

OvuSense™

Advanced Fertility Monitor

User Manual



fertility focus 

OvuSense™

User Manual

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Fertility Focus Ltd
Unit 19D
University of Warwick Science Park
Warwick Innovation Centre
Warwick Technology Park
Gallows Hill, Warwick
CV34 6UW, United Kingdom

Precautions

Safety Precautions

The plug-in charger is the mains isolating device for OvuSense, and must be easily accessible during use.

WARNING: No modification of this equipment is allowed. No serviceable parts contained inside in the Reader, Sensor or charger units. Repair must be attempted by authorised service personnel only.

Damaged or defective units, must be returned to the manufacturer for repair at the address identified at the end of this User Manual.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



The OvuSense Sensor is considered to be a B-type applied part, in terms of the classifications defined in IEC 60601-1

Charging

When the charging unit is plugged into the OvuSense Reader and the mains is switched on, the Reader will remain permanently on with the screen lit until it is fully charged. It is not recommended to unplug the charging unit before the Reader is fully charged.

Intended Use

The OvuSense advanced fertility monitor is intended for measuring and recording body temperature on a nightly basis during the non-menstruating phases of the monthly female reproductive cycle. OvuSense detects the presence and absence of ovulation, as well as predicting the fertile period for the next monthly cycle.

Contra-Indications

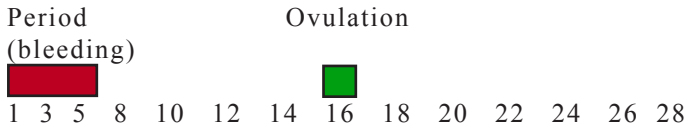
Not to be used during menstruation. OvuSense is not designed to be used as a contraceptive device. OvuSense is not designed to be used as a method for detecting or confirming pregnancy. Use of the contraceptive pill, any other hormonal contraceptive, or intra-uterine devices at the same time as use of OvuSense will invalidate the data collected.

For further precautions please refer to Section 1.7

1.0 Who should use OvuSense?

Women who are wishing to become pregnant can use the OvuSense system to identify the time during their menstrual (oestrus) cycle when they are most likely to be fertile. OvuSense takes a number of measurements of body temperature taken throughout the night to work out the time of maximum fertility.

The menstrual cycle can range from 20 to 45 days in length, but most women have a cycle length of about 28 days*. Menstrual bleeding can last from 2 to 7 days (shown as purple in the chart below), and the first day of the menstrual bleed is the first day of the menstrual cycle. Ovulation usually occurs at between 14 and 19 days into the cycle, but this is likely to vary with your individual cycle length.



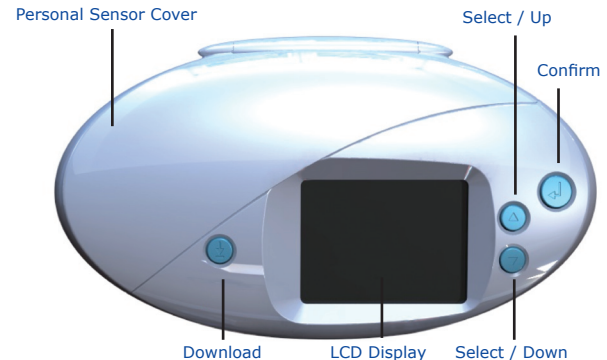
*If you know that your cycle routinely falls outside of these parameters seek medical advice about whether OvuSense will work for you. If you do not have a regular cycle length, OvuSense may still provide you with information about your menstrual cycle and ovulation.

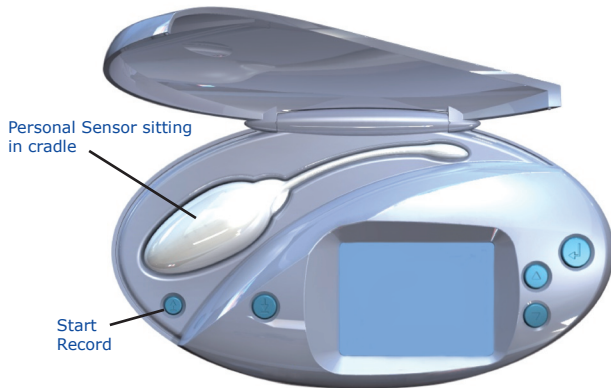
OvuSense gives you daily information about your body and the changes that occur around the time of maximum fertility. This information is collected as you sleep through your personal OvuSense Sensor and is uniquely yours. Regular use of the personal Sensor during sleep will build up a picture of your fertility information which you can review, cycle by cycle, and will also allow the period of optimum fertility to be identified to help you to achieve pregnancy.

1.1 Using the OvuSense system

OvuSense has two parts – a personal Sensor shaped like a small tampon, and a Reader, the box which stores the Sensor and which provides information on a display.

The Reader





1.2 Your personal Sensor

Your personal Sensor is included in the OvuSense Starter Pack. Each personal Sensor has a life of three menstrual cycles and has a unique code. After you have used your personal Sensor for two cycles, a message will let you know that you can only use it for one more cycle, and if you try to use the Sensor in a fourth cycle a message will warn you that this is not possible (see section 8 for these warnings). The Reader will accumulate data for each cycle that you use the personal Sensor, and will continue to accumulate data when a new personal Sensor is used.

You need to wait until a new menstrual cycle before you start using the OvuSense system. On the first day of your menstrual bleeding, you should tell the Reader

that you have started your cycle - please see section 5. You will need to wait until the first day after your menstrual bleeding stops before you can use your personal Sensor.

The personal Sensor has been designed to rest comfortably within you vagina and measures the changes in your body that take place during the night time. It should be inserted just before you go to bed on the first day after your menstrual bleeding stops. The Sensor is for your personal use, DO NOT share it with other women as this may present a risk of disease, and invalidate the personal data which will be used to work out your specific time of maximum fertility. When you are not using the personal Sensor, clean it and store it in its cradle on the Reader with the lid closed – this will keep it clean and secure.

A new personal Sensor can be purchased from your local approved supplier. If in doubt contact Fertility Focus by email at: orders@fertility-focus.com.

1.3 Sexual intercourse and the Sensor

The use of the Sensor should not prevent you from having sex as frequently as you wish. Remove your personal Sensor before sex and then clean it and re-insert it after intercourse.

DO NOT leave the device in place in the vagina during sex as this may present a risk to you and your partner.

1.4 Cleaning the Sensor

Before and after use, the Sensor should be thoroughly cleaned by washing it in hand-hot soapy water (at least 40°C). Prepare the water by pouring a small amount of washing up liquid into a basin of hand-hot water. Dip the Sensor in the soapy water and rub it thoroughly with fingers for 2 minutes. Make sure that you wash all parts of the personal Sensor, including all of the tail and the area where the tail joins the main part of the Sensor. After washing, rinse all parts of your personal Sensor thoroughly for 2 minutes in clean tap water to remove any soap residue, and then dry the Sensor on a clean towel or clean tissue paper.

You will need to clean your personal Sensor twice each day

1st time - once after you have used it overnight so that it is clean when you place it on the Reader.

2nd time - so that it is freshly cleaned before you insert it.

DO NOT clean the Sensor in strong disinfectants or alcohol or with antibacterial or disinfectant wipes. If you use a soap containing antibacterials – for example anti-acne soap or carbolic soap, do not use this on your personal Sensor.

DO NOT subject it to high temperatures (for example by boiling or microwave) as this will damage your personal

Sensor and invalidate the measurements made.

DO NOT use the Sensor if any damage to the coating occurs, or if the tail should become broken. REPLACE it with a new one.

You cannot swap Sensors in mid cycle. If your personal Sensor is lost or damaged mid way through your cycle you will need to start a new cycle with a new personal Sensor. Information downloaded from the use of a previous Sensor will be retained in the memory of the Reader.

1.5 When to use the Sensor

☾ At night - Inserting your Sensor - you should insert your personal Sensor just before you go to bed, and after you have showered or had a bath.

☀ In the morning - Removing your Sensor - you should remove your personal Sensor in the morning when you first get up. If you forget to take your Sensor out when you first get up, don't worry, simply take it out when you have an opportunity and clean and dry it.

OvuSense works most effectively if you have a regular sleeping pattern. If, for example, you work shifts that change the time of your sleep, or if you travel and alter your sleep to suit different time zones, this may invalidate the data collected by OvuSense.

1.6 Inserting your Sensor

If you are familiar with using sanitary tampons then insert the personal Sensor as you would a tampon.

If you are not familiar with sanitary tampons - before you insert the personal Sensor for the first time, gently open your labia (the lips which cover the entrance to your vagina) and explore the entrance to your vagina. This is where the Sensor will be inserted. Hold your Sensor where the tail joins the main body, and, with your vaginal muscles relaxed, insert the Sensor with a slight twisting motion until only the tail is visible.

If you find that the Sensor is ‘dry’ to insert, apply a very small amount of lubricant gel approved for vaginal use such as KY jelly®, Durex® play (not tingle), Sensilube®, Astroglide® or Condomi LUB®.

The length of the Sensor tail is such that it cannot be “inserted too high in the vagina”. However, if the tail of the Sensor should withdraw inside the vagina, it can usually be located with gentle exploration in the vagina. If it is still not identified then please see your doctor.

1.7 Precautions when using the Sensor

Personal care - Clean your personal Sensor before each insertion and insert the Sensor before you go to

bed and NOT a period of time before (for example, do not insert it before you go out in the evening if you are worried you will forget to insert it later – it is designed only for use when you are sleeping). The Sensor is not designed for daytime use, and if you do use the Sensor during the day it will not produce valid results.

Urinating - The Sensor can be left in place when you urinate. Women vary greatly in shape, and some women may find that the Sensor falls out if they strain to urinate, or if they walk about during the night. If this happens occasionally, clean the Sensor and re-insert it. If you find that the Sensor falls out on a regular basis whilst you are sleeping then it may not be possible for you to use the OvuSense system effectively.

Personal health - If you experience repeated difficulty or discomfort during insertion, or discomfort, irritation or a vaginal discharge during use of the Sensor, DO NOT continue use. Consult your doctor. DO NOT use the personal Sensor during your menstrual bleed, but should ‘spotting’ or an unexpected bleed start, simply stop using your Sensor until this bleeding stops.

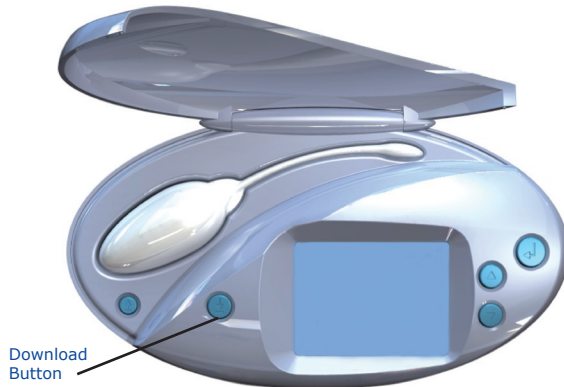
Toxic Shock Syndrome- Use of the Sensor when you are having a menstrual bleed is not recommended and will not produce valid fertility monitoring results. As with the use of sanitary tampons, there may be a small risk of toxic shock syndrome – a rare condition caused

by the bacterium *Staphylococcus aureus* growing on blood or fluids in the vagina. If you feel ill or have a high temperature (above 39°C), muscular pains, headaches, vomiting, diarrhoea, or if a skin rash appears stop using the personal Sensor immediately and see your doctor.

2.0 The Reader

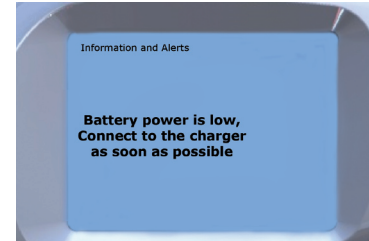
The Sensor is able to send the data it has collected when it is placed in the cradle on the Reader. The Sensor does not send any data unless it is placed in its recess on the Reader AND the download button on the Reader is pressed.

The Reader then provides you with information on your menstrual cycle and also indicates the time of



maximum fertility to help you to conceive.

The Reader contains a rechargeable battery so that you can use it whilst travelling and away from a power supply. Recharge the battery when the display says 'Battery power is low, connect to the charger as soon as possible'



the battery is re-charged.

The Reader will not lose information already stored if the main battery becomes flat, but it will not be able to download new measurements until

Keep your Reader clean. It is NOT designed to be immersed in water, but the surface, particularly the cradle for the Sensor should be wiped with clean paper tissue to keep it clean. Disinfectant or antibacterial wipes can leave a residue on your Sensor and are NOT recommended.

2.1 Switching on the Reader

The Reader is designed to be held in the palm of one hand and operated with the other. When the charging unit is plugged into the OvuSense Reader and the mains is switched on, the Reader will come on and will remain on with the screen permanently lit until the unit is fully charged. When not charging, press any key to switch the Reader on. The screen will light up and

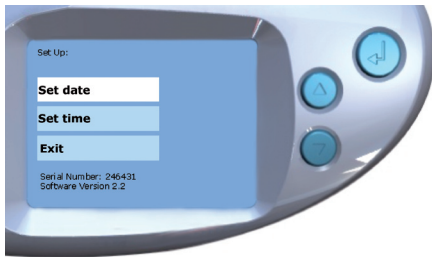
display the main menu. You can switch the Reader on at any time to review your fertility information. If the screen fails to light within a few seconds, please refer to the troubleshooting guide. If the unit is not charging, the Reader will automatically turn itself off after 5 minutes to save battery power if there is no further action. You can switch the Reader on at any time to review your fertility information.



Using the up ▲ and down ▼ keys, and the Confirm ↵ key, you can navigate and choose the option on each screen.

When you first unpack the Reader it will need to be charged overnight. When you first turn it on you may need to set the date and time. The main menu leads you to the following screens

2.2 Setup (set time and date)



Using the up ▲ and down ▼ keys on the Main menu - highlight the Set Up option, then press Confirm ↵.

Then select Set

date, or Set time, or Exit to return to main menu

To set the Date, Select the ‘Set date’ option. The current date will be displayed with the “Year” field highlighted:

1 Jan 2011

Use the up ▲ and down ▼ keys to change the current Year. Press the Confirm ↵ key to set the “Year”.

Once the year has been set, the “Month” field is highlighted:

1 Jan 2011

Use the up ▲ and down ▼ keys to change the current Month. Press the Confirm ↵ key to set the “Month”.

Once the month has been set, the “Day” field is highlighted:

1 Jan 2011

Use the up ▲ and down ▼ keys to change the current Day. Press the Confirm ↵ key to set the “Day”.

Once the day has been confirmed, the date will be shown in full with the day of the week. The date is now set and you can Accept or Cancel to return to the Setup menu.



To set the Time

Using the up ▲ and down ▼ keys on the Main menu - highlight the Set Up option, then press Confirm ↵

Select the 'Set time' option. The current time will be displayed with the "Clock" field highlighted as illustrated below:



Using the up ▲ and down ▼ keys, select whether you want to use 24 hour or 12 hour clock. For example 23:00 or 11.00 pm, then press Confirm ↵

The "Hours" field is then highlighted. Using the up ▲ and down ▼ keys, set the current "Hour", then press Confirm ↵



Once the Hours have been set, the "Minutes" field is highlighted. Using the up ▲ and down ▼ keys, set the current "Minutes", then press Confirm ↵

The time is now set and you can Accept or Cancel to return to the Setup menu.

Once you have finished setting up Date and/ or Time, use the down ▼ key on the Setup menu to highlight the Exit option, then press Confirm ↵. You will then return to the Main menu.

Note: OvuSense will not automatically make changes for daylight saving or timezones. You can change the time +/- 1 hour using the instructions above to allow for daylight saving time without this affecting your fertility information. However, greater time zone changes over 3 hours will cause errors in determination of your fertile time, and the sleep pattern changes that you will experience will also make determination of your fertile time less likely to be accurate. OvuSense works most effectively if you have a regular sleeping pattern. If, for example, you work shifts that change the time of your sleep, or if you travel a lot and alter your sleep to suit different time zones, this may invalidate the data collected by the OvuSense system.

3.0 Using OvuSense

3.1 New cycle - what to do when you start a new menstrual cycle

You need to wait until a new menstrual cycle before you start using OvuSense. On the first day of your menstrual bleeding, you should tell the Reader that you have started your cycle. You will need to wait until the first day after your menstrual bleeding stops before you can use your personal Sensor.



Using the up ▲ and down ▼ keys on the Main Menu, navigate to the New Cycle option, then press the Confirm ↵ key.

Please enter the first day of your menstrual cycle. Pressing the down ▼ key, cycles you through the options Today, 1 day ago, 2 days ago, 3 days ago, 4 days ago, 5 days ago, 6 days ago, 7 days ago.

Please note – the first day of your menstrual cycle is the first day on which a full bleed occurs – do not include days preceding this on which minor blood spotting occurs.



Today ▼
 Yesterday ▼
 2 days ago ▼
 3 days ago ▼
 4 days ago ▼
 5 days ago ▼
 6 days ago ▼
 7 days ago ▼

Select the day and press Confirm ↵. Then use the up ▲ key to select Accept, press Confirm ↵ to set the first day of your cycle, or select Cancel ▼ and press Confirm ↵ to go back to the Main Menu without

making a selection.

If you decide to stop using OvuSense for a time – for example, if you are going on holiday or travelling and don't wish to take it with you – then, on the last day of your current cycle, go through the stages above and select Today as if you were going to start a new cycle of recording – and then do not use the personal Reader. If you do this, the system will detect that you have stopped using it during this cycle, but will also know that the last cycle has ended.

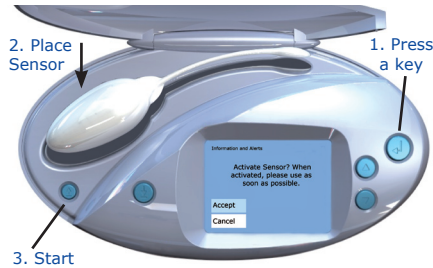
To re-start using the OvuSense, wait until a new menstrual cycle starts and then follow the steps above to indicate to OvuSense that a new cycle has started. Then simply start daily recording again.

3.2 At night

‘Start’ your personal Sensor before you insert it and before going to bed

Wake up the Reader by pressing any key. (If the Reader will automatically turn itself off after 5 minutes if there is no further action).

You need to ‘Start’ your personal Sensor before you insert it and before you go to bed so that it knows when to collect data when you are asleep.



After you have cleaned and dried your Sensor – place it on the Reader with the fins neatly aligned in the Sensor well and press the (1) Start key. You will

need to wait about 10 seconds for the Sensor to be detected.



Once your Sensor has been activated, you will receive the following message. Insert your personal Sensor. Have a good night's sleep!



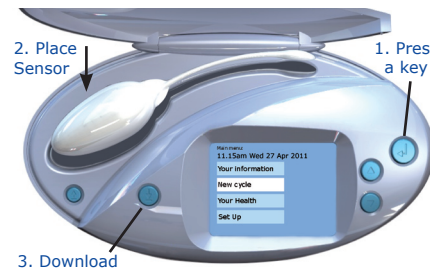
If you have not placed the Sensor correctly you will see the following screen. Follow instructions until your Sensor is successfully activated

If you forget to insert the Sensor on one night, do not worry, continue to use the Sensor on subsequent nights.

Please note – the quality of fertility information relies on regular use of the personal Sensor, and so repeated missed nights will reduce the accuracy of the information that the advanced fertility monitoring system can provide you with. Also remember that use of the personal Sensor should not prevent you from having sex. Simply remove your personal Sensor before sex and clean and re-insert it after sex.

3.3 In the morning

Collect the data from your personal Sensor using the Reader. Wake up the Reader by pressing any key. (If the Reader will automatically turn itself off after 5 minutes if there is no further action).



After you have cleaned and dried your Sensor, place it on the Reader with the fins neatly aligned in the Sensor well and press the (2) (Download) key.

Once the data download has started, you will see the following screen.



Wait until the data downloads.



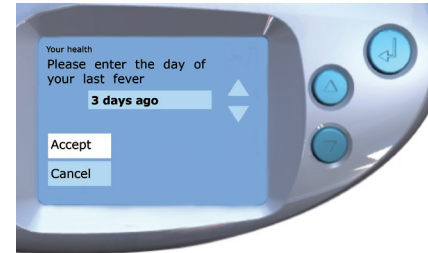
As soon as the data download is complete you will see the following screen.

4.1 Your health - what to do if you have a fever

You will need to tell the Reader if you run a temperature as a result of a fever.

The "Your health" screen allows you to enter the date if you have had a fever during the last cycle. A fever may result in an unusually high body temperature, and this information needs to be taken in to account to

ensure that an accurate measurement of fertility can be made.



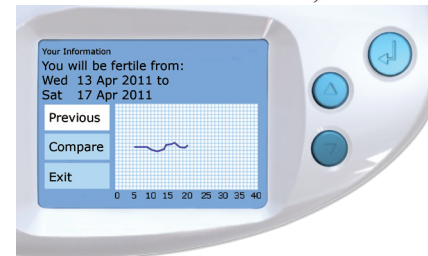
Today ▼
 Yesterday ▼
 2 days ago ▼
 3 days ago ▼
 4 days ago ▼
 5 days ago ▼

Select the day and press Confirm ↵

Then use the up ▲ key to select Accept, press Confirm ↵, or select Cancel ▼, and press Confirm ↵ to go back to the Main Menu without making a selection.

5.0 Your Information - what the Reader can tell you about your fertility status

The "Your Information" screen allows you to review the information collected in your current cycle. The display will update at each point when sufficient data has been collected, but not necessarily each day.

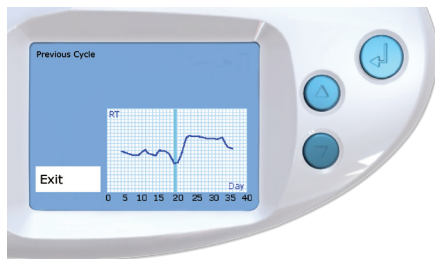


Using the up ▲ and down ▼ arrows, and the Confirm ↵ key, you can navigate up and down between Previous cycle and Compare cycles

As shown in the example on the previous page, OvuSense can also tell you that "You will be fertile from (date) to (date)". This is the time of optimum fertility, and if you are planning to get pregnant, then you should have sex as often as you wish during this time. It can also be used to review information for up to your three previous cycles.

5.1 Previous cycle

If you select this menu option, the screen will show you a graph of the information from your last cycle.



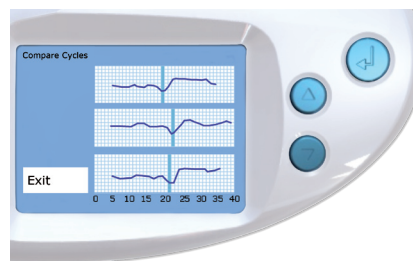
The blue band indicates the day on which you ovulated.

The blue band will only be shown when a full cycle has been recorded.

Press Confirm ↵ to Exit to main menu.

5.2 Compare cycles – the Reader enables you to review your previous cycles

If you select this menu option, the screen will show you a graph of the information from your last 3 recorded cycles.



Upper Graph - Your last full cycle recorded ▼

Middle Graph - The graph for two cycles ago ▼

Lower Graph - The graph for three cycles ago ▼

Press Confirm ↵ to Exit to main menu.

6.0 Using the fertility information provided by OvuSense to optimise your fertility

Fertility is controlled by many factors including the vitality of the egg and of the sperm, the timing of the joining of sperm and the egg, the environment of the uterus and fallopian tubes and by hormonal and biochemical factors. The data collected by your personal Sensor is used to build up a personal picture of your menstrual cycles, of your time of ovulation and of the time of your maximum fertility.

The OvuSense provides the following prompts that you are in your period of optimum fertility -

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When the charging unit is plugged into the OvuSense Reader and the mains is switched on, the Reader will remain permanently on with the screen lit until it is fully charged. It is not recommended to unplug the charging unit before the Reader is fully charged.

Intended Use

The OvuSense advanced fertility monitor is intended for measuring and recording body temperature on a nightly basis during the non-menstruating phases of the monthly female reproductive cycle. OvuSense detects the presence and absence of ovulation, as well as predicting the fertile period for the next monthly cycle.

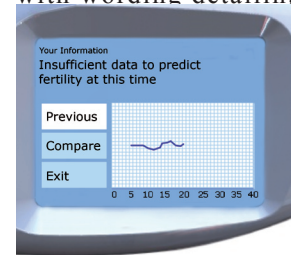
Contra-Indications

Not to be used during menstruation. OvuSense is not designed to be used as a contraceptive device. OvuSense is not designed to be used as a method for detecting or confirming pregnancy. Use of the contraceptive pill, any other hormonal contraceptive, or intra-uterine devices at the same time as use of OvuSense will invalidate the data collected.

For further precautions please refer to Section 1.7

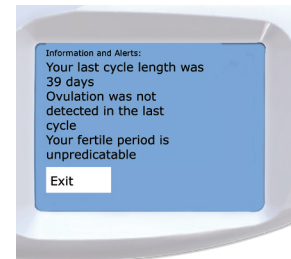
6.2 Fertility information warnings

Examples (each warning will have a similar screen with wording detailing the warning)



Insufficient data to predict fertility at this time

There are too many nights of missing data within this cycle to be able to detect ovulation.

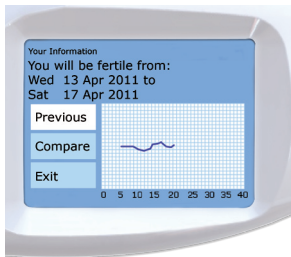


Ovulation was not detected in the last cycle

It was not possible to determine a time of ovulation in the last cycle.

Other examples:

Your last cycle length was (XX) days; this is unusually short. The data collected indicates that you have had an unusually short menstrual cycle – a Doctor's opinion should be sought if this occurs regularly.



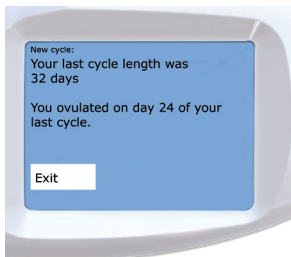
The blue band indicates the day on which you ovulated.

The blue band will only be shown when a full cycle has been recorded.

To maximise your chances of becoming pregnant, you should aim to have sex without contraception as often as you wish during the times indicated by OvuSense system.

6.1 Detailed Cycle Information

When you start a New Cycle, OvuSense produces



detailed information on the length of your cycle and ovulation. This will help you and your doctor to better understand your fertility, and the best course of action to help you get pregnant.

Your last cycle length was (XX) days; this is unusually long. The data collected indicates that you have had an unusually long menstrual cycle – a Doctor’s opinion should be sought if this occurs regularly.

Potential fertility problem. The data collected by the OvuSense indicates that there are unusual features of your menstrual cycle and calculated time of ovulation. OvuSense detects that within the last three cycles your data suggests that you may have had two incidents of any of the following;

- Ovulation not detected
- Unusual cycle lengths
- Cycles with a short post-ovulatory phase

7.0 Warning messages

Sensor not detected. Please ensure the Sensor is located correctly on the Reader and try again. The personal Sensor may not be located firmly in the cradle, try placing it again. Make sure that the fins on the Sensor are properly aligned in their recess on the Reader cradle.

A problem has been encountered with this personal Sensor. Please consult the instruction booklet supplied with the Sensor. A fault has been detected

in the personal Sensor. Re-start the Reader and replace the personal Sensor firmly in the cradle. *If this message persists at the next start up, please contact the supplier.*

This is the final cycle for this Sensor. A new Sensor will be required for the next cycle. Each personal Sensor can only be used for 3 menstrual cycles once started and has a unique code. This warning lets you know that you will need to purchase a new personal Sensor for your next menstrual cycle.

This Sensor has been used for three cycles. Please use a new Sensor. Each personal Sensor can only be used for 3 menstrual cycles once started and has a unique code. This warning lets you know that you will need to purchase and use a new personal Sensor for any further cycles.

Low battery warning: Battery power is low. Connect to the charger as soon as possible. Plug the charging unit into the Reader and switch on the mains. The Reader will remain permanently on with the screen lit until it is fully charged.

8.0 Personal care

What happened	Action
If you experience repeated difficulty or discomfort during insertion, or discomfort, irritation or a vaginal discharge during use of the personal Sensor	DO NOT continue to use the personal Sensor. Consult your doctor.
Blood ‘spotting’ or an unexpected menstrual bleed starts	DO NOT use the personal Sensor during your menstrual bleed. Should ‘spotting’ or an unexpected bleed start, stop using your personal Sensor until this bleeding stops.

If you feel ill or have a high temperature (above 39°C), muscular pains, headaches or vomiting or diarrhoea, or if a skin rash appears –

STOP using the personal Sensor immediately and see your doctor.

Use of the personal Sensor when you are having a menstrual bleed is not recommended and will not produce valid fertility monitoring results. As with the use of sanitary tampons, there may be a small risk of toxic shock syndrome – a rare condition caused by the bacterium Staphylococcus aureus growing on blood or fluids in the vagina. If you feel ill or have a high temperature (above 39°C), muscular pains, headaches or vomiting or diarrhoea, or if a skin rash appears – stop using the personal Sensor immediately and see your doctor.

9.0 Troubleshooting

What happened	Likely cause	Remedy
Screen fails to light up when a key is pressed.	Battery may be completely discharged.	Plug the charging unit into the Reader and switch on the mains. The Reader will remain permanently on with the screen lit until it is fully charged.
Screen fails to light up when the charging unit is connected.	Battery may be damaged.	Check charging unit is plugged into Reader and mains is switched on. If screen still fails to light, contact the Service Centre for a replacement unit as indicated on back page.

Sensor Reorder Number
MXXX

Support and Complaints
support@fertility-focus.com

Ordering
orders@fertility-focus.com

Web
www.fertility-focus.com

Instruction Manual
M002-30NOV11-V1.4-EN

Faulty or defective units must be returned to the following [Service Centre](#) address. Please email support@fertility-focus.com in advance for a return authorisation number:

Fertility Focus Ltd
Service Centre
Unit 3, Coped Hall Business Park
Wootton Bassett
Wiltshire SN4 8DP
United Kingdom

CE
0123