

# **INSTRUCTION BOOKLET**

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The Clearblue<sup>®</sup> Fertility Monitor must be used according to these instructions. The Clearblue\* Fertility Monitor is an *in vitro* diagnostic medical device designed for home use. The Monitor contains magnets. Not for internal use. Store in a dry place at room temperature. Keep out of the reach of children. Do not use a Test Stick if the foil wrapper containing it is damaged. Do not use a Test Stick that has passed its expiry date. THERE ARE NO PRODUCTS

AVAILABLE THAT CAN GUARANTEE SUCCESS IN ACHIEVING PREGNANCY. THE Clearblue\* FERTILITY MONITOR HAS BEEN DESIGNED TO ASSIST IN CONCEPTION. THE Clearblue\* FERTILITY MONITOR IS NOT INTENDED FOR CONTRACEPTION.



### The Time in Your Life for Children

Now that you have reached the time in your life for children, the Clearblue® Fertility Monitor can help you by identifying the days you are most likely to become pregnant. When you have sex on these days, you have the greatest chance of conceiving your baby.

There are only a limited number of days during the menstrual cycle when having sexual intercourse can lead to pregnancy. Conception is most likely to occur if you have intercourse on the day the ovaries release a new egg (ovulation), or during the days leading up to it.

Most home ovulation tests only identify the 2 Peak Fertility days during the cycle, by detecting the surge in luteinizing hormone (LH) that triggers ovulation. The Clearblue® Fertility Monitor not only shows these 2 Peak Fertility days, but also identifies additional days when you can conceive. By detecting a rise in estrogen, it can inform most women of an extra 1-5 days of High Fertility prior to their Peak Fertility. This means that you know all the days when having sex is most likely to lead to conception, allowing you to identify those days when you are most likely to conceive your baby.



# How Does the System Work

#### The Clearblue® Fertility Monitor

The Clearblue<sup>®</sup> Fertility Monitor consists of Test Sticks and a hand-held Monitor. Together these identify changes in 2 key hormones that control your fertility. The Monitor records your personal cycle to build up a complete and accurate picture of your most fertile days.

### The Information That You Need

The Clearblue<sup>®</sup> Fertility Monitor gives you comprehensive, personal information that is unique to you. You can relax

as the Clearblue<sup>®</sup> Fertility Monitor will count the days and tell you when to test. It will even warn you when your period is due. This allows you to prepare for your next cycle, or, if you think your period is late, to test for pregnancy.

- All you need to do are simple urine tests each cycle when requested by the Monitor. You will always be asked to use one set of 10 Test Sticks each cycle. If your cycles are long or irregular, the Clearblue® Fertility Monitor may ask you to use a second set of 10 Test Sticks to help you identify your most fertile days.
- The disposable Test Sticks collect hormones from your first urine of the day and convert them into information which can be read by the Monitor. The Monitor then reads the Test Stick, interprets your hormone changes, and tells you clearly if your Fertility will be Low, High or Peak, for the next 24 hours.

# Understanding Ovulation and the Menstrual Cycle

#### **The Menstrual Cycle**

- The menstrual cycle is the process during which your body prepares for pregnancy. Hormone changes during the cycle trigger the ovaries to release an egg.
- The eggs are contained within fluid-filled cavities called follicles. Both ovaries have many follicles, each containing an egg. During the first part of the menstrual cycle, one of the follicles prepares to release an egg. This follicle produces increasing amounts of estrogen, which causes the lining of the uterus to thicken and the cervix to produce 'fertile mucus'. This 'fertile mucus' is important (refer to page 4). A high estrogen level triggers the surge of another hormone, luteinizing hormone (LH). Ovulation normally occurs 24 to 36 hours after the LH surge, when the follicle ruptures, releasing an egg.
- The egg can be fertilized for up to 24 hours after ovulation. If fertilization does not occur, the estrogen level will gradually fall. The lining of the womb is shed and the menstrual flow begins, marking the start of the next cycle.



# How is the Clearblue® Fertility Monitor Designed to Help You Become Pregnant?

- The Clearblue® Fertility Monitor monitors estrogen and LH.
- High estrogen is associated with the appearance of 'fertile mucus', which is thin and slippery. Sperm can swim more easily through this mucus and can survive in it for several days. If you have intercourse during this time, there may still be sperm present several days later, when you release an egg. When the Clearblue® Fertility Monitor detects a rise in estrogen, it displays High Fertility status.
- Detection of the LH surge indicates that you are about to release an egg, and you are at Peak Fertility.

### How the Clearblue<sup>®</sup> Fertility Monitor Helps You



**Please Note:** For the greatest chance of conception you should have intercourse two or more times during your fertile period. This means you should have intercourse both when your fertility is HIGH and when your fertility is PEAK.

# Limitations on Use

The Clearblue<sup>®</sup> Fertility Monitor is suitable for women whose natural cycle normally lasts between 21 and 42 days. The majority of women will need 10 Test Sticks in each cycle. However, women with irregular or long cycles (more than 35 days) may have to use 20 Test Sticks each cycle in order to detect their most fertile time.

Certain medical conditions and medications can adversely affect the performance of the Clearblue<sup>®</sup> Fertility Monitor. Women who have menopausal symptoms, polycystic ovarian syndrome, impaired liver or kidney function, are pregnant or have recently been pregnant (even if not carried to full term), may get misleading results. Similarly misleading results may be obtained by women using antibiotics containing tetracyclines, hormonal treatments (e.g. hormonal contraception, hormone replacement therapy), fertility treatments containing human Chorionic Gonadotrophin (hCG) or luteinizing hormone (LH), or any treatment that might affect their cycle. Clomiphene citrate may elevate estrogen levels and this may result in High Fertility being declared early in the cycle and more High Days being displayed, and in some cases the Monitor may not show Peak Fertility even when ovulation occurs. We therefore recommend that women taking clomiphene citrate consult their doctor for advice before using the Clearblue<sup>®</sup> Fertility Monitor. Always read the manufacturer's instructions for any medication that you are taking before conducting a test.

Women who have recently been breastfeeding, using hormonal treatments (e.g. hormonal contraception, fertility treatments, hormone replacement therapy), or any other treatment that might affect their cycle, may wish to wait until they have at least two natural menstrual cycles in a row (each lasting 21- 42 days), before using the Clearblue<sup>®</sup> Fertility Monitor.

Women who have recently been pregnant (even if not carried to full term) may still have hCG in their bodies. HCG can adversely affect the performance of the Clearblue® Fertility Monitor. Therefore they are advised to wait until they have had at least two natural menstrual cycles in a row (each lasting 21-42 days), before using the Clearblue® Fertility Monitor.

Please speak to your doctor if you need further advice.

### **Limitations on Use**

If you have used the Monitor and still have not become pregnant, you should consult a doctor if you are under 35 years of age and you have been trying to get pregnant for over 12 months, or if you are 35 years of age or over and you have been trying for over 6 months.

**Please Note:** There are no products available that can guarantee success in achieving pregnancy. The Clearblue® Fertility Monitor has been designed to assist in conception. The Clearblue® Fertility Monitor is designed to help you become pregnant and is NOT intended to be used for contraception. Some medications are contraindicated in pregnancy and we therefore recommend that you consult your doctor if you are taking any medication before you try to conceive. Couples with medically diagnosed fertility problems should consult their doctor before using this product.

#### Step by Step Guide to Using the Clearblue® Fertility Monitor



# Knowing Your Clearblue® Fertility Monitor

In your pack you will find your Clearblue® Fertility Monitor. You will need to buy a pack of Clearblue® Fertility Monitor Test Sticks and 2 new AA alkaline (LR6) 1.5v batteries before you can get started. Only use Clearblue® Fertility Monitor Test Sticks that are purple and white with this monitor. You must wait until your next period starts before using the Clearblue® Fertility Monitor. In the meantime you should read this instruction booklet fully and familiarize yourself with the features below.

- **1. On/Off Button:** press once to turn on and again to turn off. The Monitor will also automatically dim after 30 seconds to conserve power, and the Monitor will switch off after 1 minute if not used. You will be unable to turn the Monitor off while it is reading a Test Stick.
- **2. Test Stick Slot:** this locates the Test Stick in the Monitor allowing it to read the test result accurately.
- **3. Touch Screen:** Use your finger on the touch screen do not use sharp objects. The screen provides information including:
  - 3a. Today's date and time
  - 3b. Battery level
  - 3c. Alarm
  - 3d. Your Fertility Status
  - 3e. Cycle Day Number: (day of your cycle)

Other information will also appear on the Display Screen, such as when to test.

### **Inserting the Batteries**

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The Clearblue<sup>®</sup> Fertility Monitor requires two AA alkaline (LR6) 1.5v batteries to operate. For optimal Monitor performance, use two new batteries that are the same brand. **Do not** use rechargeable batteries.

Remove the battery cover by pressing the battery cover release button. **Insert the positive end of the battery first**, aligning the + printed in the battery compartment with the + on the battery. Push down the negative end, and once both batteries are inserted replace the cover. If the batteries are not inserted correctly, the Monitor will not work.



### **Replacing the Batteries**

It is very important to use 2 AA alkaline (LR6) 1.5v batteries. If you do not there is a risk the Monitor will not work correctly. **Do not** use rechargeable batteries. You must replace the batteries as soon as requested to avoid losing information stored on your Monitor. If the batteries become very low the Monitor will switch off to save your information. You will need to replace them before continuing. See page 26.

If you do not replace the batteries as indicated the Monitor will not have sufficient power and it will need to be reprogrammed. Reprogramming deletes all stored information.

If left without power for too long it may reprogram automatically and when you replace the batteries you will see the screen requesting you select the language.

When you are ready to replace the batteries, **switch the Monitor off**, remove the old ones **taking out the negative end first**. Do not use a sharp implement to remove the batteries.

Replace using the instructions above. **Switch the Monitor back on** to allow it to do necessary checks.







Push the On/Off Button

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# Setting up the Monitor

Once you have inserted the batteries, you can turn the Monitor on and off by pressing the On/Off Button. Follow the instructions on the screen to:

- 1. Set the language.
- 2. Calibrate the screen.
- 3. Select today's date.
- 4. Select the time format and set the time.
- 5. Set a PIN (optional). If a PIN is set you will be asked to enter it each time you switch the Monitor on.

All the above may be changed through 'Settings' with the exception of the date. Once set you should not have to change this. If you do you will need to reprogram the Monitor (see page 37).

### Set a New Cycle



A new cycle can be set from day 1 to day 4 of your cycle. For further information refer to question 8.

When you set a new cycle you

- Tell your Monitor that your period has started and a new cycle has begun.
- Establish the 6 hours each day during which you can do a test. This is called the 'Testing Window'. Your Testing Window must be convenient for you to test the **first** urine of the day.
- 1. Enter the date your period started.
- 2. Enter the time your period started. If you cannot remember when your period started or it started in the night enter the time you usually wake up. It is important to try and remember when your period started as the Monitor will work out the first day of your cycle based on this.
- 3. will be displayed to show that your new cycle will start at the beginning of the Testing Window. You may find that day 1 is not shown until the day after your period started.
- 4. When you set up a new cycle, if your previous cycle was less than 21 or more than 42 days the Monitor will display a message advising you what to do (refer to question 6).
- 5. You may only change or delete your cycle set up between day 1 and day 4. To change your cycle set up

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- 6. To delete your cycle set up press 🛖 > 🔘 > 🎆
  - The Monitor will go back to the previous cycle setting.



Please Note: Your Testing Window must be convenient for you to test the first urine of the day (both weekdays and weekends).

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### Determine the Test Window That's Best For You

1. You can start using the Clearblue® Fertility Monitor on the first day of your next cycle, but not before. The first thing to do is set the new cycle.

- 2. When you set a new cycle you:
  - Tell your Monitor that your period has started and a new cycle has begun.
  - Establish the 6 hours each day during which you can do a test. This is called the 'Testing Window'. Your Testing Window should be set so that it is convenient for you to test the **first** urine of the day. This is important as this will contain the highest concentration of hormones.
- In the first cycle, the Monitor will automatically set your Testing Window from 05:00 to 11:00. You can change this by using the arrows to adjust the Testing Window and press 'OK'. At the start of each new cycle you will need to set a new cycle.
- 4. At the start of each subsequent cycle the Monitor will set the Testing Window to the same time as your previous cycle.
  - Press  $\uparrow$  >  $\bigcirc$  to check when your Testing Window is set.
- 5. You may change your Testing Window between day 1 and day 4. To change your Testing Window follow the instructions to change your cycle set up. See page 11.
- 6. You may wish to set up an alarm to remind you when to test. You can do this once you have set up a new cycle. If you delete or change your cycle during the first cycle of use, the alarm will be deleted and you will need to reset it. The alarm will only be active on test days, and can only be set during your Testing Window.
- 7. Press ♠ > 🔞 > ON. Enter time and press OK. ♠ will be displayed in the information bar to confirm an alarm is set.



Please Note: Only use Clearblue® Fertility Monitor Test Sticks with the Clearblue® Fertility Monitor. Unlike other products, they cannot be visually interpreted.

### **Performing Tests**

- Switch on your Clearblue® Fertility Monitor every morning within your Testing Window and before going to the bathroom. Check the Monitor is requesting a test - the test light will flash and the test day screen will be displayed. You can insert a Test Stick when any screen is displayed other than 'Clearblue' or an error.
- Please note that the cycle day only advances when the Testing Window opens.
- On mornings when the Monitor requires further information about your hormone changes, a test will be requested. Tests must be performed with the first urine of the day, within the Testing Window.
- In Cycle 1, your first test will be requested on day 6. The Monitor will then request a test every day for a total of 10 or 20 days depending on your cycle length, and when it sees your Peak Fertility. In subsequent cycles the first test day will vary between cycle day 6 and 9, according to what the Clearblue® Fertility Monitor has learned about your cycle, and you will still be asked for a test every day for 10 or 20 days.

**Please Note:** You will need a box of Test Sticks before starting. Always start your cycle with enough Test Sticks from the same LOT for 10 Test Sticks.

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Test Stick when removed from foil



#### Test Stick ready to insert into Monitor

Do not hold the Test Stick with the Sampling End pointing upwards as the result may be affected

#### **To Perform a Test**



- Choose your method of testing. We recommend you use the 'Dipping' method.
- Dipping: collect a sample of your urine in a clean, dry container. Remove the Test Stick from its protective foil wrapper and use immediately. Put just the Sampling End into the urine for **15 seconds**.

#### OR

• In your urine stream: alternatively hold the Sampling End of the Test Stick pointing downwards in your urine stream for **3 seconds**. This is long enough to ensure the Sampling End is sufficiently wet.

Please Note: Test Sticks can NEVER be used more than once. Only Clearblue<sup>®</sup> Fertility Monitor Test Sticks can be used with the Clearblue<sup>®</sup> Fertility Monitor.

### **To Perform a Test**

 Keeping the Test Stick pointing downwards, take the cap off the handle and place it over the 'wet' end of the Test Stick. Wipe off any excess urine from the Test Stick casing.











Check the colored side of the Test Stick is on the right hand side of the Test Stick Slot

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### **Inserting a Test Stick**

- Insert the Test Stick into the Monitor immediately. Make sure the Monitor is switched on, and wait for the Clearblue screen to disappear before inserting the Test Stick.
- Find the Test Stick Slot.
- Hold the Monitor flat, or place it on a flat surface.
- Hold the Test Stick by the cap with the cut corner of the Test Stick pointing downwards and the colored side of the Test Stick on the right. Insert into the Test Stick Slot as shown on the diagram. Push the Test Stick in until you hear a click.

### DO NOT

**Do not** insert the Sampling End into the Monitor.

**Do not** insert with the cut corner pointing upwards. **Do not** insert the cap into the Monitor.











- The Monitor will confirm the Test Stick is inserted correctly and a countdown screen will appear. This screen will also indicate which hormone it is looking for until it has detected the LH surge.
- The screen will switch off after 1 minute, but the Monitor will continue to analyze the test. The test light will flash.
- Wait 5 minutes for your result. The alarm will sound when testing is complete and the light will stop flashing.
- If the Monitor is off, switch it back on and remove the Test Stick, which can be thrown away. Your Fertility Status will then be displayed.
- Do not remove the Test Stick during the countdown. If you remove the Test Stick too early an error will be displayed. See page 25.

#### **Number of Test Sticks Required**

• You will be asked for a test on 10 days each cycle. If the Monitor does not detect your LH surge with 10 tests, it will request an additional 10 tests for that cycle. This may happen if your cycles are irregular or long. You should perform all of the tests requested by the Monitor.

**Please Note:** Always check the Test Stick is being read. The countdown screen will be displayed to indicate that the Test Stick is being read.

### **Your Fertility Status**



Low Fertility: very small chance of conception

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**Please Note:** It is important that you do all the tests requested by the Monitor. If you miss a test, the Monitor will use the information it has already collected to calculate your Fertility Status. If a test is missed close to ovulation, you may miss the chance to identify your days of Peak Fertility. Following a missed test you should perform all further tests requested by the Monitor.

#### Fertility Status: What does this mean?

• The Clearblue® Fertility Monitor will display your Fertility Status as three different levels of Fertility: Low, High and Peak. The Monitor will interpret your fertility based on the Test Stick reading and the information stored in its memory.

#### Low Fertility: What does this mean?

• Low Fertility is indicated by 'Low' displayed on screen. Low Fertility is displayed at times during the cycle when your fertility hormones are low. It is unlikely, but not impossible that you will conceive from intercourse on a Low Fertility day.



High Fertility: increased chance of conception •



Peak Fertility: highest chance of conception

### High Fertility: What does this mean?

- High Fertility is indicated by 'High' displayed on screen. These are displayed when the Clearblue® Fertility Monitor detects an increase in estrogen, which occurs as you approach your Peak Fertility.
- If you have intercourse on days of High Fertility you can maximize the chances of becoming pregnant.
- In the first cycle the Monitor will need to get to know you. It is possible therefore that you may get more than 5 High Fertility days prior to Peak Fertility in this cycle. Don't worry, from cycle 2 on the Monitor will reduce this for the majority of women to between 1 and 5 High Fertility days.

ance of conception • Please refer to questions 13 and 14 on page 32 for further information.

#### Peak Fertility: What does this mean?

- Peak Fertility is indicated by 'Peak' displayed on the screen and  $\odot$
- If you have sex during this Peak Fertility time, then you have the greatest chance of becoming pregnant.
- The Clearblue® Fertility Monitor identifies your days of Peak Fertility by detecting the surge in LH, which triggers ovulation to occur approximately 24-36 hours later. Peak Fertility will be indicated on the day of the LH surge, as well as the following day.
- There is a chance that the egg can still be fertilized after this time, therefore you will be shown 1 day of High Fertility following your days of Peak Fertility.
- There may be a small percentage of cycles in which you do not see Peak Fertility – for more information refer to question 11.

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# Approaching the End of Your Cycle



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#### Preparing for the Next Cycle or Pregnancy Testing

- Usually, a few days before your next period is due, a flashing symbol will appear indicating you are approaching the end of your cycle.
- If your period starts then you should set your Monitor for the next cycle. The procedure is the same as setting a new cycle for the first time (refer to page 11). Don't worry if the symbol is not flashing and your period starts: a new cycle can still be set.
- If the symbol flashes for several days, and you think that your period is late, then you may have conceived. You can find out if you are pregnant by using a Clearblue® Pregnancy Test.
- From the day of your expected period Clearblue® Pregnancy Tests give you a clear result that is over 99% accurate.\*
- You should consult your doctor if the pregnancy test result is 'Pregnant' as it is important to begin prenatal care as early as possible.

\*99% accurate at detecting typical pregnancy hormone levels. Note that hormone levels vary.



#### Calendar

- The calendar will store information on the current and previous 6 cycles. Older cycle information will be overwritten.
- 2. Use the arrows to navigate through the stored information



#### Understanding the symbols

- The number shown in the corner is the date. Shown are examples of what may be displayed on the calendar.
- Low fertility day in previous cycle
  High fertility day in previous cycle
  Peak fertility day in previous cycle
  Low fertility day in the current cycle
  High fertility day in the current cycle
  Peak fertility day in the current cycle
  Peak fertility day in the current cycle
  A fertility test will be requested





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#### **Recording information in the calendar**

- The Monitor can store extra information which you can enter from the calendar screen. This is not analyzed by the Monitor and does not affect your test results.
- 1. To access information, press 🛖 > 🛐

You may also access this from 🛖 > 💽 > 🚺 > 🛐

**2.** Press the day you wish to enter information (you cannot enter information in the future)

If you need to navigate to another month use

the arrows 🚺 🗰

3. Press OK

4. The calendar will be updated with the relevant symbol.



#### **Cycle Summary**

The cycle summary chart provides information on your previous 6 cycles (or less if you have not used the Monitor for 6 cycles yet), -1 being the most recent, and -6 being the oldest. This information may be useful to you and your doctor to understand your cycle pattern. The cycle summary will be available once you have completed your first cycle.

1. Go to 🛖 > 💽 > 🚺

You may also access this from 🛖 > <u>ज</u> > 🚺

2. Understanding the cycle summary

Low fertility day



Peak fertility day and cycle day





# Other Information

### Settings

Navigate to settings from the Menu

# Brightness

Reducing the brightness may preserve the battery life.



### Time

If no cycle is set up you can change the time without restriction. You may only change the time up to day 4 once a cycle is set. Between day 1 and day 4 you can only change the time by +/-1 hour and you can only do this once during each cycle. If you change the time, your Testing Window will be automatically updated. Refer to question 18.



#### Language

Select language.



#### Reprogram

Reprogramming deletes all stored information, including the cycle summary and calendar information, and you will be unable to get it back. To reprogram press: 🍙 > 🌆 > 🚺 Press YES and OK to confirm. Before you start using the Monitor, check that it is suitable for you (see page 5) and then set up the Monitor (see page 10).



### PIN

Set, change or switch off a PIN.



#### Calibration

If you find the screen is not responding as normal, calibrate the screen again.

### Symbols and Errors: Practical Advice



This test cannot be used again.

The Monitor has not requested a test. Remove the Test Stick from the Test Stick Slot, and only test when requested.



Remove the test from the Monitor.



The Test Stick has been removed before testing is completed. You may test again during the Testing Window, but avoid drinking too much liquid and wait until you are as near to the end of the Testing Window as

possible. Alternatively wait and test tomorrow during your Testing Window. Remember to wait until testing is completed before removing the Test Stick. See page 14. Fertility test error

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An error has occurred during testing.

Refer to instructions

An error has occurred during testing. It may be that:

- The absorbent sampler was not kept pointing downwards or the Test Stick was not laid flat after urine was applied.
- Too much or too little urine was applied.

You may test again during the Testing Window, but avoid drinking too much liquid and wait until you are as near to the end of the Testing Window as possible. Alternatively wait and test tomorrow during your Testing Window. Take care to follow the instructions and we recommend you use the dipping method to test. See page 14.

### Symbols and Errors: Practical Advice

Test enor

8 You have used a Test Stick that cannot be identified by the Monitor. Test again making sure you use a Clearblue® Fertility Monitor Fertility Test Stick.

# The message bar is highlighted in red.

If you enter incorrect information, or you do not enter any information but press OK, the information bar will be highlighted in red to indicate this error. Enter the correct information.



Replace the batteries now to avoid

losing your data.

Refer to instructions.

The Monitor will switch off. Replace the batteries immediately to avoid losing your data. The batteries are low and should be replaced. If you delay you may find you have insufficient battery life and you could lose your information. Leave the batteries in your Monitor until you are ready to replace them. Switch the Monitor off and only remove the batteries when you are ready to replace them. Once you have inserted new batteries you must switch on your Monitor to allow it to do necessary checks.

You will need to replace the batteries before you can test. The Monitor will switch itself off to protect stored information. Do not remove the batteries until you are ready to replace them. Once you have inserted new batteries you must switch on your Monitor to allow it to do necessary checks.



There is a problem with your Monitor. A number will also appear on the screen. Please phone our Careline. Tell them there is a problem with your Monitor and which number is on the screen.



You need to clean the Test Stick Slot before inserting a Test Stick. See page 28. It is possible that this may also be shown if the Test Stick is inserted incorrectly. See page 16.





# **Cleaning and Storing Your Monitor**

### **Cleaning the Test Stick Slot**

- 1. Remove the battery cover
- 2. Locate and push out the test carriage
- **3.** Slightly dampen a clean cotton bud with cold water and gently clean the Test Stick Slot and test carriage.
- 4. Replace the test carriage.
- 5. Replace the battery cover.

#### Monitor Care and Maintenance:

Your Monitor is made of highly durable materials and will withstand everyday use. Store your Monitor in a dry, safe place and take care not to drop or damage it. Your Monitor is not waterproof and like any electrical equipment it must not be used if it has gotten wet.

#### **Disposing of the Fertility Monitor:**

Remove the batteries from the Monitor and dispose of them according to the appropriate recycling protocol. **Caution**: Do not disassemble, recharge or dispose of the batteries in fire. Do not swallow. Keep away from children. Dispose of the Monitor according to the appropriate recycling protocol for electrical equipment. Do not dispose of electrical equipment in fire.

### Your Questions Answered

How accurate is the Clearblue<sup>®</sup> Fertility Monitor? The Clearblue<sup>®</sup> Fertility Monitor has been shown in laboratory testing to be 99% accurate in detecting the LH surge in cycles in which an LH surge had also been identified by a reference method. Most women will have 1-5 days warning of Peak Fertility during which time High Fertility will be displayed.

l l've been using basal body temperature and home ovulation tests. Does the Clearblue® Fertility Monitor replace these?

The advantage of the Clearblue<sup>\*</sup> Fertility Monitor is that, unlike the basal body temperature method, it predicts ovulation before it happens. The basal body temperature method can only tell you after ovulation has occurred, which may be too late to take advantage of all your fertile days. Home ovulation tests detect the LH surge which precedes ovulation by 24-36 hours, thus identifying your 2 most fertile days each cycle. The Clearblue<sup>®</sup> Fertility Monitor gives additional warning of ovulation by identifying days of High Fertility as well as the Peak Fertility days indicated by home ovulation tests. It also counts your days for you, tells you which days to test, interprets the tests, displays your fertility level every day and develops a personalized understanding of your cycle. It also provides a calendar display of your last 6 cycles and a cycle summary providing information on your previous 6 cycles (if available) on one screen.

How effective will the Clearblue® Fertility Monitor be for me? If you have sex during High and Peak Fertility it can help you maximize the chances of conceiving your baby. However, there are no products available that can guarantee success in achieving pregnancy.

#### Will hormonal contraceptives affect the result?

After using hormonal contraceptives your cycle may be irregular and take some time to stabilize. You may wish to wait until you have had at least two natural menstrual cycles in a row each lasting 21-42 days before using the Clearblue<sup>®</sup> Fertility Monitor.

5 What conditions or medication could interfere with my test result?

> Please Note: Some medications are contra-indicated in pregnancy. Therefore, we recommend that you consult your doctor if you are taking any medication, before you try to conceive.

Always read the manufacturers' instructions for any medication you are taking before using the Clearblue® Fertility Monitor. Most medications should not affect the way the Clearblue® Fertility Monitor works. However, certain medical conditions and medications can adversely affect the performance of the Clearblue® Fertility Monitor. Refer to 'Limitation on Use', for further information. If in any doubt, please speak to your doctor.

What if my cycle length varies from one month to the next?

If the length of your cycle is still between 21 and 42 days it does not matter if it varies from one cycle to the next.

If your cycle length falls outside this range you may not detect your fertile days.

# Your Questions Answered

0	) What if I set up a new cycle by mistake?	If you have set up a new cycle by mistake, for example if you thought your period had started but it was only spotting, you can delete it. Press $\uparrow < \bigcirc < \bigcirc$ and follow the instructions to delete your cycle. You can only delete your cycle between day 1 and day 4 of your cycle. When your period starts, set up a new cycle.
8	What if I am unable, or forget to set a new cycle between day 1 and day 4?	If you are not able to set a new cycle by day 4, you should wait until your next cycle starts and set a new cycle then.
9	Can I use more Test Sticks if I want to?	No. Tests can only be performed when requested by the Monitor.
10	How do I know if I've inserted the Test Stick correctly?	If you have inserted the Test Stick correctly a countdown screen will indicate that the Test Stick is being read. Do not remove the Test Stick until requested to do so.

0	My Monitor did not display a Peak Fertility symbol this cycle. What does this mean?	There may be a small percentage of cycles in which you do not see Peak Fertility status. Possible reasons for this are, for example, a test may have been missed or performed incorrectly or you may not have ovulated this cycle. An unusually short or long cycle may result in Peak Fertility not being detected. If Peak Fertility is not detected, the Monitor may show High Fertility for an extended period of time (up to 19 days). If this occurs, it is unlikely that you will be fertile during this entire time. If after completing 3 cycles you have not seen Peak Fertility we would recommend that you speak to your doctor.
12	My Monitor displayed Low Fertility during all of my last cycle. What does this mean?	This cycle the Monitor did not detect a change in the hormones that control your fertility. You may not have ovulated during this cycle or it may be due to a missed test, or a test being performed incorrectly. If your fertility status stays Low over a number of cycles consult your doctor.
13	My Monitor changed straight from Low to Peak Fertility this cycle. What does this mean?	This may happen for example when a rise in estrogen is detected on the same day as your LH surge or if the Monitor does not detect a change in your estrogen before your LH surge. This can happen if you miss a test, or perform a test incorrectly, or if you have a very short cycle following longer cycles.
14	I have seen more than 10 High Fertility days this cycle / more High Fertility days than I	When the Monitor has detected a rise in your level of estrogen it will display High. On subsequent days the Monitor looks for your LH surge. It will continue to display High until your LH surge is detected and Peak is
32	expected. Why is this?	displayed. If the LH surge is not detected and Peak is not displayed you may see more High days than expected. This can be as many as 19 days. If this happens it is unlikely that you are fertile for the whole of this time. It is important to continue to test as requested by the Monitor.

# Your Questions Answered

15	Can I use Test Sticks from different packs?	It is important that you always use your Test Sticks in sets of 10 from the same pack. The Clearblue <sup>®</sup> Fertility Monitor works by comparing the current day's test reading with those of previous days. As there are slight sensitivity differences between batches of Test Sticks, optimal performance is achieved when the Test Sticks are used in sets of 10 from the same pack. After carrying out your first 10 tests, the Monitor may request a further 10 tests in the same cycle. If you do not have any more Test Sticks from the same pack, then you may use 10 Test Sticks from a different pack to complete your testing. You should perform all of the tests requested by the Monitor.
6	If I lose or ruin a Test Stick can I start a new pack?	You should normally only use a second set of 10 Test Sticks if the Monitor has requested more than 10 tests in that cycle. However, if you have damaged a Test Stick and have not yet seen your Peak Fertility on that cycle, you can start a second set of 10 Test Sticks from a new pack.
17	How should I dispose of used Test Sticks?	Dispose of used Test Sticks with your household waste. Do NOT flush them down the toilet.

18	How do I test if I work night shifts or travel between time zones?	Ideally you should set your new cycle so that your Testing Window permits you to test using your first urine after waking, which may be in the afternoon.
		If your sleeping pattern changes temporarily during your testing period, you should collect a sample of your first urine upon waking. You should store the collected urine and check your Monitor during your next Testing Window and, if you need to do a test, use the collected urine. (Refer to page 14 on testing with collected urine.)
19	Can the information in the Monitor's memory be lost?	The Monitor retains data from your last six cycles. This data is constantly overwritten as you continue to use the Monitor to ensure it has the most up to date information available.
20	How will I know if the Monitor is working properly?	When the batteries are inserted correctly and the Monitor has power, it will warn you if there is a problem by displaying an error symbol. For a definition of these symbols, refer to the symbols section.
2)	Since it tells me when I'm fertile, can I use the Clearblue® Fertility Monitor as a contraceptive?	No. The Clearblue <sup>®</sup> Fertility Monitor is designed to tell you when you are most likely to conceive. As sperm can survive for several days, you may still have a chance of becoming pregnant if you have sex before you detect your High or Peak Fertility.

# Your Questions Answered

22	Can I be sure of getting pregnant if I am using the Clearblue <sup>®</sup> Fertility Monitor?	There are no products available that can guarantee success in achieving pregnancy. However, the Clearblue® Fertility Monitor allows couples to make the best use of their natural fertility by timing sex around ovulation. The majority of conceptions occur from sex in a 6 day window (the day of ovulation and the days leading up to it). The Clearblue® Fertility Monitor is a simple, effective way of identifying your most fertile days, helping you maximize the chances of conceiving your baby.
23	Can I stop using the Clearblue® Fertility Monitor and start again in the future?	Yes. Remove the batteries. Store the Monitor in a dry place. For instructions on resuming use of your Monitor refer to page 37.
24	I have been using Clearblue* Fertility Monitor for several cycles and have still not become pregnant. Why not?	Conception is a complex biological process and there are many influencing factors. It can take many months to become pregnant. If you have not conceived after 6 consecutive cycles or you have other concerns, you should consult your doctor.

Can I share my Monitor with a friend or relative when I am done using it? The Monitor has been designed to be used. Once it has been used, it stores your personal data and modifies the testing schedule based on the data. If you transfer the Monitor to another person, it may take several months for the Monitor to adjust to the new person's data. This could result in a delay for the new user to see Peak Fertility. Additionally, once your Monitor has been used, it is contaminated with your urine, which may contain an infectious disease. There are no reliable methods for you to clean or remove infectious diseases from the Monitor. It is for these reasons that we do not recommend that anyone use your Monitor but you.

What do the blue lines mean on the Test Stick and can I tell when I'm ovulating by looking at the color or intensity of the lines? Unlike other home ovulation test sticks that can be read visually by comparing the color intensity of a test line and a reference line, the Clearblue® Fertility Monitor Test Sticks are designed to be read by the Monitor only. It is strongly recommended that you do not attempt to read the sticks visually as it can result in missing your Peak Fertility and delay your opportunity to become pregnant.

I've forgotten my PIN.What should I do?

You have 2 attempts to enter the correct PIN. If you enter your PIN incorrectly 2 times, the monitor will lock itself and switch itself off. To unlock the monitor, switch it back on and when it asks you to, enter the PIN '0000'. You will then need to change the PIN by following the instructions on screen.



# How to Start Using Your Monitor Again

Read the following notes first.

- Check that you are still suitable to use the Clearblue® Fertility Monitor.
- Reprogramming your Monitor erases all the previous information stored about your cycles and is not reversible.
- Ensure working batteries are in your Monitor prior to reprogramming.

### **Reprogramming Procedure**

- To reprogram press: ♠ > 🛃 > 🚺 Press YES and OK to confirm.
- Set up the monitor (see page 10), and set a new cycle when your period starts (see page 11).

# HELP IS AT HAND

The Clearblue\* Fertility Monitor is designed to help you maximize your chances of conceiving a baby.

We understand that you may need advice or reassurance during use, from someone who is familiar with the Monitor and how it is designed.

The Clearblue<sup>®</sup> Fertility Monitor Helpline has been set up to fulfill this need and offers free support for all Clearblue<sup>®</sup> Fertility Monitor users. Our highly trained staff will be pleased to help you and to answer any questions you may have about using the Monitor.

#### TOLL-FREE HELPLINE 1-800-321-3279

#### Monday - Friday 8:30 a.m. - 5:00 p.m. ET

From time to time we monitor calls to the Clearblue<sup>®</sup> Fertility Monitor Helpline for training purposes.

You may also find the answers to your questions on our website www.clearblueeasy.com.

**PLEASE NOTE**: THERE ARE NO PRODUCTS AVAILABLE THAT CAN GUARANTEE SUCCESS IN ACHIEVING PREGNANCY. THE Clearblue\* FERTILITY MONITOR HAS BEEN DESIGNED TO DETECT ALL YOUR FERTILE DAYS AND IS NOT INTENDED TO BE USED FOR CONTRACEPTION.

Certain personal circumstances, medical conditions and medications can adversely affect the performance of the Clearblue<sup>®</sup> 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<sup>®</sup> Fertility Monitor is most suitable for women whose natural monthly cycle normally lasts between 21 and 42 days. Women who have recently been pregnant, stopped breast feeding or stopped using hormonal contraception (e.g. the pill), or any other treatment that might affect their cycle, may wish to wait until they have at least two natural menstrual cycles in a row (each lasting 21 to 42 days) before using the Clearblue<sup>®</sup> Fertility Monitor. Refer to page 5 and 6 for further information.

# The Clearblue® Fertility Monitor At a Glance Guide

This summary is for quick reference only. Please ensure that you read the instruction booklet in full before starting to use the Clearblue\* Fertility Monitor.

- 1. Set a new cycle when your period begins.
- Enter the date and time your period started. If you cannot remember when your period started or it started in the night enter the time you usually wake up. It is important to try and remember when your period started as the Monitor will work out the first day of your cycle based on this.

#### Set a new cycle.

When you set a new cycle you tell your Monitor that your period has started and a new cycle has begun.

- 1. Enter the date your period started.
- Enter the time your period started. If you cannot remember when your period started or it started in the night enter the time you usually wake up. It is important to try and remember when your period started as the Monitor will work out the first day of your cycle based on this.
- 3. Set the Testing Window.

**Remember:** the Testing Window is the time during which you must do all the tests required. Make sure your Testing Window is convenient for testing your first urine of the day on weekdays and on weekends. Refer to page 11 for full instructions on how to set a new cycle.

- 4. Turn on your Monitor each morning within your Testing Window, and before going to the bathroom, to see if you need to do a test. Check the Monitor is requesting a test - the test light will flash and the test day screen will be displayed. Your Fertility Status will be shown after you remove the Test Stick.
- 5. Your Fertility Status:

**Peak:** Ovulation is about to occur - your chances of becoming pregnant are at their Peak. **High:** You are near ovulation - the chances of becoming pregnant are High.

Low: Your chances of becoming pregnant are Low.

- 6. Performing a Test: ALWAYS test within your Testing Window, using the first urine of the day.
  - · Take one Test Stick out of its protective foil.
  - Hold the Test Stick pointing downwards in your urine stream for 3 seconds only.
  - Still keeping the Test Stick pointing downwards, take the cap off the handle and place it over the Sampling End of the Test Stick.
  - Make sure that the Monitor is ON and the Clearblue screen is no longer displayed before you insert your Test Stick.
  - Holding the Test Stick with the cut corner pointing downwards and the colored side of the Test Stick on the right, put it into the Test Stick Slot as shown on page 16. When the Test Stick is correctly inserted, the countdown screen will appear. Wait for 5 minutes
  - If the monitor is off, switch it back on, remove the Test Stick and throw it away.
  - When you have removed the Test Stick, the Monitor will display your Fertility Status.

#### **Remember:**

- Always START your cycle with enough Test Sticks from the same box to do at least 10 tests.
- ONLY test when the Test Day screen is displayed.
- MAKE SURE you test during the Testing Window.
- Always put your Test Stick into the Test Stick Slot immediately after 'wetting'.
- SET a new cycle between day 1 and day 4. Day 1 is the day your period starts.
- To prevent permanent damage to your Monitor, keep it dry and avoid dropping or damaging it.
- 7. If you require further guidance please call the Clearblue<sup>®</sup> Toll Free Helpline at 1-800-321-3279.

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This device complies with FCC Title 47 CFR Part 15 for Class B digital devices. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The EMC countermeasures employed within the design will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment. Mobile phones can produce high levels of electromagnetic radiation. It is recommended that the Monitor is not used in close proximity with a mobile phone.

# LIMITED WARRANTY AND LIMITATION OF LIABILITY

#### LIMITED WARRANTY

SPD Swiss Precision Diagnostics GmbH, doing business as Clearblue<sup>\*</sup>, warrants to the Original Retail Purchaser ("Purchaser") that each product sold at retail shall be free from any defects in material or workmanship for a period of one (1) year from the date of purchase. During the limited warranty period, Clearblue<sup>\*</sup> will, at its sole election, either repair or replace any Fertility Monitor that in the sole judgment of Clearblue<sup>\*</sup> is shown to be defective in material or workmanship through no fault of the Purchaser and that has not been subjected to improper usage, cleaning, handling or storage. In order to claim the benefit of this limited warranty, the Purchaser must notify Clearblue<sup>\*</sup> by calling the Clearblue<sup>\*</sup> Helpline, which may include returning the defective Fertility Monitor. This limited warranty extends only to Purchaser of a new Fertility Monitor and not to any subsequent acquirer. This warranty does not cover damage due to customer training or education, acts of God, accident, misuse, abuse, negligence, or modification of or to any part of the product. This warranty does not cover damage due to exist warranty does not cover damage due to product. This warranty does not cover damage due to end to the product. This warranty does not cover damage due to product. This warranty does not cover damage to prove the product.

#### LIMITATIONS OF REMEDY

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THE LIABILITY OF CLEARBLUE\* UNDER THIS LIMITED WARRANTY SHALL BE LIMITED TO REPAIR OR REPLACEMENT AT CLEARBLUE\*'S OPTION AS SET OUT IN ITS LIMITED WARRANTY. IF IN THE SOLE JUDGMENT OF CLEARBLUE\* REPAIR OR REPLACEMENT OF THE PRODUCT IS NOT PRACTICABLE, THEN CLEARBLUE\* MAY REFUND THE RETAIL PURCHASE PRICE, BUT IN ANY EVENT, CLEARBLUE\*'S LIABILITY SHALL NOT EXCEED THE RETAIL PURCHASE PRICE OF THE PRODUCT WHICH IS CLAIMED TO BE DEFECTIVE. CLEARBLUE\* EXPRESSLY EXCLUDES ALL LIABILITY FOR CONSEQUENTIAL AND INCIDENTAL DAMAGES, INCLUDING LOST PROFIT ARISING FROM THE DESIGN, SALE OR USE OF ITS PRODUCTS, EVEN IF CLEARBLUE\* HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE.

THE FOREGOING SETS FORTH CLEARBLUE<sup>®</sup>'S SOLE OBLIGATION AND PURCHASER'S EXCLUSIVE REMEDY IN THE EVENT OF ANY BREACH OF THIS LIMITED WARRANTY. ALL OTHER WARRANTIES, ORAL OR WRITTEN, EXPRESS, IMPLIED, ARISING FROM COURSE OF DEALING OR USAGE OF TRADE, OR STATUTORY, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NONINFRINGEMENT OF THIRD PARTY RIGHTS, QUIET ENJOYMENT AND ACCURACY, ARE, TO THE FULL EXTENT PERMITTED BY LAW, HEREBY EXPRESSLY LIMITED AND/OR EXCLUDED. In addition to the limited warranty and remedies set out above, you may have other warranties and remedies available under particular state laws. Applicable law may not allow the exclusion of certain warranties or the limitation or exclusion of liability for incidental or consequential damages. Accordingly, some of the above limitations or exclusions may not apply to you.







Clearblue® Helpline Monday - Friday 8:30 a.m. - 5:00 p.m. Eastern Time **Toll-free. 1-800-321-3279** Please have the lot numbers [II] from both the outer and inner packaging. Calle are recorded for training and guality control.

packaging. Calls are recorded for training and quality control. www.clearblueeasy.com

The US Surgeon General advises pregnant women to abstain from alcohol consumption as this may lead to harmful effects on the baby such as Fetal Alcohol Syndrome Disorders (FASD). More information is available at www.surgeongeneral.gov

Store in a dry place, between  $50^{\circ}$  and  $104^{\circ}$ F ( $10^{\circ}$  and  $40^{\circ}$ C). Do not freeze. For *in vitro* diagnostic use only. Not for internal use.

Monitor contains magnets.

Please read instructions before use. This device is for home use. Keep out of the reach of children.

Distributed by Procter & Gamble, Cincinnati, OH 45202

Clearblue<sup>®</sup> is a registered trademark of SPD Swiss Precision Diagnostics GmbH.

Made in PRC. Packaged in USA.

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Pat. - see www.swissprecisiondiagnostics.com/patents

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