my “use protection” days?

If you've had penetrative sex without a barrier method on a "Use protection" day, there's a chance of pregnancy.

Next steps:

1. Consider emergency contraception options (emergency contraceptive pill or copper IUD) as soon as possible
 - a. If you used the **Emergency contraceptive pill**: Continue using a male condom for the rest of the cycle until you get a "Not fertile" prediction
 - b. If you use the **Copper IUD for emergency contraception**: you won't be able to participate in the study any longer. Please log this in the Flo app and Flo Digital Contraception will be deactivated for you.
 2. Log the unprotected sex and any emergency contraception you use in the Flo app
 3. Take a pregnancy test if your period is late, or about three weeks after unprotected sex happened
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10. Problems / Troubleshooting

If you cannot access Flo, or if you suspect something is wrong with your current fertility status, please follow the steps below:

1. **Use protection**, such as a male condom, until the error has been fixed.
2. **Contact our support team** via the Flo app or email support@flo.health, and our trained support agents will assist you.
3. **For study-related questions**, contact the trial study team through the contact information provided in the app or using flo_birth_control_study@lindushealth.com.

For urgent safety concerns, participants are encouraged to contact the study team **immediately** rather than waiting for the next scheduled survey. The study team will be reachable Monday to Friday, from 9 AM EST to 5 PM PST. If the safety concern constitutes an emergency or occurs outside of these hours, you should contact your healthcare provider or go to the nearest emergency medical service.

Participants may contact the study team at any time via:

- **Phone:** [833-930-8220](tel:833-930-8220) (available Mon–Fri, 9am–8pm EST)
 - **Email:** flo_birth_control_study@lindushealth.com
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11. Security and data privacy

Flo is committed to protecting your data. We take various technical and organisational steps to protect your personal data from loss, theft, misuse, and unauthorised access, disclosure, alteration, and destruction. These measures include:

- encryption: your personal data is encrypted both in transit and at rest;
- vulnerability scanning: we conduct regular scans and penetration testing;

- data integrity protection: we have measures in place to protect the integrity of your data
- organisational and legal measures: for example, our employees have different levels of access to your personal data, limited to what is necessary for operating the Services; and
- privacy assessments: we conduct regular data protection impact assessments to ensure that the Services comply with privacy principles.

If there is a security breach and where required by law, we will either post a notice or try to contact you by email. We will take reasonable steps to fix the issue according to applicable laws and our [Privacy Policy](#). For potential personal data breaches, we may take additional actions, such as logging you out from all the devices, resetting your password and other necessary steps to address the situation.

Please keep your password secure and don't share it with others. Consider adding a passcode or enabling face ID for an extra layer of protection.

Watch out for emails or messages asking you to provide your Flo login details. Flo will not send you emails asking for your password, unless you have initiated this process yourself via support or a password reset.

If you believe there is a security issue, including unauthorized access to your account, please contact security@flo.health.

For more information on privacy and security practices, please read the [Privacy Policy](#) and [Data Security at Flo](#).

How your study data is used

Flo uses data related to your use of the Digital Contraceptive to assess how effective it is, and to provide evidence to the Food and Drug Administration (FDA) and Institutional Review Board (IRB) to meet regulatory requirements.

Flo has partnered with Lindus Health, a contract research organization that helps investigate how effective the technology is. For this purpose only, your clinical study data will be shared with Lindus Health.

All data is de-identified and will remain so during the analysis stage. All results shared will be in aggregate form.

12. Manufacturer information

Name of the Manufacturer:

Flo Health UK Limited

Address of the Manufacturer:
Fourth Floor, International House
1 St Katharine's Way
London, E1W 1UN
United Kingdom

Customer Support:
support@flo.health

Device Name:
Flo Digital Contraceptive

Date of publication:
April 2026

Document version:
v1.1

13. Accessing the Instructions for Use

The Instructions for Use can be found online and in your app.

14. Platform description

Application Version: Compatible with Flo app version as specified in your study enrollment

Devices that may be used:

- iPhone or iPad running iOS version 16 or above, with internet connection
 - Apple Watch ® Series 8, 9, 10, 11, Ultra, or Ultra 2 capable of sensing sleep wrist-skin temperature
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This document is provided as part of the Flo Digital Contraceptive investigational study and contains information specific to study participation. For questions about the study, please contact the clinical research team at flo_birth_control_study@lindushealth.com