

Persona



Hormone Free Contraception



Instruction Booklet

Welcome to Persona

Persona is a natural method of contraception that works in harmony with your body. It has no side effects, involves no drugs and is easy to use. It works by monitoring hormone changes in your urine to identify the days of your menstrual cycle (your cycle) when you are very likely to become pregnant.

Please read this instruction booklet carefully before using Persona.

Persona consists of a touch screen monitor and test sticks (these sticks test the hormones in your urine). Two batteries (AA alkaline (LR6) 1.5v) are supplied with the monitor. Test sticks are sold separately. You will need 16 test sticks for the first cycle that you use Persona and 8 test sticks from your second cycle onwards.

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Is Persona right for me?

Before using Persona you need to be sure it is the right method of contraception for you.

You must not use Persona if:

- your **cycles are shorter than 23 days or longer than 35 days** (you can work out the length of your cycle by counting the number of days from the first day of your period until the day before your next period starts);
- you have had **menopausal symptoms**, such as night sweats or hot flushes;
- you are **breastfeeding**;
- you are **using hormonal treatments**, for example, **hormonal contraception, fertility treatments and hormone replacement therapy**;
- you are using any other **treatments which may affect your cycle**;
- you are **taking antibiotics containing tetracyclines**. Once you have finished your treatment you may start using Persona at the beginning of your next cycle;
- you have **impaired liver or kidney function**;
- you have **polycystic ovarian syndrome (PCOS)**;
- **you cannot or do not want to become pregnant under any circumstances.**

Persona **does not** protect against sexually transmitted infections (STIs) or HIV.

You cannot use Persona straight away if you have recently been:

- **breastfeeding**;
- using **hormonal contraception or treatments**;
- using **any other treatment which may affect your cycle**;
- **pregnant (even if you have not carried to full term).**

After pregnancy or once you have completely stopped breastfeeding or finished taking hormonal contraception or other treatments which may affect your cycle, you will need to wait until you have had at least 2 natural menstrual cycles in a row. Both of these cycles must last between 23 and 35 days. You can then start to use Persona on your third cycle.

Please refer to this section regularly to check that Persona is still suitable for you to use. If you wish to stop using Persona refer to question 20 and if you start using your monitor again, you will need to check it is still suitable for you to use.

How does Persona work?

Your cycle is controlled by hormones. Two important hormones that control your cycle are estrogen and luteinising hormone. Using simple urine tests Persona monitors the changes in both of these hormones to identify the days when you are at high risk of becoming pregnant (we call these red days), and the days when you can have sex without using contraception (we call these green days).

Red days are around the day you ovulate (this is when an egg is released from your ovary) and take into account the lifespan of an egg and sperm.

See page 9 for more information on red days and green days.

How reliable is Persona?

Persona is 94% reliable if you follow the instructions properly and use it as the only method of contraception. This means that if 100 women use Persona for one year, we expect 6 will become pregnant because they have had sex on a day when Persona incorrectly showed they were not at risk of becoming pregnant (green day).

For Persona to be 94% reliable, you must not have sex on red days. You are much more likely to become pregnant if you have sex on a red day, even if you use a barrier method of contraception, such as a condom.

Using Persona

What these symbols mean



You can choose the language you want to be displayed.



You can set a PIN (personal identification number) to lock your monitor.



You can change the display brightness.



You can reprogram your monitor. See page 18.



You can see information about your current cycle and information about your last 6 cycles.



You can set and change the time.



You can re-calibrate the touch screen.



You **must** set a new cycle each time you start a new period.



You can set an alarm on test days.



You can change the settings (such as the PIN, time, language, brightness or reprogram your monitor or calibrate the touch screen).



The '●' symbol is shown when you are at highest risk of getting pregnant.



The battery symbol shows how much battery life is left.



The bell symbol shows the alarm is set.



This deletes your current entry.



This lets you return to the previous screen.



This confirms what you want to do and/or moves to the next screen.

Getting started

To insert the batteries, press the button at the back of your monitor and release the battery cover. **Insert the positive end of the battery first**, placing it on top of the battery tab. (The tabs are provided to help when you need to remove the batteries.) Align 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.

To switch the monitor on, open the lid and press the 'on/off' button on the front of the monitor.

The monitor has a touch screen which, if you stop using it, will dim after 30 seconds and switches off after 1 minute. Use your finger on the touch screen – do not use sharp objects.

Instructions on the screen will guide you through setting up Persona. This includes calibrating the screen, which simply checks the positioning of the buttons when you touch them.




Setting a PIN

You may want to set a PIN. To do this, enter and confirm a 4 digit number. Once you have set this, you will be asked to enter your PIN each time you switch your monitor on. If you enter your PIN incorrectly twice, the monitor will lock. To unlock your monitor, see page 20.



Setting a new cycle

You **must** set a new cycle **each** menstrual cycle. You should do this on day 1, which is the first day of your period. (The first day of your period is the first day of blood flow – you should ignore spotting.) Press  and follow the instructions on the screen. If you forget to do this on day 1, you may still set up a new cycle until day 4 of your cycle. If you do not set up a new cycle within the first 4 days of your cycle, see question 4.

Enter the date on which your period started, then enter the time. If your period started in the night and you are not sure of the exact time, enter the time that you woke up. It is important to remember the time your period started, because your monitor will work out the first day of your cycle based on this. You need to inform your monitor when **each** new cycle begins. To do this you **must** set a cycle every time a new period starts.

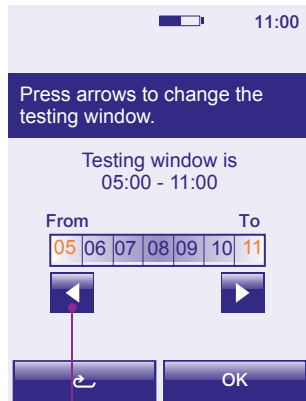
The testing window

The testing window is the 6-hour time period in which your monitor will ask you to test. (You will only be asked to test on certain days of your cycle.) You can set the testing window to any 6-hour time period in 24 hours, but you must test using your first urine of the day after you wake up, as this contains the most hormones.

Persona will automatically set your testing window from 0500 to 1100. You can change this on the screen shown here.

Once you have set your new cycle the monitor will show the day of your cycle and whether you are on a red day or a green day.

If you do not set a new cycle within the first 4 days of



Use the arrows to adjust the testing window and then press 'OK'.


your cycle, your monitor will not have enough information to show whether you are on a red day or a green day. See question 4.


The cycle day shown on your monitor will depend on the time your period started and when your testing window is set to finish. For example after you set a new cycle, you may find that day 1 is not shown until the day after your period started. When this happens the menu screen will tell you the new cycle is pending.


At the start of each cycle the monitor will set the testing window to the same time as your previous cycle. You can change this, but when setting your testing window, remember that it must allow you to test using your first urine of the day after you wake up.



Setting an alarm


You can set an alarm to remind you to test. You can only set it to go off during the testing window. On test days the alarm will sound at the set time. To set an alarm, press  from the menu and follow the instructions on the screen.

Once you have set an alarm, the alarm symbol  will appear above the information bar. (You will not be able to set an alarm until you have set up your cycle).

The alarm will sound until you switch your monitor on, or until your testing window ends. You can turn off the alarm by going to the main menu, pressing  and following the instructions on the screen.

If you change the testing window at the start of a new cycle and the time of the alarm set in the previous cycle is not within this new testing window, it will automatically be cancelled. To set an alarm during your new testing window, press  from the menu and follow the instructions on the screen.

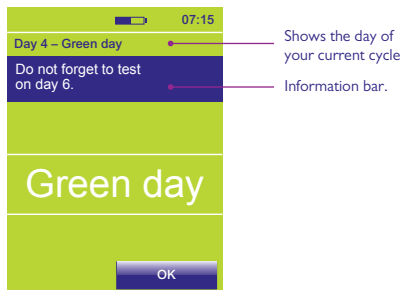
Changing or deleting your cycle set up

If you want to delete or change your cycle set up press  from the menu. Changing your cycle allows you to change the date and time your period started. You can only change your cycle between day 1 and day 4 of your cycle.

You may delete your cycle up to day 4. You may want to do this if you thought your period had started but it was only spotting. When your period starts, set up your new cycle as normal.

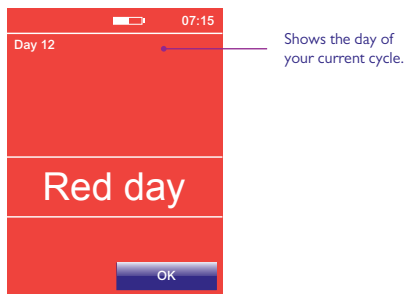
Green days, red days and test days

Each day the monitor will show the current date and time, and the day of your cycle. Turn your monitor on every morning within the testing window to check whether it is a green day, a red day or a test day. You will probably want to check before having sex and use the advice displayed. If it is a test day the result of the test will apply.



Green days mean you are free to have sex without using contraception.*

On green days, the screen may also give you more information, for example tells you when you need to do your next test.




Red days are days around the time you ovulate and mean you are at a high risk of getting pregnant if you have sex, even if you use a condom. On red days, the screen may also give you more information, for example tells you when you need to do your next test.

When using Persona, you must **not** have sex on red days. See question 9.

Persona will typically identify 6 to 12 red days in each cycle. You will probably have 10 to 15 (but you may have up to 22) red days in the first few cycles you are using Persona, while your monitor is learning about you.

Cycles vary from woman to woman and cycle to cycle. This means that the number and timing of red days can vary. If you have irregular cycles, you may have more than 12 red days in each cycle. To minimise the number of red days, make sure you carry out all tests correctly.

If the 'O' symbol  is displayed in a cycle, it will appear for 2 days in a row. The first day it appears means that you should ovulate within the next 1 to 2 days. This is the time when you are at the highest risk of getting pregnant, but you must still not have sex on any red days.

If a test is requested the day after the first 'O' symbol is displayed and you miss this test, the screen will display this as a missed test.

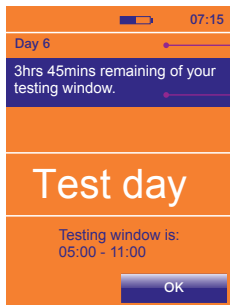
It is quite normal for the 'O' symbol not to appear in some cycles. If you have used Persona for 3 complete cycles and have not seen the 'O' symbol, call our advice line.

Test days mean you will need to do a test to see if you are on a red day or a green day.

Check the calendar to see which days you need to test. See page 15. During your first cycle you will be asked to test on 16 days. You will be asked for the first test on day 6 and the rest of the tests on days 9 to 23.

After your first cycle you will be asked to do a test on 8 days of each cycle. **You will always be asked to do your first test on day 6.** Your monitor will ask for the rest of the tests on any 7 days in a row. Test days may vary from cycle to cycle.

It is important that you do all tests correctly. If you miss a test, the monitor will decide on a red day or green day based on the information available to it. This may mean you will have more red days in your cycle.



Shows the day of your current cycle

Information bar

Testing

Each day, during the testing window, you will need to check your monitor. You must test using your first urine of the day after you wake up, so check before going to the toilet. If you need to do a test the test light will flash. If you have set an alarm, this will sound at the time you need to test.

If you press OK from the test day screen you will return to the menu. You may insert a test stick from any screen with the exception of the Persona screen. The Persona screen is displayed as soon as the monitor is switched on while it carries out necessary checks. You must wait until this screen is no longer displayed before inserting a test stick.

You must only use Persona test sticks with the monitor. Make sure that all the test sticks you use in any one cycle are from the same lot number. You can find the lot number, shown as LOT, on the test stick's foil wrapper or on the test stick box. Do not use test sticks that are out of date or if the foil wrapper is damaged.

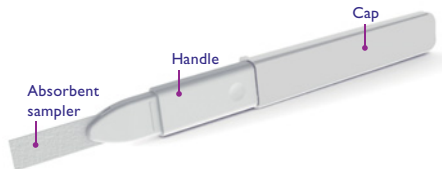
If you want to collect your urine to test later, for example, if you need to go to the toilet before your testing window starts, use a clean, dry container and store it at room temperature until you are ready to test. Remember to test within the testing window.

How to test

1. When you are ready to test, remove a test stick from its foil wrapper and use it straight away.

2. Put just the absorbent sampler pointing downwards into your urine stream for **3 seconds** only. **Or**, you can collect a sample of your urine in a clean, dry container and put just the absorbent sampler into the urine, as shown, for **15 seconds** only.

3. Keeping the test stick pointing downwards, **take the cap off the handle and place it over the absorbent sampler**. Wipe any excess urine off the test stick.



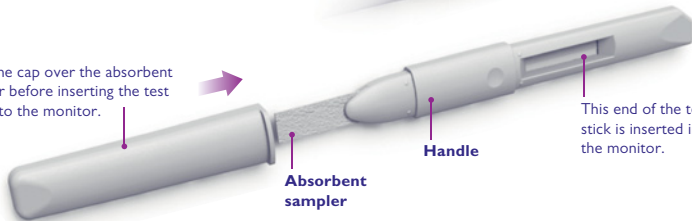
OR



Cap
Remove the cap from the handle.



Place the cap over the absorbent sampler before inserting the test stick into the monitor.



This end of the test stick is inserted into the monitor.

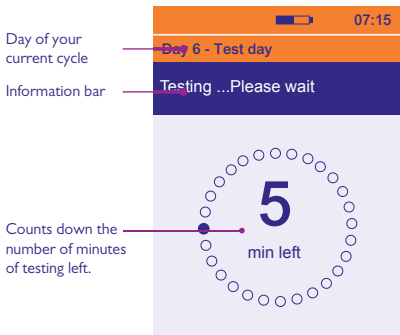
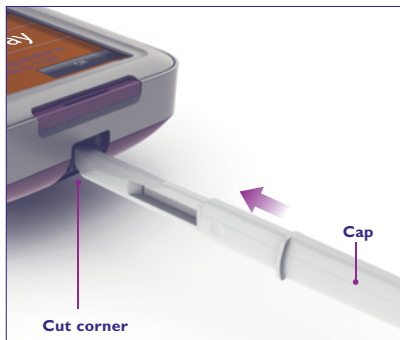
3. If the monitor is switched off you must **switch it on and wait for the Persona screen to disappear.** As soon as the Persona screen is no longer displayed insert the test stick, as shown, into the test stick slot straight up and place the monitor on a flat surface.

Wait for 5 minutes. The screen will switch off after 1 minute, which is normal. The monitor will continue to analyse the test. The test light will flash during testing.

4. Once testing has finished, the alarm will sound. If the monitor is off, switch it back on. The screen will ask you to remove the test stick. Throw the test stick away with your normal household waste. You must not reuse a test stick.

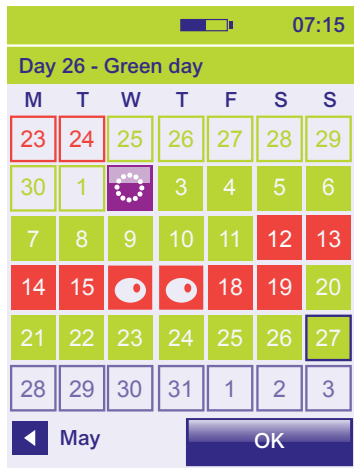
5. Once you have removed the test stick, the screen will show whether it is a green day or a red day.

While you are testing, **do not** hold the test stick with the absorbent sampler pointing upwards as the result may be affected.



Calendar

Below is an example of how your calendar may look.



Start of new cycle (day 1).

3

Green day.

14

Red day.



'O' symbol.

26

Red day of previous cycle.

30

Green day of previous cycle.

27

Today's date (shown by a black border).




Press the arrow to go back through your past cycles.



If you miss a test  will appear on that day. The background will be red or green depending on the type of day it was.

At the beginning of a new cycle, the days you must test on will have an orange background. During the first cycle that you use Persona, 16 test days will be shown. For your second cycle onwards, 8 test days will be shown (see example below).

The first test of every cycle will always be requested on day 6 of your cycle.

M	T	W	T	F	S	S
23	24	25	26	27		29
30	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20

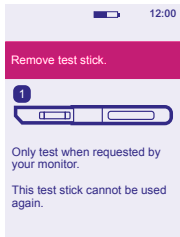
Each test day will change to a red day or green day once the test is complete. If you miss a test the monitor will change to show a missed test symbol with the background colour being red or green.

Your monitor will store information from your previous 6 cycles, as well as your current cycle. You can see this information by pressing  and  on the screen.

Tips and solving problems

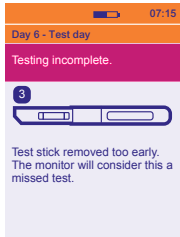
If your monitor needs attention, or there is a problem, the screen will show advice and what you need to do.

There is a message saying 'Remove test stick 1'. Remove the test stick from the test stick slot.

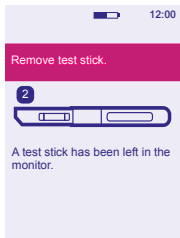


There is a message saying 'Testing incomplete 3'.

The test stick has been removed before testing is completed. The monitor will consider this a missed test.

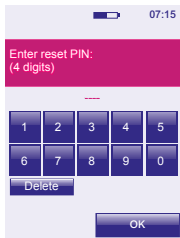


There is a message saying 'Remove test stick 2'. You need to remove the test stick from the test stick slot before the screen will show red, green or test day



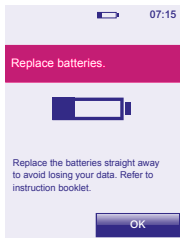
The message bar is highlighted in red.

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



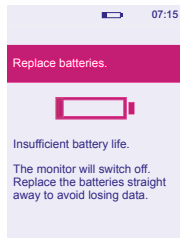
There is a message saying 'Replace batteries'. The batteries are low and should be replaced straight away to avoid losing your data. It is very important to use 2 AA alkaline (LR6) 1.5v batteries. **Do not** use rechargeable batteries.

The batteries must not be replaced during your testing window and only remove them when you have new ones to insert. Switch the monitor off first and remove the batteries using the battery tabs, taking out the negative end first. Do not use a sharp implement to remove the batteries.



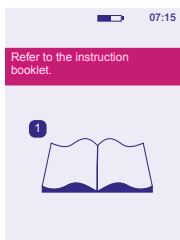
There is a message saying 'Replace batteries!' You will need to replace the batteries before you can test. The monitor will switch itself off to protect stored information. Do not remove the batteries until you have new ones to insert. It is very important to use 2 AA alkaline (LR6) 1.5v batteries. **Do not** use rechargeable batteries.

Remove the batteries using the battery tabs, taking out the negative end first. Do not use a sharp implement to remove the batteries. Once you have inserted new batteries you must switch on your monitor to allow it to do necessary checks.



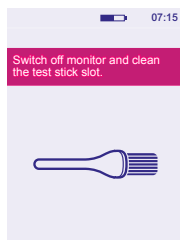
There is a message saying 'Refer to instruction booklet.'

This means there is a problem with your monitor. A number will also appear on the screen. Please phone our advice line. Tell them there is a problem with your monitor and which number is on the screen.



There is a message saying 'Switch off monitor and clean the test stick slot'.

You need to clean the test stick slot before inserting a test stick.



Cleaning the test stick slot

1. Remove the battery cover and test stick carriage.
2. Slightly dampen a clean cotton bud with cold water and gently clean the test stick slot and test stick carriage.
3. Replace the test stick carriage and battery cover.



Storing your monitor

Store your monitor in a dry place, at a room temperature between 10°C and 40°C.


Reprogramming your monitor

Reprogramming your monitor deletes all the information you have already stored about your cycles. Once this information is deleted, you cannot get it back. There are certain circumstances when you will need to reprogram your monitor (for example, if you forgot to set up a new cycle).

Once you reprogram your monitor, it will think you are using it for the first time and will treat you as a new user. You will need to set up your monitor again and do 16 tests in the first cycle. You may also have more red days during your next few cycles.

To reprogram your monitor, click  from the settings menu and follow the instructions on the screen.

Changing the time

You can change the time on your monitor by pressing  from the settings screen. You can increase or decrease the time by one hour once during your cycle, and this must be done between day 1 and 4. Your testing window will be updated automatically.

It is advisable to only change the time on your monitor for daylight saving time during the year.

If you need to change the time for more or less than 1 hour you will need to reprogram your monitor which will delete all the information you have already stored about your cycle. See page 18.

If you are travelling and the time zone changes by more than 1 hour see question 16

Questions and answers

1. Can I use Persona if I am taking medication or suffering from a medical condition?

You **must not** use Persona if:

- you are using hormonal treatments (for example, the contraceptive pill, emergency contraception, fertility treatment or hormone replacement therapy (HRT));
- you have had menopausal symptoms such as night sweats or hot flushes;
- you are using any treatments that may affect your cycle;
- you are taking antibiotics containing tetracyclines. Once you have finished your treatment you may start using Persona at the beginning of your next cycle;
- you have impaired liver or kidney function;
- you have polycystic ovarian syndrome (PCOS).

If you take any medication, you should always read the manufacturer's instructions to check whether or not it affects your cycle. If you are not sure after reading the instructions, contact the manufacturer. If you need more advice, you should see your doctor. Refer to "Is Persona right for me?" on page 3 for further information.


2. What happens if I am ill during a cycle?

If you are able to, you should continue to use your monitor and do all the tests when your monitor asks you to. If you cannot test, your monitor will make a decision based on the information it has stored. This may mean you have more red days for that cycle and your next few cycles.


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

If the length of your cycle is still between 23 and 35 days it does not matter if it varies from one cycle to the next. If you have a cycle that is shorter than 23 days or longer than 35 days call our advice line for more information.

4. I forgot to set up a new cycle the day my period started. What should I do?

You can set up a new cycle between day 1 and day 4 of your cycle. To set up a new cycle, press  on the menu. (See page 7 for how to set up a new cycle.) **If you have not set up your new cycle by day 4**, you will need to reprogram your monitor (see page 18). You may then set up a new cycle when your next period starts (see page 7). Until you have set up a new cycle, you should not rely on Persona for contraception.

5. I thought my period had started and have set up a new cycle but it was only spotting. What should I do?

Press  on the menu, 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.

6. What if I need to delete my cycle after day 4?

If you need to delete your cycle after day 4, you will need to reprogram your monitor (see page 18). You may then set up a new cycle when your period starts (see page 7). Until you have set up a new cycle, you should not rely on Persona for contraception.

7. What do I do if I need to go to the toilet before my testing window starts?

You should always test using the urine passed after your longest sleep. This may mean you need to collect a sample of urine to test later (see page 11).

8. 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 the screen.

9. Can I really not have sex on any red days?

For Persona to be 94% reliable*, you must not have sex on any red days. If you choose to have sex on a red day using an alternative method, the reliability is based on the method of contraception you choose to use, and not on Persona.

10. I haven't used my monitor for some time. What should I do?

If you haven't used your monitor for more than one cycle, you will need to reprogram it. (See page 18). You should also check that you are still suitable to use Persona (see page 3).

11. Can I have sex during my testing window before checking my monitor?

You will probably want to check your monitor before having sex and use the advice displayed. If it is a test day the result of the test will apply.

12. What happens if I get up late, or forget to test during the testing window?

If you do not test during the testing window the monitor will show you have missed a test and work out whether you are on a green day or a red day using the information it has stored about you.

If you miss tests, you may find you have more red days during the current cycle and in your next few cycles. So, it is important to remember to test when the monitor asks you to.

13. Is my monitor waterproof?

The monitor is not waterproof and you should try to make sure it does not get wet. Always remove excess urine from the test stick before putting it into the test stick slot.

14. Can I lose the information stored in my monitor?

The monitor depends on a constant supply of battery power. It is very important that you replace the batteries when the monitor asks you to.

If the batteries are about to run out, the monitor will switch itself off to try to protect your information. However, if the batteries are not replaced straight away and it is left without power an error will occur and your information will be lost. You will be unable to use your monitor until you replace the batteries and reprogram it.

15. What type of batteries should I use?

It is very important to use AA alkaline (LR6) 1.5v batteries. If you do not there is a risk the information stored on your monitor will be lost. **Do not** use rechargeable batteries.

16. What should I do if I am travelling and the time zone changes?

When you travel, you should carry your monitor in your hand luggage. The monitor is not affected by X-ray equipment.

It is advisable to only change the time on your monitor for daylight saving time. See page 18. If you are travelling between time zones that are less than 6 hours apart you can still test if your testing window is set so that you can use the first urine after your longest sleep in your new time zone. You may wish to set an alarm to remind you when the testing window starts, but remember that the time on the monitor will be set to your home time zone.

If travelling between time zones that are more than 6 hours apart, you can set the testing window according to your home country time (the monitor time) or your destination time. This may mean collecting your first urine of the day and testing later when the Testing Window starts. Alternatively you can miss tests during the cycle you are travelling. See question 20.


17. What happens if I do shift work?

When you set up a new cycle, set the testing window so that you can test using your first urine of the day after you wake up. If you are working night shifts, this may be during the afternoon. If your shift changes during your cycle, you can only test during the testing window, but you should still use the first urine after your longest sleep. This may mean collecting the urine in a container and testing it later on within your testing window.

18. If my monitor stops working, what should I do?

If your monitor stops working, phone our advice line.

19. The touchscreen does not appear to be working. The buttons are not responding. What should I do?

You may need to re-calibrate the screen which checks the positioning of the buttons when you touch them. Press  from settings and follow the instructions on the screen.

20. What happens if I want to stop using Persona?

You can stop using Persona for one cycle by setting up your new cycle as normal, but then ignoring any tests your monitor asks for during that cycle. During this cycle, you should not rely on Persona for contraception.

When you start using Persona again you may have more red days.

If you want to stop using Persona for more than one cycle, remove the batteries and store the monitor and batteries in a dry place. If you want to start using Persona again, you will need to check it is still suitable for you to use and then reprogram your monitor.

21. Can I let anyone else use my monitor?

No. The monitor adapts and stores information in relation to your cycle and should not be used by anyone else. Also, for hygiene reasons, you should not share your monitor.

22. How do I dispose of the monitor and batteries?

If you wish to dispose of your monitor permanently you should do so according to the appropriate recycling scheme for electrical equipment. Do not dispose of electrical equipment in fire.

You should dispose of the batteries according to the appropriate recycling scheme. Caution: do not disassemble, recharge or dispose of the batteries in fire. Do not swallow. Keep away from children.

* Persona is 94% reliable if you follow the instructions properly and use it as the only method of contraception. This means that if 100 women use Persona for one year, we expect 6 will become pregnant because they have had sex on a day when Persona incorrectly showed they were not at risk of becoming pregnant (green day).

Advisors available 07:00 – 15:00hrs Mon-Fri, excluding Bank Holidays.

UK 0800 917 2710 • IE 1800 812 607

Free from landlines, mobiles may be charged. All calls are recorded and may be monitored for quality purposes. Please be ready to quote the **LOT** number.

www.persona.info

Manufacturer: SPD Swiss Precision Diagnostics GmbH,
Route de St Georges 47, 1213 Petit-Lancy, Geneva, Switzerland.

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For *in vitro* diagnostic use.

This device is for home use.

Not for internal use.

Keep out of the reach of children.

Monitor contains magnets.

Dispose of batteries according to the appropriate recycling scheme.

This IVD digital device meets the emissions and immunity requirements of EN 61326-2-6:2006. The EMC countermeasures employed within the electronic instrument will provide reasonable protection against electromagnetic interference effects likely to be encountered in the home environment. The following preventive warnings apply to EN 61326-2-6:2006 compliant equipment.

- a) Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- b) Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. mobile phones), as these may interfere with the proper operation.

