



OvaCue[®]
FERTILITY MONITOR

Owners Manual

Welcome

Thank you for purchasing the OvaCue® Fertility Monitor!

Recommended by fertility specialists, this convenient, easy to use fertility monitor provides up to seven days advance notice of ovulation with 98% accuracy.

We are pleased that you are among the thousands of couples using the OvaCue Fertility Monitor to aid in conception.



www.ovacue.com

email: support@ovagraph.com

version #: 1607

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The OvaCue Fertility Monitor was developed to assist in conception. It must be used in accordance with the instructions contained in this manual. Use of this product does not guarantee success in achieving pregnancy. The OvaCue is an in vitro diagnostic medical device designed for home use. Store in a dry place at room temperature. Keep out of the reach of children. The OvaCue is not intended to be used to prevent pregnancy.

The Key to Conception: Understanding Your Cycle

You have decided that now is the time in your life to have a baby, but you might be learning that becoming pregnant is not as easy as you once thought. The OvaCue Fertility Monitor may help to increase your chances of conceiving by predicting your most fertile days up to seven days in advance. But, before you begin using your OvaCue, it is important to understand how your menstrual cycle works.

The menstrual cycle is the process during which your body prepares for pregnancy. It is regulated by a complex interaction of several key hormones, and for most women, lasts between 24 and 35 days. Your cycle begins with menstruation (day 1 of your cycle is the first day of your menstrual period), with ovulation occurring sometime close to the midpoint of your cycle.

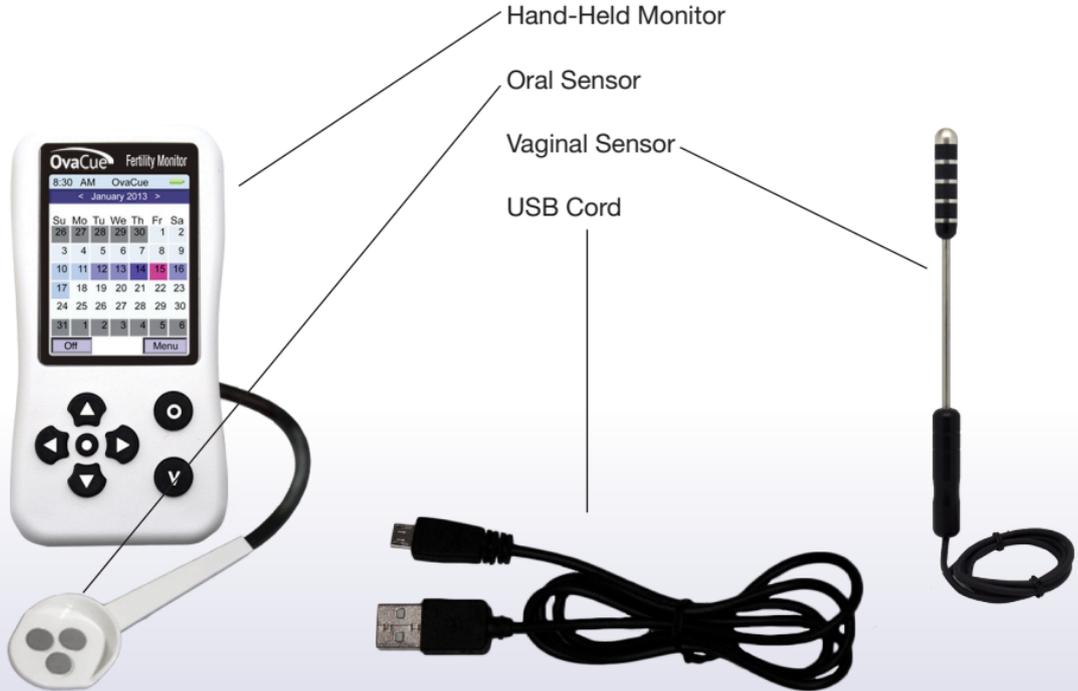
Ovulation is the process through which an egg is released from the ovary. Within the ovaries, each egg is stored in a fluid-filled cavity called a follicle. While both ovaries store many follicles, only one follicle (called the dominant follicle) is selected each month to release an egg. The maturation process of the dominant follicle occurs approximately 5-7 days before ovulation.

As the dominant follicle matures, the amount of estrogen produced in your body increases. At the same time, luteinizing hormone (LH) is produced and stored in the anterior pituitary gland. Just prior to ovulation, the anterior pituitary gland secretes a surge of LH, which causes the wall of the dominant follicle to weaken and rupture, thereby releasing the egg and propelling it into the opening of the nearby fallopian tube.

Once the egg is released from the follicle, the follicle cells transform into the corpus luteum, a glandular structure that secretes large amounts of progesterone. If the egg is fertilized (which must occur within 24 hours after ovulation), increasing amounts of progesterone are released. Progesterone acts to build the uterine lining for implantation of a fertilized egg and prevents menstruation. If conception does not occur, the corpus luteum will disintegrate towards the end of the menstrual cycle, progesterone levels will drop rapidly, and menstruation will occur.

By tracking changes in the concentration of electrolytes in your saliva, the OvaCue detects the hormonal changes that coincide with the maturation of the dominant follicle, and uses this information to predict the days you will be most fertile. With data collected by the vaginal sensor, the OvaCue detects the surge in estrogen that occurs just prior to ovulation, and the shift to progesterone dominance that occurs at ovulation. This information allows the OvaCue to help confirm the date of ovulation.

Description of Parts



How the OvaCue Works

The OvaCue Fertility Monitor predicts ovulation up to seven days in advance using the patented Electrolyte Method™ — a technique that has been demonstrated to be 98.3% accurate in predicting ovulation.

Here's how it works: The OvaCue consists of a hand-held monitor with a color screen, a spoon-sized oral sensor, and a vaginal sensor. Throughout your menstrual cycle, the electrolyte (minerals such as sodium and potassium) levels in your saliva and cervical mucus fluctuate as the hormone levels in your body change. Starting with Cycle Day 2, you will use the oral sensor each morning to measure the electrolyte levels in your saliva. The OvaCue will store the information gathered from these oral readings, track the changes in electrolyte levels in your saliva during your cycle, and process this information to precisely define your time of peak fertility.

Pinpoint Your Fertile Window!

Look for the blue days!

About a week before ovulation occurs, the OvaCue will identify a Cue Peak in your oral readings.

The Cue Peak is defined as a high oral reading followed by two lower oral readings. Once your Cue Peak is reached, the OvaCue can then predict, several days in advance, the day you will likely ovulate. This advance notice of ovulation will give you the best possible chance of conception. The OvaCue uses a calendar on the hand held-monitor to show your peak fertility days. After several days of taking oral readings, the OvaCue will begin to “color-in” the calendar, indicating possible fertility to high fertility days with light to dark blue colors.

Look for the pink day!

Once you begin using the vaginal sensor, the OvaCue tracks changes in the electrolyte levels in the cervical mucus, which allows the monitor to detect the switch from estrogen to progesterone dominance that accompanies ovulation. When this shift occurs, you will see an increase in the vaginal readings (called the Vaginal Rise) and a pink box will appear, indicating that ovulation has likely occurred. After the pink box is displayed, we expect to see the vaginal readings remain elevated to indicate ovulation was likely successful.



White: indicates not fertile

Light blue: indicates possible fertility

Medium blue: indicates high fertility (good day for intercourse)

Dark blue: indicates highest fertility (best day for intercourse)

Pink: indicates possible ovulation

Dark purple: indicates possible ovulation (see page 19 for more info)

Gray: indicates no readings were saved

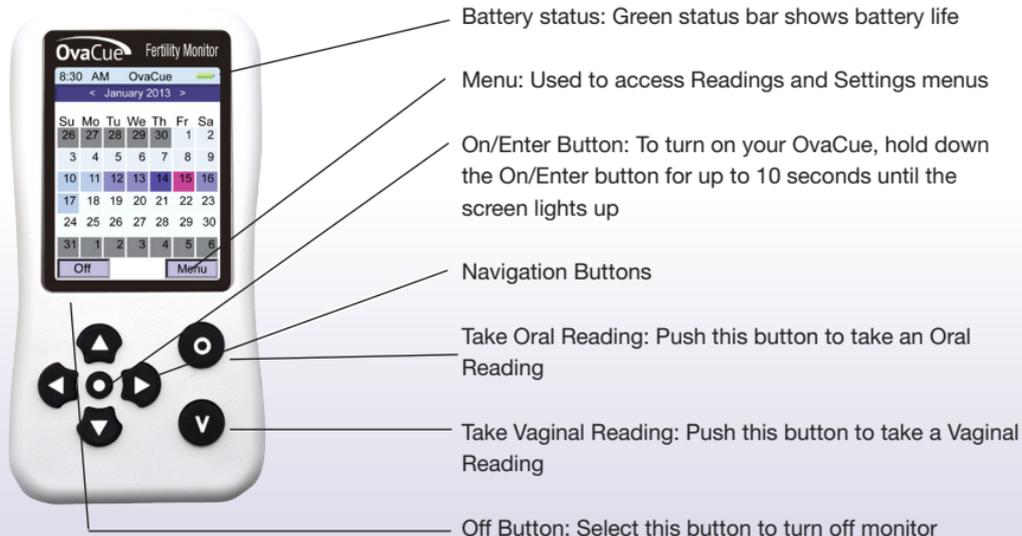
Yellow: Error

IMPORTANT: For the best chance of conception, plan intercourse for any blue, pink, or purple days.

Step by Step Guide

Now that you are ready to begin using your OvaCue, please read the following step by step instructions carefully.

IMPORTANT: You must start using your OvaCue on the second day (Cycle Day 2) of your menstrual period, or by Cycle Day 4 at the latest. Until then, take some time to familiarize yourself with how your OvaCue works.



Programming Your Personal Settings

Before you take your first oral reading on Cycle Day 2 (or Cycle Day 4 at the latest), you must program your personal settings.

1. Use the navigation arrows to select the **Menu** option and press the **Enter** button
2. Scroll down to **Settings** and press **Enter**
3. Enter your
 - Current cycle day (remember, this **MUST** be a number between 1 and 4)
 - Your average cycle length (the number of days between the start of one menstrual period to the day before the start of your next period, take the average of your previous 3 cycles)
 - Current date and time
 - Cycle day you start fertility medications*
 - Language

To save each of these values, select the item you intend to modify by pressing **Enter** (the entry will blink), scroll up or down until you have the desired value, then press **Enter** again (entry will stop blinking).

*If you have been prescribed an ovulation stimulation medication (for example, Clomid™ or Femara™) please enter the cycle day that you will begin taking the medication. If you are not taking a prescription ovulation stimulation medication, leave the setting at 0.

Starting a new cycle

Once a new cycle begins, you must reset your settings and let the monitor know that you have started a new cycle. Please navigate to the settings, and reset your current cycle day (must be on Cycle Day 1-4). At this time, you can change your cycle length as well. Make sure you update your settings before you take your first reading for your new cycle. **IMPORTANT:** You cannot adjust settings mid-cycle so make sure all of your settings are correct before beginning a new cycle!

Taking an Oral Reading

IMPORTANT: You must begin taking oral readings on Cycle Day 2, or by Cycle Day 4 at the latest. You may take your first reading on Cycle Day 1 — however, most women are not aware first thing upon waking that they are on Cycle Day 1.

1. Once you've inputted your settings, turn on the monitor, plug in your oral sensor making sure it clicks into place, and press the "O" button.
2. Place sensor in your mouth, pressing it on your tongue with the silver sensors facing down and hit **Enter**.
3. After about 2-3 seconds your oral reading will appear, remove the sensor.
4. Save the reading by pressing the **Enter** button.
5. Clean your sensor with mild soap and water.

IMPORTANT: Once your first oral reading has been taken and saved successfully, the current day (and previous days in your current cycle) on your calendar will change from dark grey to white. For example, if you took your first reading on Cycle Day 3, Cycle Day 1-3 will show as white on the calendar. If this does not occur, your reading may not have been saved correctly.

Oral Sensor Dos:

- Start taking your readings on Cycle Day 2, or by Cycle Day 4 at the latest.
- Take your oral readings first thing in the morning, about the same time every day.
- Take your oral readings before you eat, drink, smoke or brush your teeth. Putting anything in your mouth before you take your reading will stimulate your salivary glands to produce more saliva, which will impact the electrolyte levels in your saliva and affect the readings.
- Take your oral reading every day until you ovulate or return to non-fertile days.

Oral Sensor Don'ts:

- Don't take several readings on the same day. If you do, the readings may be quite different and could impact the ability of the OvaCue to make an accurate fertility prediction.
- Don't miss a reading. Depending on which cycle day is missed, the OvaCue may not be able to detect the trends in readings it is looking for and may not provide an accurate prediction.
- Don't use sodium based antacids from Cycle Day 1 through ovulation

Taking a Vaginal Reading

IMPORTANT: To confirm ovulation with the vaginal sensor, you must begin taking vaginal readings each evening once your menstrual period has ended.

1. Turn on your monitor, plug in your vaginal sensor making sure it clicks into place, and press the “V” button.
2. Insert the vaginal sensor into your vagina until you feel it just touch the cervix, then pull it out slightly (approximately $\frac{1}{4}$ to $\frac{1}{2}$ inch) and tilt the handle upward slightly. Press **Enter** to begin taking the reading.
3. After about 2-3 seconds your vaginal readings will appear. Remove the sensor.
4. Save the reading by pressing the **Enter** button.
5. Clean your sensor with mild soap and water.

Vaginal Sensor Dos:

- Take your vaginal reading at about the same time every day.
- Take your vaginal reading every day, starting immediately after menstruation has ended and then until your next cycle begins.
- Take your reading before, or at least eight hours after, intercourse.
- If undergoing artificial insemination: take your reading the day you are scheduled for artificial insemination before you go to the doctor's office. Be sure to take your vaginal reading early enough so that you can call your doctor the same day the vaginal reading rises.

Vaginal Sensor Don'ts:

- Don't take vaginal readings after midnight.
- Don't miss a reading. Missing readings from Cycle Day 8 through ovulation may result in inaccurate interpretation.
- Don't take more than one reading per day.

What Do The Numbers Mean?

The OvaCue Fertility Monitor uses the patented Electrolyte Method™ to measure changes in the electrolyte levels in your saliva and cervical mucus. These characteristic changes signal the onset and completion of ovulation. As your body moves through its monthly cycle, the levels of various hormones circulating in your body go up and down, and these hormonal fluctuations produce changes in the electrolyte characteristics of your saliva and cervical mucus. Using measurements obtained from the oral and vaginal sensors, the OvaCue produces a numerical reading that reveals the relative trends in electrolyte levels. This allows the OvaCue to identify when the hormonal changes that signal ovulation have occurred. When interpreting the numbers, it is important to remember that there is no predefined “normal” range into which your readings should fall, and readings will vary from person to person.

Oral readings:

About a week before ovulation occurs, a high oral reading followed by two lower oral readings will be detected, which is called the Cue Peak. Once the Cue Peak is detected, the OvaCue can then predict, several days in advance, your most fertile days.

Vaginal readings:

When using the vaginal sensor, the OvaCue tracks changes in the electrolyte levels in the cervical mucus. This allows the monitor to detect the estrogen surge that occurs just prior to ovulation, and the subsequent shift from estrogen to progesterone dominance that coincides with ovulation. In the days just prior to ovulation, your vaginal readings will be relatively low. Low vaginal readings reflect high estrogen levels, and indicate high fertility. Once ovulation occurs, your vaginal readings will increase, indicating the shift to progesterone dominance and the end of your fertile window.

Viewing Stored Readings

Date	CD	O	V
1/19/10	19	185	269
1/18/10	18	193	252
1/17/10	17	195	261
1/16/10	16	201	249
1/15/10	15	181	240
1/14/10	14	184	191
1/13/10	13	175	229

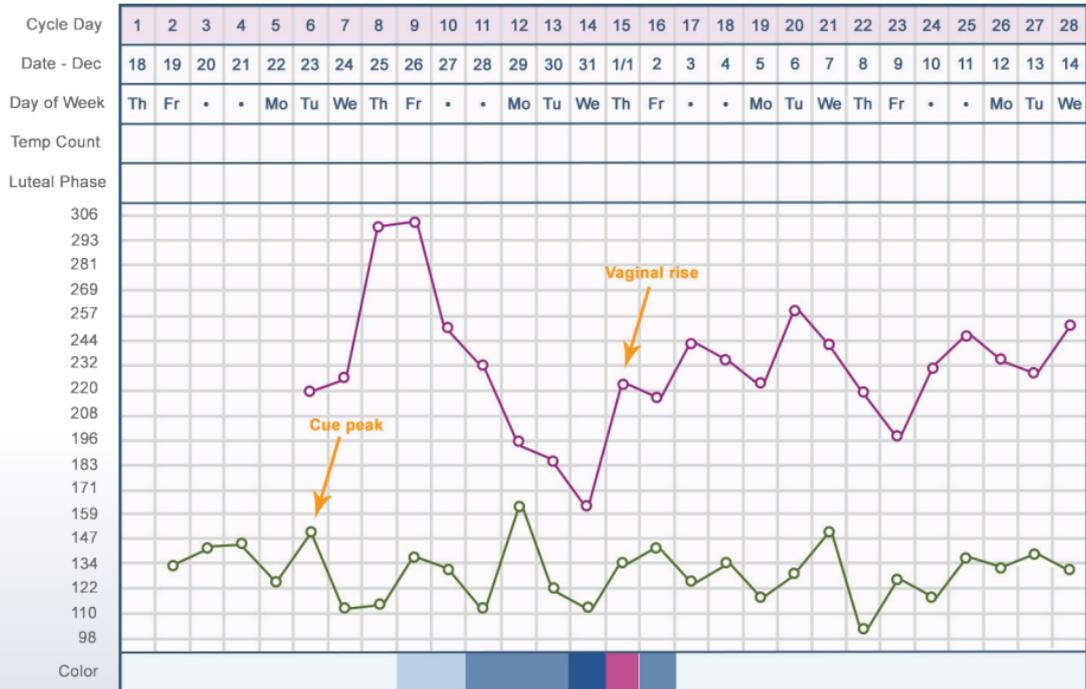
Page 1/1 Delete All

The OvaCue can save a couple cycles worth of data, however, we do recommend you delete data at the end of every cycle so you don't reach the data storage limit.* To view stored readings, select **Menu > Readings > View Readings**.

- Use the **Up** and **Down Arrow** buttons to move through the readings on each page. Use the **Left** and **Right Arrow** buttons to move through additional pages of stored data.
- To delete an entire day (you cannot delete just one reading for the day), select the day, press **Enter**, then press **Yes**.
- To delete all readings, select the **Delete All** button and press **Enter**.

*Save your data and chart your readings at www.ovagraph.com

Graph of Typical 28 Day Cycle



Sample chart from www.ovagraph.com

Understanding the Purple Box

With the vaginal sensor, the OvaCue tracks changes in the electrolyte levels of the cervical mucus, which allows the monitor to detect the shift from estrogen to progesterone dominance that accompanies ovulation. When this shift occurs, you will see an increase in the vaginal readings (called the Vaginal Rise) and a pink square will appear on your monitor's calendar. After the monitor detects a rise in the vaginal readings and displays the pink box, it will expect the vaginal readings to remain elevated, which confirms that ovulation occurred successfully and that you have entered the luteal phase of your cycle.

If, after the Vaginal Rise (pink day), the OvaCue detects a dip in your vaginal readings, and then a subsequent rise in your vaginal readings, you will see the purple box appear. Because both the pink and purple days can represent ovulation, it will be necessary to do some data interpretation to determine which day represents the day that you actually ovulated. The appearance of the purple day suggests that your vaginal readings for the current cycle did not follow the typical pattern of remaining elevated after the first Vaginal Rise. There are a number of possible explanations for why vaginal readings might dip, and then increase again, including hormonal fluctuations or the occurrence of secondary fertility (multiple follicular stimulation). For more information about the purple day and secondary fertility, please contact Customer Service or visit www.ovacue.com.

Uploading Your Data to OvaGraph.com

To upload data to OvaGraph.com, please follow these steps:

1. Set up your OvaGraph account at www.ovagraph.com
2. Plug the USB cord into your unit and your computer.
3. Turn on your OvaCue unit.
4. If the upload doesn't occur automatically or doesn't instruct you on how to do so — please visit our tutorials at www.ovagraph.com.

Frequently Asked Questions

GENERAL

Why won't my monitor turn on?

Ensure that there are batteries in the monitor and that they hold a charge. Hold down the On/Enter button for 5-10 seconds until the screen turns on.

How do I change the language back to English?

From the calendar screen, select the Menu button (bottom right hand corner of screen) and press the Enter button. Select the second item in the list (Settings) and press Enter. The Language selection is the last item in the Settings list. Scroll down and reselect English.

I have been testing daily but my calendar continues to remain grey. Why is this?

After you have successfully taken and saved your first oral reading, the current day (and previous days in your current cycle) on your calendar will change from dark gray to white. It will vary for all women how long it may take for your monitor to “color in” the calendar on your monitor. It will take longer for the fertile window to populate for women with longer cycles. The fertile window will populate once your oral ‘cue peak’ trend is detected.

When should I begin intercourse?

The OvaCue will predict your fertile window and display your most fertile days using light to dark blue colors. When the calendar shows light blue, plan intercourse every other day. Plan intercourse daily on medium blue and dark blue days. It is also recommended that you have intercourse on the day of possible ovulation, displayed with a pink or purple box.

What does the OvaCue measure?

It measures the change in electrolyte levels in salivary and cervical mucus that signal the onset and completion of the ovulatory process. As your body moves through its monthly cycle, the levels of various hormones circulating in your body go up and down, and these hormonal fluctuations produce changes in the electrolyte characteristics of your saliva and cervical mucus. Using measurements obtained from the oral and vaginal sensors, the OvaCue produces a numerical reading that reveals the relative trends in electrolyte levels. This allows the OvaCue to identify when the hormonal changes that signal ovulation have occurred.

Can I use the OvaCue while taking Clomid?

Yes. The OvaCue can be used by those taking ovulation stimulating medications such as Clomiphene Citrate (Clomid™, Femara™, etc.). When entering information into Settings, be sure to include the day that you will start your medication.

What do I do if I continue to receive an over 400 reading (with either sensor) after trying all the suggestions provided?

If you continue to receive an “over 400” reading after ensuring the sensors are plugged in correctly and placed properly, please contact Customer Service for help.

ORAL SENSOR

On what cycle day must I start to take oral readings?

You must start taking oral readings on Cycle Day 2 (Cycle Day 1 is the first day of menstruation) or by Cycle Day 4 at the latest.

Do I have to take oral readings all month?

To have a full picture of your cycle, we do recommend you take readings every day beginning on Cycle Day 2. You may elect to discontinue the oral readings once ovulation has taken place. After ovulation, your calendar will turn white (indicating you are not fertile).

When taking oral readings, should I test at the same time each morning?

Yes, if possible. A variance of fewer than two hours will not significantly change results, but for the most accurate data, try to take readings at the same time each day.

Does it matter if I take a drink before taking an oral reading?

Yes. Do not eat, drink, brush your teeth, smoke or put anything in your mouth before taking your oral reading.

How come the oral numbers seem different if I take them 2 times in a row?

The act of taking an oral reading stimulates saliva production and impacts the quantity and quality of saliva.

What should I do if I get a reading over 400?

First, make sure the sensor is plugged all the way into the monitor. Then ensure correct sensor placement — slide the sensor on the tip of your tongue and apply some pressure to ensure all three of the silver disks are in contact with saliva and retake the reading the correct way. The OvaCue will overwrite the valid reading over the erroneous one.

VAGINAL SENSOR

When do I take vaginal readings?

To confirm ovulation, vaginal readings should be started the day after your period has ended and continue through the rest of your cycle. Take vaginal readings at the same time each day and at least 8 hours after intercourse.

When taking the vaginal reading, where exactly should the sensor be?

The easiest way to describe how to place the sensor is to imagine you are lying on your back. Insert the sensor vaginally just until you feel it touch the cervix. Then pull the sensor out slightly (approximately 1/4 to 1/2 inch) and lift the handle so it would essentially be pointing towards the ceiling and the sensor itself pointing towards your backbone. This will drop the sensor into the vaginal mucus pool, the ideal placement to get an accurate reading.

Can semen affect the results?

Yes, we recommend using the vaginal sensor prior to intercourse or taking the reading at least 8 hours after intercourse.

What should I do if I get a vaginal reading over 400?

First, make sure the sensor is plugged all the way into the monitor. If this does not remedy the problem, it may be an issue of sensor placement. Please see the description above for where the sensor should be placed. Retake the reading right away. The OvaCue will overwrite the valid reading over the erroneous one.

Does the vaginal sensor confirm that I ovulated successfully?

The vaginal sensor detects the hormonal shifts that accompany ovulation. Specifically, it will identify the estrogen surge that occurs just prior to ovulation and the increase in progesterone levels that occur at the time of ovulation. In the vaginal readings, you will see a low vaginal reading just prior to ovulation followed by a rise on the day of ovulation. The OvaCue will identify the day that this hormonal shift occurred with a pink box, indicating that ovulation may have occurred on that day. While only a vaginal ultrasound can confirm successful ovulation with 100% accuracy, the OvaCue provides valuable information about the hormonal changes that are necessary for ovulation to take place. After the pink box populates, we expect to see continued elevated vaginal readings to indicate ovulation was successful.

Cleaning and Storing Your OvaCue

When not in use, store your OvaCue Fertility Monitor in the carrying case provided. Please be sure to wash the oral and vaginal sensor after each use with mild soap and water. When storing your OvaCue for long periods of time, please remove the batteries. Replace batteries as needed. Two AAA batteries required.

Help

We want you to get the most from your OvaCue Fertility Monitor. For additional technical support and customer service, please contact us at (800) 367-2837 or support@ovagraph.com, or visit us at www.ovacue.com.

Warnings

- The OvaCue Fertility Monitor is internally powered equipment (2x1.5v).
- Equipment has a type BF applied part.
- Equipment type is continuous operation.
- If the equipment is receiving interference or causing interference, the equipment should be relocated away from other equipment.
- There is no preventive inspection or maintenance required on the system or on parts of the system.
- Remove the batteries if the equipment is not going to be used.
- Environmental requirements for storage and transport:

Ambient temperature: -40C to +70C

Relative humidity: 10% to 100%

Atmospheric pressure: 500hPa to 1060hPa



Follow local governing requirements when disposing of equipment or batteries



CAUTION: General Warning - refer to accompanying documents.



OvaCue is a registered trademark of Fairhaven Health, LLC.

Chart All Your Fertility Tracking Methods at ovagraph.com



- Chart your basal body temperature, OvaCue readings, ovulation and pregnancy test results, cervical position and mucus consistency, and more!
- View your fertility data in color coded calendars and charts
- Interact with an active, supportive trying-to-conceive community
- 100% Free!

**Download the OvaGraph
Mobile App at
ovagraph.com**



The logo for OvaCue Fertility Monitor features the brand name "OvaCue" in a large, white, sans-serif font. A white, curved line arches over the text, ending in a small white circle with a registered trademark symbol (®). Below the brand name, the words "FERTILITY MONITOR" are written in a smaller, white, all-caps, sans-serif font.

OvaCue®
FERTILITY MONITOR