Natural Cycles

User Manual / Instructions for Use

Please read this manual before you start using Natural Cycles.

Indications for Use

Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).

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 be able to measure her body basal temperature on a regular basis

Intended Use Environment

The device is intended for external use by lay persons in home environments only. The device is not intended for professional use.

Contraindications

There are no known contraindications for use of Natural Cycles.

Side-Effects

The product has no known direct side effects on the human body. As with any contraceptive device, unintended pregnancies may occur.

Natural Cycles may not be right for you if

- You have a medical condition where pregnancy would be associated with a significant risk to the mother or the fetus. Using Natural Cycles does not guarantee 100% that you will not get pregnant. If pregnancy presents a significant risk, you should talk to your doctor about the best contraceptive option for you.
- You are currently taking hormonal birth control or undergoing hormonal treatment that inhibits ovulation. Natural Cycles will mainly provide red days if you do not ovulate. You can explore the app in Demo Mode until you discontinue your hormonal birth control or treatment.

Warnings

⚠ No method of contraception is 100% effective. Natural Cycles does not guarantee that you cannot get pregnant, it only informs you whether and when you can become pregnant based on the information that you enter into the application.

⚠ Even with using the app perfectly, you can still have an unintended pregnancy. Natural Cycles is 93% effective under typical use, which means that 7 women out of 100 get pregnant during 1 year of use. With using the app perfectly, i.e. if you never have unprotected intercourse on red days, Natural Cycles is 98% effective, which means that 2 women out of 100 get pregnant during 1 year of use.

⚠ On red days, you must either abstain or use protection, such as condoms or another form of barrier protection, to prevent pregnancy. If you have not been using a non-hormonal method of contraception before, make sure to have a method on hand to use during red days.

⚠ Our data show that women transitioning to Natural Cycles from hormonal contraception have a higher risk of becoming pregnant due to generally not yet being accustomed to using other forms of protection, such as a condom or another form of barrier protection.

⚠ If you are discontinuing hormonal contraception, you may first experience a withdrawal bleed, which is much lighter than your true period. You will normally get your true period a few weeks later. Withdrawal bleeding should not be entered as “period”. If you are unsure if you are experiencing withdrawal bleeding or a period, please consult your doctor.

⚠ Natural Cycles does not protect against sexually transmitted infections (STIs). Use a condom to protect against STIs.

⚠ Always check your fertility status for the day. Be aware that fertility predictions for upcoming days are only predictions and may change in the future. If you are unsure of your fertility status and can’t access the app, abstain or use protection in the meantime.

⚠ If you are exploring the demo version of the app, this is for informational or instructional purposes only and does not display real data. Do not use the information displayed in Demo Mode for contraceptive purposes.

⚠ If you have taken the emergency contraceptive pill, you should indicate it in the app. You can then continue measuring your temperature as normal and the algorithm will take the additional hormones from the pill into account. Note that the bleeding you may experience a few days after taking emergency contraception is not the same as your regular period and should not be entered into the app. If your period is more than one week late after it would normally start you should take a pregnancy test.

Precautions

- As a contraceptive, Natural Cycles may be less suitable for you if you have irregular menstrual cycles (i.e. cycles with length less than 21 days or greater than 35 days) and/or fluctuating temperatures as predicting fertility is more difficult in these circumstances. Natural Cycles’ effectiveness as a contraceptive is not affected by irregular cycles, but

you will experience an increased number of red days, which can reduce your satisfaction with Natural Cycles. This can be the case:
    - **If you discontinue hormonal contraception**. It can take several cycles after discontinuing hormonal contraception before becoming more regular again. You should expect more red days during these cycles and therefore expect to use protection or abstain more frequently.
    - **If you are breastfeeding**. For the first 4-6 months after giving birth, many women who are exclusively breastfeeding may not ovulate. Natural Cycles will detect your first ovulation 2 weeks before your first menstruation but until then you will only see red days in the app. Even though you are not ovulating, it is still important to use contraception or abstain from intercourse on red days.
    - **If you have medical conditions that lead to irregular cycles such as polycystic ovary syndrome (PCOS) or thyroid-related conditions**.
    - **If you experience symptoms of menopause.**
- When you start using Natural Cycles, it can take some time to get to know your unique cycle, resulting in an increased number of red days during your first 1-3 cycles. This is to ensure that the app is effective from the first day of use, and once Natural Cycles has detected your ovulation you are likely to receive more green days. It is important to note that you can rely on the fertility status indicated by the app from the first day of use.
- Always make sure to update your software app, so that you have the latest version. Natural Cycles recommends that you set your smartphone to update the app automatically.
- To ensure that your temperature measurements are accurate always use a basal thermometer to take your temperature.
- Always follow the directions for 'Measuring Your Temperature' stated below in order to increase the accuracy of ovulation detection.

Checklist

To get started with Natural Cycles you will need the following:

1. A Natural Cycles account

You can access Natural Cycles via your web browser, by visiting www.naturalcycles.com. For access via the app, download the app on your Android, iPhone or iPad on Google Play or the App Store. Follow the registration steps to create your personal account. Make sure the device you use to access Natural Cycles is connected to the internet. Your Natural Cycles account is personal and should not be used by anyone except you.

2. A Basal thermometer

To get started you will need a basal thermometer. Basal thermometers are more sensitive than regular fever thermometers as they show two decimals (e.g. 36.72°C / 98.11°F). Temperature changes during the menstrual cycle are quite small, so to get the most out of Natural Cycles and receive more green days you will need the correct thermometer. The thermometer you use should be CE marked if you are in Europe or FDA cleared if you are in the US. A basal thermometer is included when you sign up for Natural Cycles with an annual subscription.

3. Ovulation tests (optional)

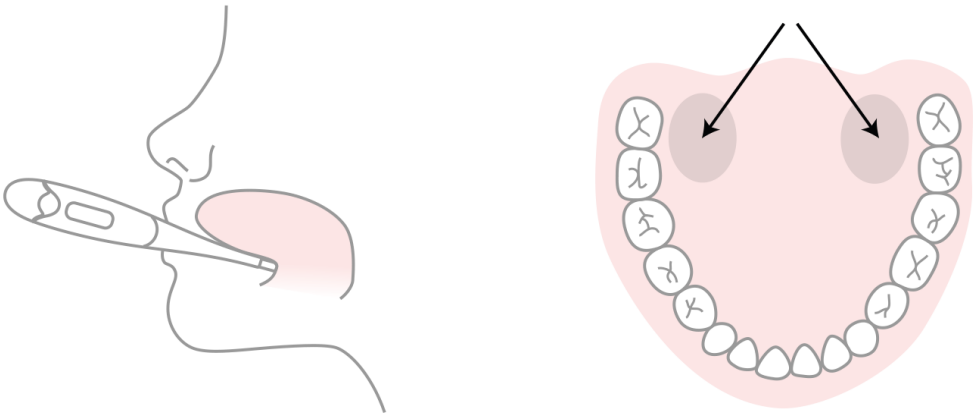
Ovulation (LH) tests are urine test strips which detect the surge of luteinizing hormone that occurs 1-2 days before ovulation. It is optional to use LH tests with Natural Cycles, but they can help to increase the accuracy of detecting ovulation and can, therefore, increase the number of green days you will see if you are preventing a pregnancy. Using LH tests will not affect the effectiveness of Natural Cycles as a contraceptive. If you are planning a pregnancy, we recommend using LH tests as they can help to find your most fertile days. You can purchase LH tests at shop.naturalcycles.com or from within the app itself.

Measuring your temperature

How to measure

Follow the user manual provided with your basal body temperature thermometer. If the thermometer was provided to you by Natural Cycles we recommend that you follow these steps when measuring your temperature:

1. Place the thermometer in your mouth and under your tongue, as far back as possible, next to the root of your tongue as depicted in the diagrams below.



2. Only press the power button once the thermometer is in your mouth and in place.
3. Try to keep still while measuring, close your mouth to keep any cool air out and breathe through your nose.
4. Wait until it beeps (approx. 30 seconds).
5. Once you have your reading, add the temperature into the app.

You can use the ‘Measuring Training’ and the ‘Measuring Guide’ in the app to check your measuring skills.

The thermometer will save your reading, so you can check your reading once again later. To do this press the “on” button once; the saved reading will appear for a few seconds before the temperature resets.

When to measure

Measure your temperature once a day, on as many days as possible, so that the algorithm can quickly get to know your unique cycle. Aim to measure at least 5 days a week. A tip to help you remember is to place your thermometer on top of your phone before going to bed.

Measure first thing in the morning when you wake up, before you get up and out of bed. Ideally measure at around the same time every day (within +/- 2 hours).

When to exclude temperatures

Certain circumstances may affect your basal temperature. This can lead to variating temperatures and make it harder for the algorithm to track your cycle. To help our algorithm learn about your cycle and accurately find ovulation, use the “Exclude temperature” function in the app if you:

- Feel hungover
- Slept differently (>2 hours more/less than usual)
- Feel sick

Remember that everyone is different with different routines and, for instance, little sleep might affect you more or less than others. Exclude your temperature only if you feel that something was out of the ordinary for you and you feel differently this morning because of it.
Medication can also affect your temperature. If you take regular medication it’s worth consulting with your doctor to discover its impact on your basal body temperature. or anti-pyretics (fever reducing substances)

Changing your thermometer

If you need to replace your thermometer, do this at the start of your period. A basal thermometer is highly accurate, but from one thermometer to another , there can be a small difference in how each one measures. For example, if one thermometer is showing one temperature, the second can show a 0.1°C difference. As the app is looking for the smallest differences in temperatures to be able to locate where you are in your cycle, you should only use one thermometer at a time.Do not change these during the course of a cycle, instead wait until a new cycle has started before changing your thermometer.

Natural Cycles products

Natural Cycles offers three modes for our users to choose from depending on their fertility goal:

- NC° Birth Control - for preventing pregnancy
- NC° Plan Pregnancy - for increasing chances of conception
- NC° Follow Pregnancy - for monitoring the course of a pregnancy

These three modes can be chosen by the user prior to signing up and then within the app, if the user would like to switch between modes.

Contraception: NC° Birth Control

How it works

Your daily morning routine with Natural Cycles is as follows:

1. Measure your temperature when you wake up as described in the section above.

2. Add your temperature and whether you have your period into the app. The view to add data will automatically open, or you can press the '+' icon in the top right-hand corner. You can also add additional data, such as the result of ovulation (LH) test. Once you save today's data, the app will calculate your status for the day.

3. Check your fertility status for the day - every day. The app will provide your fertility status directly after your first set of data is entered. Your status for the day is displayed in red and green colors throughout the app.



Green = Not fertile
Green days indicate you are not fertile and can have sex without protection. Green days are indicated by a green outlined circle with the words "Not fertile" inside.



Red = Use protection
Red days indicate you are likely to be fertile and at risk of becoming pregnant. Use protection (such as condoms or another form of barrier protection) or abstain in order to prevent a pregnancy. Red days are indicated by a red outlined circle with the words "Use protection" inside.

The app will indicate your ovulation as well as when you have entered and are expected to have your period. The application also shows predictions for upcoming days and months. The predictions may change and should not be used as the final result, which is why you should check your status for the day - every day.

Summary of clinical studies - how effective is Natural Cycles for contraception?

Natural Cycles is 93% effective under typical use. Under perfect use, i.e. if you never have unprotected intercourse on red days, Natural Cycles is 98% effective.

Clinical studies have been conducted in order to evaluate the effectiveness of Natural Cycles for contraception. The current version of the algorithm (v.3) has been investigated on 15,570 women (on average 29 years old). At the end of the study, the following commonly used failure rates were determined:

1. The app has a method failure rate of 0.6, which is a measurement of how often the app incorrectly displays a green day when the woman is actually fertile and gets pregnant after having unprotected intercourse on this green day. This means that 0.6 out of 100 women who use the app for one year get pregnant due to this type of failure.
2. The app has a perfect use Pearl Index of 1, which means that 1 out of 100 women who use the app for one year and who get pregnant will do so either because:
    a. They had unprotected intercourse on a green day that was falsely attributed as non-fertile (i.e., method failure); or
    b. They had protected intercourse on a red day, but the chosen method of contraception failed.
3. The app has a typical use Pearl Index of 6.5, which means that in total 6.5 women out of 100 get pregnant during one year of use due to all possible reasons (e.g. falsely attributed green days, having unprotected intercourse on red days, and failure of the contraceptive method used on red days).

Summary of clinical data from 15,570 women on the effectiveness of Natural Cycles of the current algorithm version.

Algorithm Version	**Study Date Range**	**# women**	**Exposure time** **(Women-years)**	**# pregnancies** **[worst-case]**	**Typical use PI** **(95% confidence interval)** **[worst-case]**	**Method failure rate** **(95% confidence interval)**
v.3	Sept 2017 - Apr 2018	15,570	7,353	475 [584]	6.5 (5.9-7.1) [7.9]	0.6 (0.4-0.8)

Effectiveness of Natural Cycles for two subgroups - women who used hormonal contraception within 60 days prior to using the app and women who did not use hormonal contraception within 12 months prior to using the app.

Subgroup	**Typical Use PI (95% confidence interval)**
Recent Hormonal Contraception 3779 women	8.6 % (7.2-10.0)
No Hormonal Contraception 8412 women	5.0 % (4.3-5.7)

You can find an overview of the effectiveness of different contraceptive methods in the Appendix of this manual. This will help you to understand the expected effectiveness of all forms of contraception.

Instructions if you are discontinuing hormonal contraception

Type of Contraception	**When can you start Natural Cycles?**

The Pill (Combined, Medium or Mini)	We recommend that you finish all the active pills of your packet. You can start using Natural Cycles as soon as you finish. You will have a high number of red days to begin with but this will improve over time.
Hormonal IUD (Intrauterine Device)	You can start using Natural Cycles the day after it has been removed.
Contraceptive Implant	You can start using Natural Cycles the day after it has been removed.
Hormonal Patch, Hormonal Contraceptive Ring	You can start using Natural Cycles the day after it has been removed. You will have a high number of red days to begin with this but this will improve over time.
Contraceptive Injection	You can start using Natural Cycles when the effect of the injection has worn off. This takes 8-13 weeks depending on which injection you had.

If you are discontinuing hormonal contraception you may first experience a withdrawal bleed, which is much lighter than your true period. You will normally get your true period a few weeks later. Withdrawal bleeding should **not** be entered in the app as “period”.

Note: a copper IUD does not contain hormones and does therefore not inhibit ovulation. You can thus use Natural Cycles alongside a copper IUD to get insights on your body and menstrual cycle without having to use a barrier method on red days.

If you become pregnant on Natural Cycles

If your period is overdue and your temperature does not drop, you may be pregnant and the app will encourage you to take a pregnancy test to confirm the pregnancy. If the test is positive, please talk to your doctor and indicate it in the app.

NC° Plan Pregnancy

When you are planning a pregnancy, select NC° Plan Pregnancy while signing up in the app. If you are already signed into the app, you can go to the settings page and choose NC° Plan Pregnancy . In this mode, your fertility is displayed as a scale, so you can identify the days you are most likely to become pregnant. The same morning routine as in NC° Birth Control mode applies here as well - measure, add data and check your fertility status.



Peak fertility | Very high fertility | High fertility | Medium fertility | Low fertility | Fertility unlikely | More data needed | Not fertile

When you’re planning a pregnancy, we recommend taking LH tests since the occurrence of LH coincides with your most fertile days. If your period is overdue and your temperature does not drop, the app will encourage you to take a pregnancy test to confirm the pregnancy.

NC° Follow Pregnancy

Once you are pregnant, the app can be used as a pregnancy calendar and you can follow your weekly development and the development of your baby.

Demo Mode

In Demo Mode you can take a tour of the app. This is for demonstration purposes only, demo mode cannot provide you with any fertility information.

If you are currently on hormonal contraception you will access the app in Demo Mode. Once you stop using hormonal contraception you can then easily access the full version of the app. The app will now function for contraception or for planning a pregnancy.

Problems/ Troubleshooting

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

1. Use protection, such as a condom or another form of barrier protection, until the error has been fixed.
2. Please contact our service desk via help.naturalcycles.com and our trained support agents will assist you.
3. Serious incidents involving this device should be reported both to Natural Cycles 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:
    a. the death of a patient, user or other person,
    b. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
    c. a serious public health threat;

Application Overview

Your fertility status for the day is shown through different views within the app.

Calendar tab

This tab provides the overview of today’s fertility and gives insights into the data logged in the past through various views as described below.

Today view
On this screen, you will get all of the info you need in one glance. A screen to enter your temperature pops up automatically when you open your app in the morning. Once you've entered your data, your fertility status will appear as a colored circle with additional information inside. Below the circle, you will see the weekly predictions. You can add or

update your input data, such as temperature, period, or LH tests, at any time by tapping the '+' icon.

Month view
Tap the "Month" tab in the calendar view to access the monthly view. Here you can see your predicted red and green days for the month, as well as when you are predicted to ovulate and have your period. These may change over time, so you should only rely on the information provided in the "Today" view for contraceptive or pregnancy planning purposes. You can easily access your past data by tapping on any past day.

History view
The "History" tab is a log of all the data that you've previously entered. Scroll up and down to view your temperature readings, all added data for each cycle day, as well as an extraction of your notes.

Graph view
The graph is a visualization of your temperature curve which will continue to develop as you measure throughout your cycle. Information about ovulation, period, and fertile days is also visible. Swipe from left to right to view your past cycles, and tap '3 cycles' or '6 cycles' to compare them to each other. You can also access the compare mode to compare your period and cycle length, temperature variation and ovulation window and day.

My Cycle tab

This view will give you an overview of your cycle data. You will see your cycle length and regularity, as well as a detailed analysis of the phases of your menstrual cycle - follicular and luteal phase.

Messages tab

These are gentle messages and useful information we send you, so you can get the very most out of your Natural Cycles experience. Messages are tailored to your unique cycle and are only sent if they are relevant to you. Learn more about your body, enjoy knowing about when your period is coming up, and more.

The messages can also contain instructions for better use of the app such as:

- If you enter a temperature that is unreasonably high or low, a message will inform you immediately to verify the entered temperature.
- If you enter that you had unprotected sex on a red day in the Natural Cycles application, it displays a cautionary message.
- An in-app message will be sent to you if your period is overdue and your temperature does not drop, as this indicates that you may be pregnant. The message will encourage you to take a pregnancy test.
- On some days, an in-app message will ask you to take an LH test. LH tests are optional to use but can help to increase the number of green days per cycle.

My Data tab

This tab will provide you with useful insights on your measuring and on the data that you put into the app. It will guide you through the journey of building a habit and will notify you along the way on your progress.

Learn tab

This is an entry point to all the educational content the app provides. Here you can learn about the menstrual cycle, how to notice patterns in your body and how well the algorithm knows you based on the data you provide.

Top menu

Under the top menu, you can access and manage all the information regarding your personal profile, the app and privacy settings, and your account including subscriptions. Here you can also manage whether or not you will get reminders about when to use protection, take an LH test, expect PMS, measure your temperature and check your breasts. Note that you must enable Natural Cycles to send you push notifications in your device settings to receive these.

Offline mode

When you are offline you can continue to add your temperature and other data to the app. When offline, the app does not calculate your fertility status. Instead, the app will show an orange outlined circle indicating your status as “Use protection”. Use protection (such as condoms or another form of barrier protection) or abstain until you are back online and the app has calculated today’s fertility status.

Platform description

Natural Cycles Application Version: 4.1.2 and onwards
Medical Device version: C

Devices that may be used to access the application:

- A mobile phone running Android OS (version 7 or above) or iOS (version 13 or above), 250 kbps or faster internet.
- A computer or tablet with an Internet browser: Google Chrome, Apple Safari. 250 kbps or faster internet.

Accessing the Instructions for Use

The Instructions for Use can be found online on the Natural Cycles website and in your app under the “Regulatory” page.
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.

Cease using Natural Cycles

When you sign up for Natural Cycles, whether it's for a Monthly or Yearly subscription, you will need to cancel it if you don't want your subscription to be automatically renewed for the next renewal period. Cancellation of your subscription must be done at least 24 hours before the subscription is scheduled to be renewed. Please refer to help.naturalcycles.com for a full description on how to cancel your subscription successfully. Please refer to our Privacy policy for further information on how Natural Cycles processes your data.

Security

Natural Cycles maintain a high security and data privacy level in our application. The application is monitored for security events and data breaches. If a security event or data breach should occur, the issue will be contained and resolved with urgency according to our established processes and you as a user will receive the information you need regarding your continued safe and secure use of the application.

It is strongly recommended that you choose a strong password to protect your account from unauthorized use. While not recommended, if you should 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 and contacting support in order to close existing sessions.

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

General information

Explanation of symbols

 Manufacturer

CE 0123 CE Mark

 Caution

 User Manual/Instructions for Use

EC Declaration of Conformity

Name of the Manufacturer:
NaturalCycles Nordic AB

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

Customer support:
help.naturalcycles.com

Device Name:
Natural Cycles

We declare that this product meets all applicable requirements of the Regulation (EU) 2017/745for medical devices (MDR) and bears the mark CE0123.

Date of publication:
March 2021

Document version:
EU & US v2.15

APPENDIX: This table provides information about the effectiveness of different contraceptive methods ranging from least effective to most effective under typical use.
Reference: Contraceptive Technology (Table 26 - 1). 21st Edition, 2018.

Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year. United States.

Method	% of women experiencing an unintended pregnancy within the First Year of Use		% of women continuing use at one year[3]
	Typical use[1]	Perfect use[2]	
No method[4]	85	85	
Spermicides[5]	21	16	42
Female Condom[6]	21	5	41
Withdrawal	20	4	46
Diaphragm[7]	17	16	57
Sponge	17	12	36
Parous Women	27	20	
Nulliparous Women	14	9	
Fertility awareness-based methods[8]	15		47
Ovulation method[8]	23	3	
TwoDay method[8]	14	4	
Standard Days method[8]	12	5	
Natural Cycles[8]	8	1	
Symptothermal method[8]	2	0.4	
Male condom[6]	13	2	43
Combined and progestin-only pill	7	0.3	67
Evra patch	7	0.3	67
NuvaRing	7	0.3	67
Depo-Provera	4	0.2	56
Intrauterine contraceptives			
ParaGard (copper T)	0.8	0.6	78
Skyla (13.5 mg LNG)	0.4	0.3	
Kyleena (19.5mg LNG)	0.2	0.2	
Liletta (52mg LNG)	0.1	0.1	

Mirena (52mg LNG)	0.1	0.1	80
Nexplanon	0.1	0.1	89
Tubal occlusion	0.5	0.5	100
Vasectomy	0.15	0.1	100

Emergency Contraceptives: Use of emergency contraceptive pills or placement of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.[9]

1 Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason other than pregnancy. Estimates of the probability of pregnancy during the first year of typical use for fertility awareness-based methods, withdrawal, the male condom, the pill, and Depo-Provera are taken from the 2006–2010 National Survey of Family Growth (NSFG) corrected for under-reporting of abortion. See the text for the derivation of estimates for the other methods.

2 Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method

3 Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

4 This estimate represents the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether. See text.

5 150 mg gel, 100 mg gel, 100 mg suppository, 100 mg film.

6 Without spermicides.

7 With spermicidal cream or jelly

8 About 80% of segments of FABM use in the 2006-2010 NSFG were reported as calendar rhythm. Specific FABM methods are too uncommonly used in the U.S. to permit calculation of typical use failure rates for each using NSFG data; rates provided for individual methods are derived from clinical studies. The Ovulation and TwoDay methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19. Natural Cycles is a fertility app that requires user input of basal body temperature (BBT) recordings and dates of menstruation and optional LH urinary test results. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

9 However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

Version History

VER.	DATE	DESCRIPTION	
2.10	2018-08-07	Re-write according to FDAs input.	-
2.11	2019-02-05	Updated the warning #emergencypill. Added the new feature My Cycle view. Changes in languages after review from medical writer. Updates colors for plan a pregnancy mode.	-
2.12	2019-03-11	Updated the term 'calibration tool' to Thermometer Training guide. Updated the colors (green prevent and green plan)	-
2.13	2019-08-23	Minor updates of language, added the "Cease using Natural Cycles section" and demo mode section updated since free trial is not an option and users can't add data into demo mode anymore.	-
2.14	2019-10-22	Changes and clarification on When to measure and When to exclude temperatures. Changes described in "FOR1012 - Design Review - Communication on excluding measurements". Removed a statement in "Natural Cycles may not be right for you if" section duplicated in Precautions. Clarified when to expect period after using contraceptive pill. Updated heading style and colour to align over document.	-
2.15	2021-03-01	New add data interface details added. Security information added in line with risks #525, #528, #236, #222. Information on access to the electronic and acquiring the IFU in paper format added. Information on how to report a serious incident added. New mode names; NC Birth Control, NC Prevent Pregnancy, NC Follow Pregnancy added. Minor updates on app navigation. Added a note on changing thermometer as a mitigation for more red days in line with risk #203. Updated medical device version. Updated OS supported.	The changes in the IFU are an effect of changes initiated for app, documented in design reviews and other development documentation, and from risk management. 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.
2.16	2022-03-17	Added Intended Target Population, Intended Use Environment, and Side-Effects sections as a result of Clinical Evaluation work. Updated iOS version requirement from 12 to 13.	The changes are a result of the clinical evaluation work. The iOS change is due to no longer supporting iOS version 12. 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	2022-03-17	DocuSigned by: Megan Callanan Signer Name: Megan Callanan Signing Reason: I am the author of this docu Signing Time: 2022-03-17 | 2:23:12 PM CET 246ADC039ABE4BE7B44E18DDB27D83E
REVIEW & APPROVAL	Elina Berglund	CEO	2022-03-17	DocuSigned by: Elina Berglund Signer Name: Elina Berglund Signing Reason: I approve this document Signing Time: 2022-03-17 | 2:16:14 PM CET AADDC65741994678893901 71DD22BD14
REVIEW & APPROVAL	Jack Pearson	Head of Medical Affairs	2022-03-17	DocuSigned by: Signer Name: Jack Pearson Signing Reason: I approve this document Signing Time: 2022-03-17 | 2:47:05 PM CET 2312022B8D334954B0CABAE40D19B5DC
REVIEW & APPROVAL	Magda Chelstowska	Product Owner	2022-03-17	DocuSigned by: Magda Chelstowska Signer Name: Magda Chelstowska Signing Reason: I approve this document Signing Time: 2022-03-17 | 7:17:43 AM PDT 13FE291423C94C3EB2299A8E53312510
RELEASE	Megan Callanan	Regulatory & Compliance Manager	2022-03-17	DocuSigned by: Megan Callanan Signer Name: Megan Callanan Signing Reason: I release this document Signing Time: 2022-03-17 | 3:21:43 PM CET 246ADC039ABE4BE7B44E18DDB27D83E