



CLEARBLUE FERTILITY MONITOR

The most advanced home method to help women maximize their chances of getting pregnant naturally¹⁻⁵



Clearblue Professional Series

FERTILITY



About Clearblue

Clearblue® is the world's number one selling brand in home pregnancy and fertility tests.[†] Consumers trust the Clearblue brand because it delivers the accurate information they want. The Clearblue product range is built on a strong foundation of peer-reviewed science and consumer understanding. Clearblue products are also trusted and recommended by doctors,* many of whom recognize that Clearblue is supported by 30 years of expertise, quality, and innovation in consumer diagnostics.

[†] Based on international sales in nearly 20 countries compiled using independent market research data.
^{*} Data on file. Research into recommendations of Ovulation Tests & Fertility Monitors with 204 US Ob-Gyns (Kantar Health, 2011).

Clearblue Fertility Monitor, technology in the palm of her hand

Today's busy lifestyles mean women often wish to actively plan their families and expect pregnancy to happen quickly. There are, however, a limited number of days in each cycle when a woman can become pregnant.² Many women are unaware of the timing of their fertile window, or miscalculate when it occurs.⁶ This means they may be missing the times at which intercourse would give the highest chances of conceiving.

The Clearblue Fertility Monitor is designed to accurately identify the entire fertile window;^{7†} this information can help women get pregnant faster, naturally.^{1-5*} It consists of a hand-held Monitor and disposable Test Sticks. It identifies changes in urine levels of two key hormones that control fertility to typically identify up to six fertile days; this is four more than traditional ovulation tests, which only detect luteinizing hormone (LH).

The Clearblue Fertility Monitor now has an intuitive touch screen display and other features that make it an effective and easy-to-use aid for women trying to conceive.

The Monitor:

- Accurately and reliably identifies more fertile days than traditional ovulation tests that only measure LH
- Uses urine Test Sticks which contain a dual-hormone assay to detect changing levels of estrone-3-glucuronide (E3G),** a urinary metabolite of estradiol, and LH
- Identifies and displays the user's daily fertility status: Low, High or Peak
- Displays the result on screen and stores it for future reference once the user has performed a test
- Allows the user to input additional personal information, such as dates of intercourse and menses
- Stores six cycles of information, if available, which can be displayed as a summary chart and shared with healthcare professionals.



[†] Number of fertile days will vary. In a German study of 149 cycles, Monitor results correlated with serum hormone levels and ultrasound-observed ovulation.
^{*} Using the Clearblue Fertility Monitor to identify a woman's most fertile days can help her get pregnant faster than not using any method.
^{**} Estrone-3-glucuronide (E3G) is a principal metabolite of estradiol which is recognized by the World Health Organization (WHO) as the best parameter for identification of the onset of the fertile phase.⁸ The urinary levels of E3G correspond to the serum levels of estradiol.⁹

The fertile window typically lasts for 6 days

The duration of the fertile window is determined by the viability of the sperm in the days preceding ovulation and the lifespan of the ovum. While it is generally accepted that sperm can survive for up to 5 days in sperm-supportive cervical mucus,² ova typically only survive for 12–24 hours after ovulation.^{10,11}

A study of 221 women found that the fertile window lasts for up to 6 days, from 5 days prior to the estimated day of ovulation to the estimated day of ovulation itself (Figure One). In this study, in every cycle in which conception occurred, there was intercourse at least once in this 6-day window. In contrast, the cycles in which intercourse occurred outside this time did not result in pregnancy.²

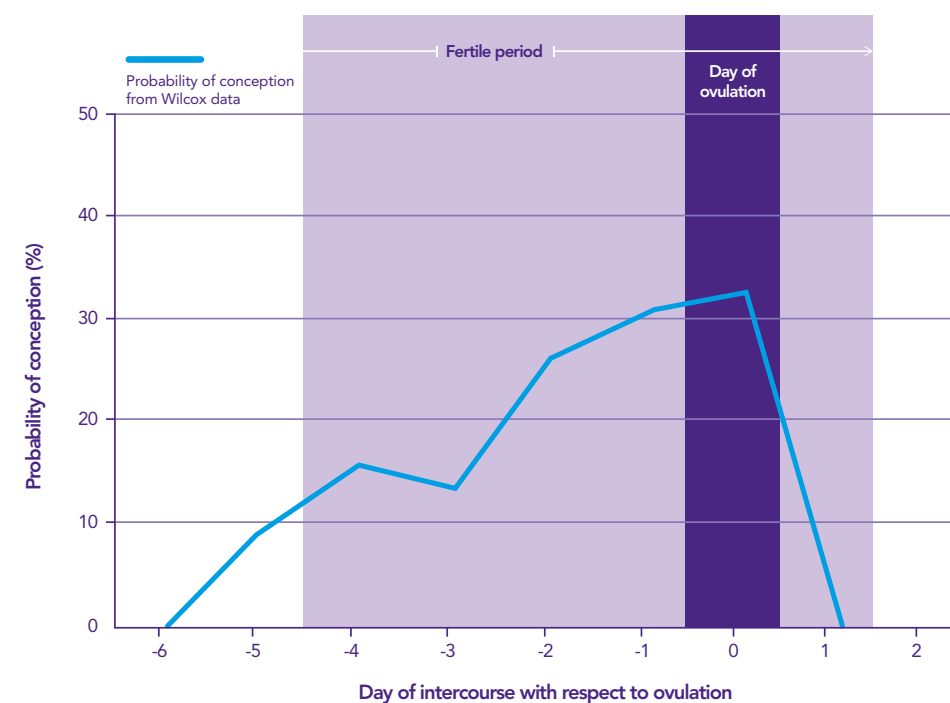


Figure One: Probability of conception with respect to day of ovulation. Data from ovulatory cycles in which a single act of intercourse led to pregnancy were used to calculate the probability of conception, and data from the statistical model applied to the ovulatory cycles examined in this study, n=625. Adapted from Wilcox AJ, *et al* (1996).²

The fertile window can be identified by tracking two key hormones

Changes in hormone levels control the fertile window

The menstrual cycle is controlled by the anterior pituitary gonadotropins (follicle-stimulating hormone and LH) and the gonadal sex hormones (estrogen and progesterone).¹² Changing plasma hormone levels throughout the menstrual cycle control ovum development and ovulation (Figure Two).^{12,13}

Plasma estradiol is the major physiological determinant of the onset of the fertile window; it stimulates secretion of cervical mucus that is favorable for the survival and transport of sperm. Estradiol levels gradually rise in the early stage of the woman's cycle, reaching a threshold that triggers a sudden increase in LH – the LH surge.¹³

The LH surge is the best indicator of impending ovulation; it causes the dominant follicle to rupture and release a mature ovum. Ovulation typically occurs 24–36 hours after the LH surge, and will not occur in its absence.¹⁴

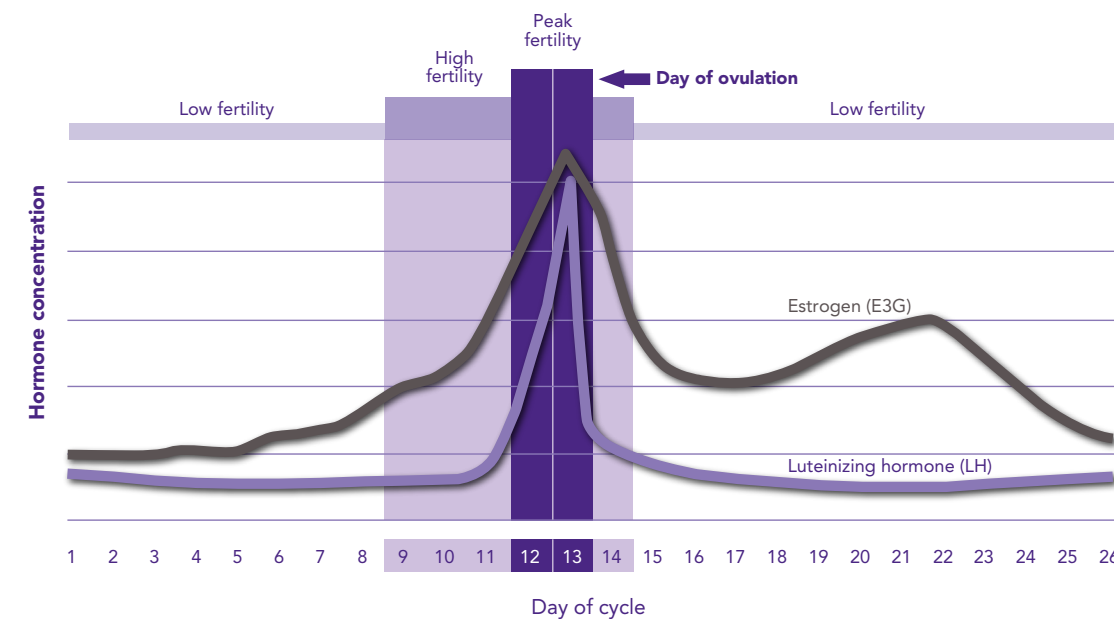


Figure Two: Schematic of typical hormone levels found in urine throughout the cycle.^{12,13}

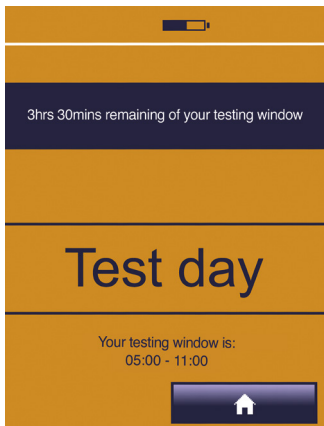
Identifying the fertile window by monitoring hormone changes through urine tests

The Clearblue Fertility Monitor uses patented technology which has been developed into a unique dual-hormone assay for E3G and LH. E3G is a principal metabolite of estradiol which is recognized by the World health Organization (WHO) as the best parameter for identification of the onset of the fertile phase.⁸ Urinary levels of E3G correspond to serum levels of estradiol.⁹

The Clearblue Fertility Monitor identifies days of high and peak fertility

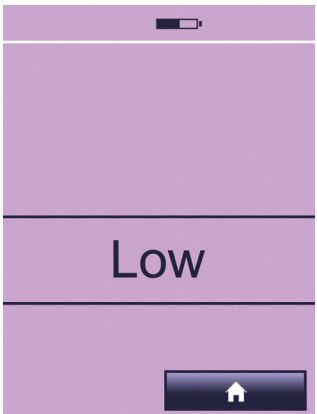
The Clearblue Fertility Monitor gives women comprehensive, personalized information that is unique to each cycle. It has an intuitive touch screen display that guides a woman through her cycle; it will prompt her when to perform tests and clearly displays the result.

The user sets a new cycle from the day her period starts. In cycle 1, the first test will be requested on day 6. The Monitor will then request a test every day for either 10 or 20 days, depending on cycle length and when it detects the LH surge. These testing days are clearly indicated to the user via the display of a Test day screen on the Monitor. In subsequent cycles, the first test day will vary between day 6 and 9, according to data collected in previous cycles; the user will still be asked for a test every day for 10 or 20 days.

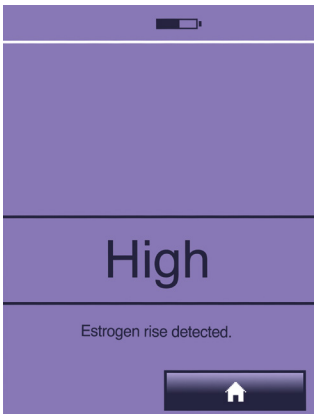


When prompted to perform a test, the user needs to unwrap a Test Stick and then either dip a Test stick in a urine sample collected in a clean, dry container for 15 seconds, or hold a Test Stick pointing downwards in her urine stream for 3 seconds. For both methods, urine from the first morning urination should be used for testing. The Monitor will automatically set a testing window from 05.00 to 11.00am (as urine tests need to be performed on the first morning urine) and the user can only perform a test during this 6-hour window. However, the user can change the timing of this testing window if they wish. After performing the test, the user should insert the Test Stick into the Test Slot for the Monitor to read the result. During this time a countdown screen will appear, and after 5 minutes the screen will display the result.

The Test Sticks contain monoclonal antibodies, conjugated to blue latex particles, which detect and identify E3G and LH in urine. After sampling, blue lines form on the Test Stick. The Monitor uses optical technology to measure the intensity of these blue lines to track the levels of E3G and LH present in the urine. A sophisticated algorithm collects this information, along with menstrual cycle characteristics, and transforms it into a simple-to-understand indicator of fertility level; this is displayed on screen as Low, High or Peak.



Low is displayed on days when it is unlikely, but not impossible, that intercourse will result in pregnancy.



High is displayed when the Monitor detects an elevated level of E3G and indicates that there is a higher probability that intercourse may lead to pregnancy. The Monitor will continue to display High on subsequent days until the detection of the LH surge.



Peak is displayed on the day of the LH surge and the following day; these are the two days when the chances of conceiving are highest.

To increase the chance of getting pregnant, it is beneficial to identify as many fertile days as possible. The screen on the Clearblue Fertility Monitor will display High when it first detects a rise in E3G, prior to the LH surge. For most women, the Clearblue Fertility Monitor will identify between 1 and 5 days of high fertility before they reach their peak fertility status. Informing a woman that her fertility status is high provides advance warning of her 2-day period of peak fertility; she can use this information to increase her chances of conception as intercourse on days of high fertility may also lead to pregnancy.

When the display on the Clearblue Fertility Monitor shows Peak, this indicates that the Monitor has detected the LH surge. Assay results from the Clearblue Fertility Monitor compare to serum hormone levels;⁷ in laboratory studies it was 99% accurate in detecting the LH surge in urine.¹⁵ Furthermore, in a clinical evaluation the Clearblue Fertility Monitor detected the LH surge in 96.6% of women.¹⁶

The Clearblue Fertility Monitor provides a more accurate indication of days of peak fertility than traditional home methods, including basal body temperature.¹⁷ In addition to prompting when to perform a test, the Monitor also records test results, together with dates when tests have been performed or missed, for future reference.

The Clearblue Fertility Monitor algorithm is clinically proven to predict ovulation

The technology used in the Clearblue Fertility Monitor has been shown to accurately predict ovulation compared with serum hormone measurements and vaginal ultrasound scans.¹⁶ In 150 cycles the measurement of urinary hormones by the Monitor correlated very closely to serum levels; ovulation was detected by ultrasound during two days of peak fertility in 91% of cycles (Figure Three).⁷

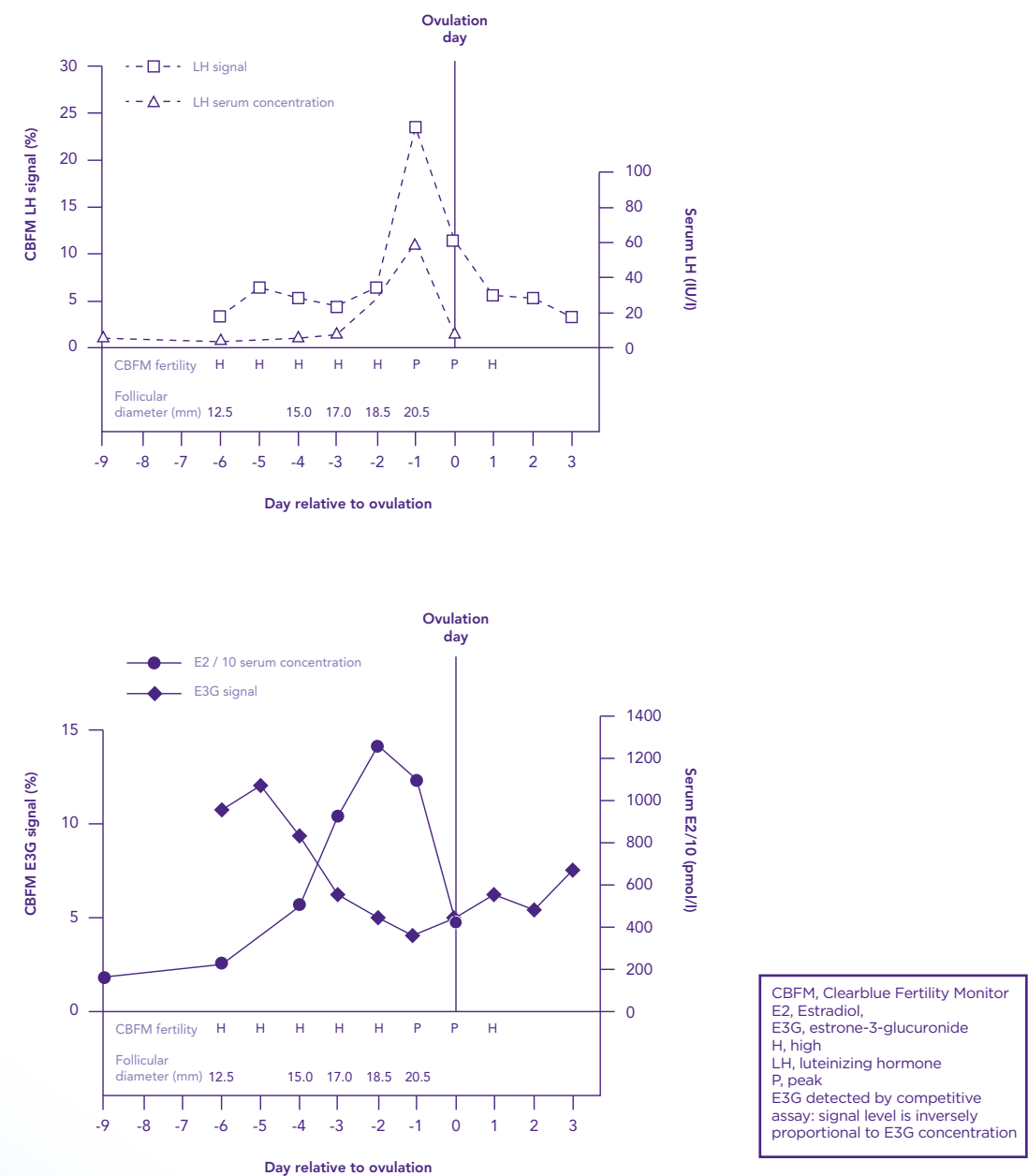


Figure Three: Ovulation prediction using serum hormone measurement, vaginal ultrasound scan and the Clearblue Fertility Monitor. Adapted from Behre HM, *et al* (2000).⁷

The importance of identifying the entire fertile window

There is a rational hypothesis that with fertility-focused intercourse, conception is likely to occur more quickly.^{2-4,18} Conception is most likely to occur when intercourse takes place on the day before, or day of ovulation,¹⁹ but conception is possible throughout the fertile window. Furthermore, it has been proposed that intercourse across the fertile period is more likely to lead to pregnancy than intercourse at peak fertility alone.¹⁹

In addition, couples may be unaware of the most appropriate time in their cycle to try to conceive. A study amongst women trying to get pregnant found that only 13% correctly estimated their ovulation day.⁶ In the same study only 55% of women provided an estimate of their day of ovulation that fell within their fertile window.

Identification of a woman's entire fertile window is important because:

- It gives women warning of their days of peak fertility to allow for better planning of intercourse to coincide with this window
- It notifies women of more fertile days and thus more opportunities to get pregnant naturally
- Women who know their entire fertile window have an increased chance of conceiving.⁴

The Clearblue Fertility Monitor is designed to identify the entire fertile window^{7†}

In a laboratory analysis of daily urine samples from 352 menstrual cycles, the mean duration of the combined days of high and peak fertility detected by the Clearblue Fertility Monitor was 6.01 ± 2.33 days. Of these menstrual cycles, all of which demonstrated an LH surge, 62% had between 3 and 6 days, and a further 23% had 7 or 8 days of combined high and peak fertility.²⁰

In a study of 54 couples who were seeking conception assistance, the Monitor identified a median of seven fertile days; more than 60% of cycles had between 1 and 5 days of high fertility, prior to peak fertility, over four cycles.²¹

[†] Number of fertile days will vary. In a German study of 149 cycles, Monitor results correlated with serum hormone levels and ultrasound-observed ovulation.

Further innovative features of the Clearblue Fertility Monitor

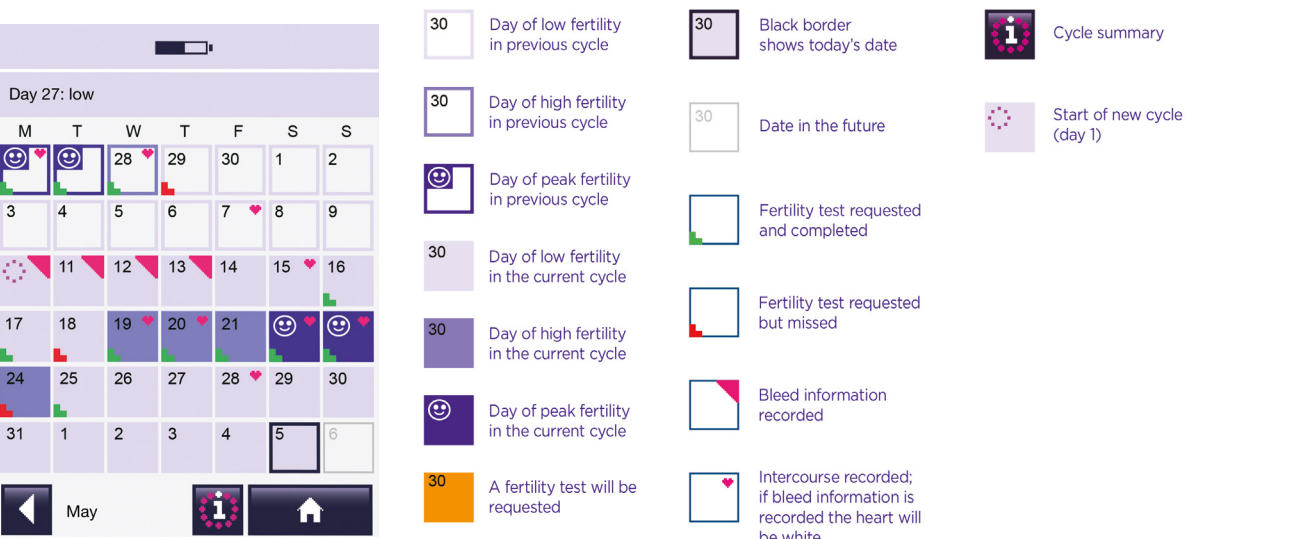
Additional information can be stored in the Clearblue Fertility Monitor:

- Days and levels of menstrual bleeding
- Intercourse events – these data are useful to enable the user to track whether she has been having well-timed intercourse.

All information recorded in the Clearblue Fertility Monitor is displayed on a monthly summary screen and cycle summary chart. Data for the previous six cycles (if available) can be stored and viewed. The user can then share and discuss this information with their healthcare professional if she does not become pregnant.

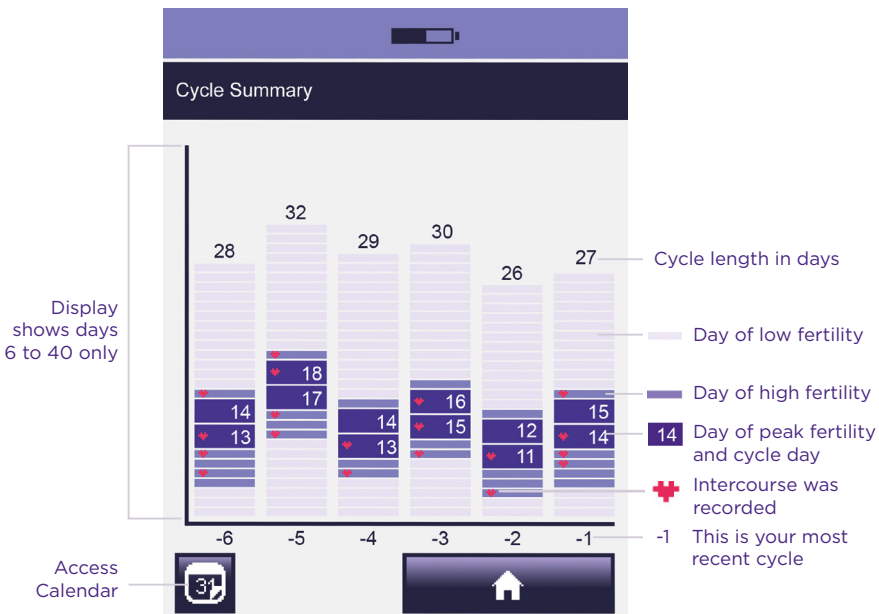
The Clearblue Fertility Monitor monthly summary screen displays the following pieces of information:

- Test days (missed, completed and required)
- Days of high and peak fertility
- Dates of intercourse and menstrual bleeding
- Cycle start day.



Example monthly summary screen and explanation of symbols

The cycle summary chart screen displays data from the previous six cycles (if available) in a graph format. It displays a summary of length of cycle and days of high and peak fertility, together with recordings for intercourse on days of high and peak fertility.



Example cycle summary chart

Additional user functionality

Additional user functions of the Clearblue Fertility Monitor include:

- Option to set a PIN which the user will be asked to enter each time the Monitor is switched on, to ensure privacy of personal data
- The user can set an alarm to remind them when to test:
🔔 This symbol will be displayed in the information bar to confirm an alarm has been set.

† Using the Clearblue Fertility Monitor to identify a woman's most fertile days can help her get pregnant sooner than not using any method.

Advantages of the Clearblue Fertility Monitor over other methods

The Clearblue Fertility Monitor has significant advantages over many other methods of aiding conception because it is designed to accurately identify the entire fertile window in real time, i.e. based on hormone changes vs. secondary effects of hormone changes.⁷

Calendar calculations are unreliable for the purpose of timing intercourse to conceive, because women's cycles are known to vary from cycle to cycle; the day of ovulation itself is therefore variable. In a study of 895 cycles from 101 women, which compared the calendar method with ovulation day calculated from the detection of urine LH surge, the calendar method was found to identify appropriate fertile days in only 35% of the cycles tested.²² This was thought to be most likely due to the variability in cycle length, as over 60% of the cycles in the data set varied by more than 2 days. Another commonly-used method to detect ovulation is **basal body temperature (BBT)**; this also has recognized limitations.²³⁻²⁷ Use of BBT identifies ovulation after the event, so a woman uses retrospective information to predict her next ovulation. The efficacy of this method is dependent upon very regular cycles. **Charting of vaginal discharge** can be used effectively to identify the fertile period, however many women find that the Clearblue Fertility Monitor is easier to use. Through the use of innovative technology, it is proven to have a positive impact on factors such as stress and anxiety for couples; this can improve their confidence that conception will happen.⁵

Ovarian follicular ultrasound by transvaginal scanning is highly accurate for identifying the approach and occurrence of ovulation, however it is a costly procedure with limited availability for routine use. The Clearblue Fertility Monitor has been shown to accurately predict ovulation when compared with serum hormone measurements and vaginal ultrasound scans.⁷

In a review of methods to time intercourse and achieve conception, the Clearblue Fertility Monitor was recommended as one of the most appropriate methods to identify the entire fertile window for the purpose of achieving pregnancy.⁷

Why recommend the Clearblue Fertility Monitor?

The Clearblue Fertility Monitor is a unique innovation in fertility management that women can use at home to increase their chances of conception.

The Monitor:

- Detects changes in urinary levels of E3G and LH to typically identify up to six fertile days, four more than traditional ovulation tests^{7,16}
- Accurately predicts ovulation when compared with serum hormone measurements and vaginal ultrasound scans⁷
- Is designed to accurately identify the entire fertile window for the purpose of achieving pregnancy^{7*}
- Is the only monitor that utilizes a direct measure of the fertile window[†] to give women advance notice of ovulation; this can help maximize their chances of getting pregnant
- Is able to help women get pregnant faster^{1-5**}
- Provides cycle summary information to assist healthcare professionals in assessing the fertility status of the user and potentially fast-tracking them to treatment if there is an obvious problem.

† Unlike other methods that rely on indirect detection, e.g. an increase in BBT.

* Number of fertile days will vary. In a German study of 149 cycles, Monitor results correlated with serum hormone levels and ultrasound-observed ovulation.

** Using the Clearblue Fertility Monitor to identify a woman's most fertile days can help her get pregnant sooner than not using any method.

For your patient, the Clearblue Fertility Monitor:

- Is suitable for women planning pregnancy that have cycles lasting between 21-42 days
- Accurately predicts ovulation^{7†}
- Clearly identifies their daily fertility status (low, high or peak)
- Helps them get pregnant faster*
- Now has an intuitive, easy-to-use touch screen
- Provides advance notification of the days to test each cycle, and of the date the next period is due
- Has an alarm to remind them when to test
- Has the ability to record days of menses and intercourse
- Can store up to six cycles of fertility information.

Ensuring effective performance

The Clearblue Fertility Monitor should not be recommended if the woman:

- Has experienced menopausal symptoms
- Is, or has recently been breastfeeding
- Has recently been pregnant (even if not carried to full term)
- Has impaired liver or kidney function
- Has polycystic ovary syndrome
- Is taking antibiotics containing tetracyclines
- Is, or has recently been undergoing treatments which will affect her cycle (e.g. hormonal contraception including emergency contraception, certain fertility treatments and hormone replacement therapy)
- Has been prescribed clomiphene citrate. This may elevate estrogen levels and may result in high fertility being noted early in the cycle and more high fertility days being displayed. In some cases the Fertility Monitor may not show peak fertility even when ovulation occurs.

† Clearblue Ovulation assay showed 97% agreement with ultrasound-observed ovulation.

* Using the Clearblue Fertility Monitor to identify a woman's most fertile days can help her get pregnant sooner than not using any method.

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[†] Studies conducted using the Clearblue Fertility Monitor. The chemistry used to detect E3G and LH in the Clearblue Fertility Monitor with touch screen and the methodology used to convert test signals to fertility status are the same as those used in the Clearblue Fertility Monitor.

Limitations of use

There are no products available that can guarantee success in achieving pregnancy. The Clearblue® Fertility Monitor has been designed to assist in conception. It must NOT be used for contraception. The Clearblue® Fertility Monitor is suitable for women whose natural cycle normally lasts between 21 and 42 days. If her cycles are always shorter than 23 days or are always longer than 37 days, it is possible that her LH surge may not be detected in some cycles. The majority of women will need 10 Test Sticks in each cycle. However, women with irregular or long cycles may have to use 20 Test Sticks in each cycle in order to detect their most fertile time. Certain personal circumstances, medical conditions and medications can adversely affect the performance of the Clearblue® Fertility Monitor. These include menopausal symptoms, breast feeding, impaired liver or kidney function, polycystic ovarian syndrome, antibiotics containing tetracyclines and treatments that might affect your cycle e.g. hormonal contraception, certain fertility treatments and hormone replacement therapy. Couples with medically diagnosed fertility problems should consult their physician before using this product. The Clearblue® Fertility Monitor is most suitable for women whose natural monthly cycle normally lasts between 21 and 42 days. Women who have recently been pregnant (even if not carried to full term), breastfeeding, or using hormonal contraception or any other treatment that might affect her cycle are advised to wait until they have at least two natural menstrual cycles in a row (each lasting 23 to 37 days) before using the Clearblue® Fertility Monitor. Refer to page 11 for further information.

About SPD Swiss Precision Diagnostics GmbH

SPD Swiss Precision Diagnostics GmbH is a world leader in the research, design, production and supply of advanced consumer diagnostic products. Clearblue® is trusted for its accuracy and simplicity by women keen to know more about their own reproductive health. SPD brands are acclaimed for their pioneering innovation: Clearblue was the first brand to introduce a one-step pregnancy test, a one-minute test, a urine sample indicator, digitally-displayed results and a weeks estimator feature.

At SPD, we are committed to helping people make informed decisions about their health and well-being, through a continuing flow of new and inventive developments. Our research centre is at the leading edge of innovation, and is fully engaged in the development of reliable diagnostic products for better health and personal self-care.

If you are a healthcare professional and wish to contact a member of the Clearblue support team about any product in the Clearblue range, please send an email to: spdproductsupport@spdspark.com

Alternatively, you can write to us at:
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The Clearblue Fertility Monitor is:

- Accurate** – results compare to serum hormone measurement and ultrasound scan[†]
- Unique** – provides daily fertility status by measuring two urinary hormones, E3G and LH, and providing a clear indication of fertility status (low, high or peak)
- Effective** – designed to accurately identify the entire fertile window^{7*} to help women to conceive more quickly^{**}
- Easy** – intuitive and easy-to-navigate touch screen
- Personalized** – monitors individual hormone levels and adapts based on last six cycles of data, if available
- Recommended** – Clearblue® is the number one ovulation brand recommended by OB-GYNs^{***}
- Trustworthy** – from Clearblue®, 30 years of experience make it the world's number one selling brand in home pregnancy and fertility tests^{****}

† Clearblue Ovulation assay showed 97% agreement with ultrasound-observed ovulation.

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*** Survey of 204 OB-GYNs in the US conducted by Kantar Health on recommendation of home ovulation tests and fertility monitors (2011).

**** Based on international sales in nearly 20 countries compiled using independent market research data.

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