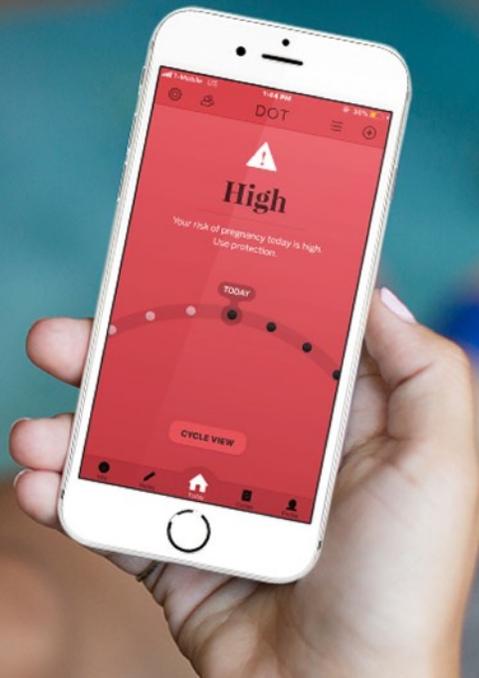


DOT

FERTILITY TRACKER

USER MANUAL / INSTRUCTIONS FOR USE



Please read this manual before you start using DOT.

INDICATIONS FOR USE

The DOT Fertility app [DOT] is a stand-alone software application intended for women 18 years of age and older to monitor their fertility. DOT can be used for preventing pregnancy (contraception) or planning pregnancy (conception), or for cycle and period tracking.

CONTRAINDICATIONS

There are no known contraindications for use of DOT.

DOT 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 DOT 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.
- You have irregular menstrual cycles that are shorter than 20 days, longer than 40 days, or vary in length by more than 9 days from shortest to longest cycle. Irregular cycles result in DOT determining a larger number of days during the cycle with pregnancy risk. This would mean many days of requiring use of a barrier method, like condoms, or avoiding sexual intercourse. This could reduce your satisfaction with DOT as a contraceptive method.

WARNINGS

- ⚠ No method of contraception is 100% effective. DOT does not guarantee that you cannot get pregnant. DOT informs you of your pregnancy risk for each day of your cycle based on the information that you enter and fertility data that is already loaded in the application.
- ⚠ Even when using DOT perfectly, you can still have an unintended pregnancy. DOT is 95% effective with typical use, which means that 5 women out of 100 will become pregnant during one year of use. With perfect use, DOT is 99% effective. This means that when never having unprotected intercourse on High risk days, 1 woman out of 100 will become pregnant during one year of use.
- ⚠ On High risk days, you must either abstain from sexual intercourse or use a barrier method for protection, such as condoms, to prevent pregnancy. Make sure to have a method on hand to use during High risk days.
- ⚠ If you are transitioning to DOT from hormonal contraception, you are at risk for pregnancy during the waiting time required to start with DOT. Use barrier protection, such as condoms during the transition time to prevent pregnancy. See Instructions for Special Circumstances below.
- ⚠ DOT does not protect against sexually transmitted infections (STIs). Use a condom to protect against STIs.
- ⚠ Always check your pregnancy risk for the day. If you can't access your device with the DOT app on it and are unsure of your pregnancy risk, abstain from sexual intercourse or use protection in the meantime.
- ⚠ **If you are using DOT to prevent pregnancy, make sure that the DOT mode is set to Prevent Pregnancy.** (see Image 1: Profile screen)

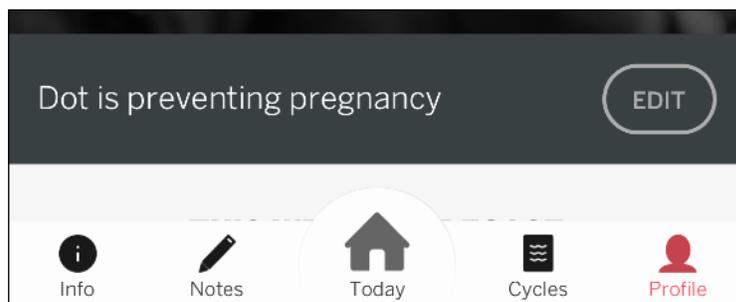


IMAGE 1: PROFILE SCREEN

- ⚠️ If you have used emergency contraception in the cycle prior to starting DOT, wait until your next period to begin using DOT.
- ⚠️ If you use emergency contraception while using Dot, it may affect the length of the cycle in which you took it. If this happens, ask Dot to ignore that cycle, then enter the start date when you get your next period and use DOT normally again.
- ⚠️ If your period is delayed by more than one week from the date predicted by Dot after using emergency contraception, it is recommended you take a pregnancy test.

PRECAUTIONS

- As a contraceptive, DOT can accommodate a range of cycle lengths. You can use DOT for effective pregnancy prevention, if your cycles are at least 20 days long and no more than 40 days long, and the difference between the shortest and longest cycles is less than 10 days. If you have a cycle outside of this range, DOT should not be used for pregnancy prevention. DOT monitors your cycle regularity and will display a message, if you have a cycle outside the range. DOT will also switch your mode of use to “Tracking” when your cycle pattern shows you should not use DOT for pregnancy prevention.

See Start-up Instructions for Special Circumstances in the next section below for how to be using DOT for special circumstances:

- When you start using DOT, it will take a few cycles for DOT to customize to your unique cycles. This results in up to 16 days determined as High risk in your first 1 to 3 cycles. This is to ensure that the app is effective from the first day of use. DOT will begin to narrow the number of days as soon as the second cycle and will continue to narrow the number of High risk days based on your unique cycles.
- Always make sure to keep DOT updated, so that you have the latest version. DOT recommends that you set your smartphone to update the app automatically.

CHECKLIST

To get started with DOT you will need the following:

1. A smartphone, either iOS or Android.
2. A wifi connection for downloading the app from either the iTunes App Store or the Google Play Store. You will not need a wifi connection thereafter to use the DOT app.

CONTRACEPTION: PREVENT A PREGNANCY

How it works

1. After downloading the DOT app, go through the screener to get started.
2. Select the mode of use: Prevent Pregnancy.
3. Enter your most recent period-start date. If you do not know it, wait until you get your next period, then enter the start date. DOT will determine the pregnancy risk for each day of your cycle. On days when there is high enough risk for pregnancy to be possible, DOT displays the word HIGH and a red screen color. When the risk of pregnancy is very unlikely, DOT displays the word Low and a blue/green screen color.
4. To prevent pregnancy, use barrier protection, such as condoms, or abstain from sexual intercourse on days marked HIGH. Under the word High, DOT displays the phrase "Use protection". (See *Image 2: Today Screen*)

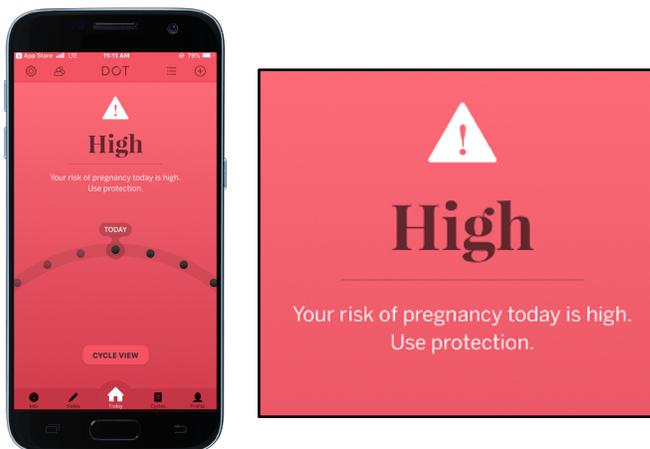


IMAGE 2: TODAY SCREEN

You can view all the days of the cycle on the Today screen by tapping on "CYCLE VIEW". Press your finger on the dots of the cycle and drag around the circle to view the cycle day numbers and the High/Low designation. The days can also be viewed in a calendar format by tapping on the "Cycles" screen. The High risk days are bolded on the calendar. The Low risk days are unbolded numbers.

CONTRACEPTIVE EFFICACY STUDY

A full-scale clinical trial was conducted to test the effectiveness of using DOT for pregnancy prevention. This study followed 718 women for up to 13 cycles from February 2017 to October 2018. Participants provided data on 6,616 cycles which included detailed information on sexual activity and behavior throughout the study.

The study found that when used correctly, DOT is 99% effective in preventing pregnancy. In typical use, when the method is not always used perfectly, DOT is 95% effective.

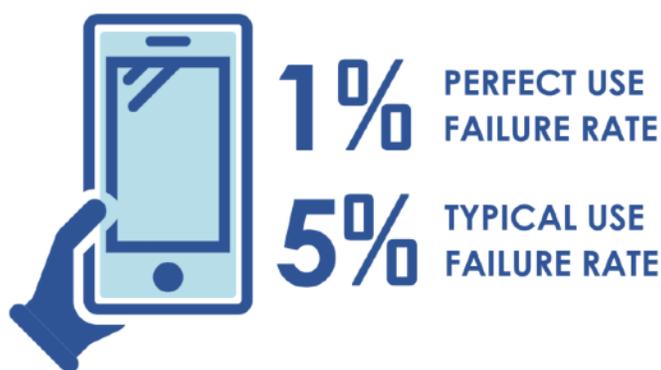
Dot has a perfect use failure rate of 1% which means that 1 out of 100 women who use the app for one year and who get pregnant will do so either because:

- a. They had unprotected intercourse on a low risk (green) day that was falsely attributed as “low risk” (i.e., method failure); or
- b. They had protected intercourse on a high risk (red) day with a condom, but the condom failed.

Dot has a typical use failure rate of 5% which means that in total 5 women out of 100 get pregnant during one year of use due to all possible reasons:

- a. They had intercourse without a condom on high risk days;
- b. They had intercourse with a condom on a high risk day and the condom failed; or
- c. The algorithm incorrectly identified a day as low risk when it was high risk and the user had unprotected sex on this day.

See the published research article for additional information about the results of the **Dot Contraceptive Efficacy Study**.



START-UP INSTRUCTIONS FOR SPECIAL CIRCUMSTANCES

Special Considerations for Getting Started	Instructions Provided
Breastfeeding	If you have recently been breastfeeding, as soon as you have your first period you can begin using Dot to track your cycles. Continue using Dot for tracking for four periods (three cycles). To prevent pregnancy during this time, use condoms or another effective back-up method. When you get your fourth period, reset Dot and use normally.
Recently Pregnant – Carried to Full Term	Use Dot to track your cycles when they return for four periods (three cycles). To prevent pregnancy during this time, use condoms or another effective back-up method. When you get your fourth period, reset Dot and use normally.
Recent Miscarriage	Wait until you have had three periods (two cycles) to begin using Dot. Use Dot to track your periods. To prevent pregnancy during this time, use condoms or another effective back-up method. When you get your third period, reset Dot and use normally.
Recent Abortion	Wait until your next period to begin using Dot. Use condoms or another effective back-up method until this time.
Birth Control Pill/Vaginal Ring/Birth Control Patch	Use Dot to track your cycles until you have had three periods (two cycles) after discontinuing any of these methods. If you are preventing pregnancy, use condoms or another effective back-up method while you wait for your third period. When you get your third period, reset Dot and use normally.
Birth Control Shot	Wait until the protection period of the shot has ended, then use Dot to track your cycles for three periods. If you are preventing pregnancy, use condoms or another effective back-up method until you get your third period. When you get your third period, reset your Dot app and use normally.
Hormonal IUD	Use Dot to track your cycles until you have had three periods (two cycles) since removal of your hormonal IUD. If you are preventing pregnancy, use condoms or another effective back-up method while you wait for your third period. When you get your third period, reset your Dot app, and use normally.
Emergency Contraception	If you have used emergency contraception this current cycle, wait until your next period to begin using Dot. In the meantime, use condoms or another effective back-up method while you wait. If you use emergency contraception while using Dot, it may affect the length of the cycle in which you took it. If this happens, ask Dot to ignore that cycle then enter the start date when you get your next period and use Dot normally again.
Non Hormonal IUD	If you have a non-hormonal IUD removed, you can begin using Dot as soon as you have your next period. Use condoms or another effective back-up method until this time.

MEDICAL CONDITIONS AND USING DOT

- If you have a medical condition that causes irregular cycles, such as polycystic ovarian syndrome (PCOS) or thyroid-related conditions, you can use DOT as long as your cycles remain in the cycle-length range of 20 to 40 days with fewer than 10 days difference between shortest and longest cycles. If your cycles fall outside this range, then DOT should not be used for pregnancy prevention.
- If you experience symptoms of menopause, you can use DOT as long as your cycles remain in the cycle-length range of 20 to 40 days with fewer than 10 days difference between shortest and longest cycles. If your cycles fall outside this range, then DOT should not be used for pregnancy prevention.

IF YOU BECOME PREGNANT WHILE USING DOT

If your period is overdue by a week past the predicted next period start, you may be pregnant. The recommendation is to take a pregnancy test to confirm pregnancy. If the test is negative and you don't get your period after another 2 to 4 days, you should take another pregnancy test in case the first test was taken too early to detect the pregnancy. If the test is positive, consult with your doctor or healthcare provider. If the test is negative and you still do not get your period, consult with your doctor or healthcare provider.

PLANNING A PREGNANCY

When you are trying to conceive, select "Plan a pregnancy" mode during the start-up process. If you are already using DOT, you can go to your Profile screen and edit the mode of use to "Plan a pregnancy". In Planning mode, DOT also displays High, Medium, and Low chance of pregnancy. The screen colors are red, orange, and green respectively.

The guideline when trying to conceive with DOT is to have frequent intercourse (2-3 times per week) during the High and Medium days for 1 to 6 months. For some couples, conception can take up to a year. However, if you are not pregnant after six months, it is recommended to consult your doctor or healthcare provider for a fertility evaluation.

WHEN TO TAKE A PREGNANCY TEST

Take a pregnancy test if your period has not started by a week after the predicted start date. If a first test is negative and you still do not get your period after another 2-4 days, take a second test in case the first test was taken too early to detect pregnancy. Consult with your doctor or healthcare provider about the results.

DOT PREGNANCY MODE

When you become pregnant, go into DOT's Settings and switch the app to Pregnancy Mode. DOT will display an estimated due date based on your last period start date and a countdown to delivery. You can edit the due date if you receive a revised due date from your doctor. Other DOT functions will be put on hold during the duration of your pregnancy.

To exit pregnancy mode, tap the bottom of the screen.

TROUBLESHOOTING

If you experience a problem using DOT, please use the contact form through the app. Go to Settings, then tap on Report An Issue. Include your email address so that a response can be sent to you. If you have a question about the dates you have entered in the app, be sure to have the "Include cycle info" button turned ON. You can also report a problem by email. Contact the DOT team at hello@DotTheApp.com.

APPLICATION OVERVIEW

Display of Pregnancy Risk or Pregnancy Chance

Once you've entered your period-start date, DOT displays your current pregnancy risk or pregnancy chance in three locations. The primary display is on the Today screen. When in Preventing Pregnancy mode, the Today screen displays pregnancy risk as High with red screen or Low with green screen. It also reinforces this information with symbols (a thumbs-up symbol for low risk and a caution symbol for high risk). The Today screen is the default screen for the app.

In Planning Pregnancy mode, the Today screen displays pregnancy chance as High with green screen, Medium with orange screen, and Low with red screen. In Tracking Cycles mode, the Today screen displays pregnancy risk as High with red screen, Medium with orange screen, and Low with green screen. Both screens also reinforce this messaging with symbols.

The other two locations of showing pregnancy risk or chance are on the calendar in the Cycles screen and on the bar calendar in Notes. On the calendars, the dates of High and Medium days are bolded on the calendars. Days with Low pregnancy risk or chance are not bolded.

CYCLE HISTORY

You can view all of your cycles in List View. Find the List View icon in the upper right of the Today and Cycles screens. In List View swipe to see each cycle. You can view period-start and end dates and notes that have been entered through the Notes screen.

In List View, you can edit or delete start and end dates and use the Ignore function for cycles.

To edit cycle dates, tap on the edit icons, tap the desired date on the calendar, then save.

To delete or use the ignore function, press your finger on the start date and pull downward. The screen will reveal the options to Delete and Ignore. Select the desired option and follow the prompts to complete the action.

PROFILE SCREEN

The Profile screen allows you to edit DOT's mode of use. On this screen you can also view your week's forecast for chance of pregnancy, your estimated ovulation date, your cycle-length range for the past year, and your period-start predictions for the next six months.

DOT PRO

DOT Pro is an in-app purchase that give you extra features, including the ability to sync with your outside calendar, use different color palettes, and share information with your partner.

NOTIFICATIONS

DOT sends notifications on key cycle days, including notifications when your fertile days begin and end, notifications of when to expect your next period, and reminders to entry the new period-start date.

Notifications can be turned on and off. Go to Settings and tap Manage Notifications. Turn notifications on or off as well as set the time you'd like to receive them.

IN-APP MESSAGING

DOT monitors your cycle lengths and will send an in-app message if your cycles fall outside of the recommended range for using DOT.

HEALTH ALERTS

DOT monitors your cycle pattern and will display a health alerts if your cycles indicate a possible health issue.

APPENDIX:

This table provides information about the effectiveness of different contraceptive methods ranging from least effective to most effective under typical use.

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	
Dynamic Optimal Timing™ (DOT™) ⁸	5	1	
Symptothermal method ⁸	2	0.4	

METHOD	TYPICAL USE ¹	PERFECT USE ²	
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 (13.5mg 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	0.5	0.1	100

REFERENCES:

- *Contraceptive Technology*. 2019. (Table 26-1) 21st edition.
- Jennings V, Haile L, et al. 2019. *Perfect- and typical-use effectiveness of the Dot fertility app over 13 cycles: results from a prospective contraceptive effectiveness trial*. *The European Journal of Contraception and Reproductive Health Care*. 24:2, 148-153

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. Dynamic Optimal Timing is an algorithm-based fertility app that uses biological parameters, fertility data sets, and requires user input of menstruation start dates. 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.

PLATFORM DESCRIPTION

DOT Application Versions iOS 10.1 and onwards and Android 4.3 and onwards.

Medical Device version: B

Devices that may be used to access the DOT application:

- A mobile phone running Android OS (version 4.3 or higher) or iOS (version 10.1 or higher)
- A tablet running Android OS (version 4.3 or higher) or iOS (version 10.1 or higher).

GENERAL INFORMATION

Explanation of symbols



Manufacturer



Caution

Name of Manufacturer:

Cycle Technologies Inc.

Address of Manufacturer:

5335 Wisconsin Avenue NW, Ste. 440, Washington, DC, USA 20015

Customer support:

hello@DotTheApp.com

Device Name:

DOT Fertility

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