

GvulaRing



USER MANUAL

*OvulaRing shows you when
your fertile days are, no
matter how your cycle ticks.*



Product overview



- 1 Ring made of medical plastic
- 2 Biosensor
- 3 OvulaRing, comprising a medical plastic ring with clicked-in biosensor
- 4 Reading device with sensor holder and cap
- 5 myovularing software can be reached at www.myovularing.com

Dear OvulaRing User,

Thank you for choosing OvulaRing.

Using a vaginal biosensor, OvulaRing records your core body temperature automatically, around the clock. Without the need for tiresome morning temperature taking. Instead of one measurement, OvulaRing records 288 measurements a day, thus enabling a much more precise observation of your cycle, independent of cycle length and external influences such as stress, sleep, sport or nutrition. Medical algorithms evaluate the data and identify your individual cycle and fertility pattern.

With OvulaRing you can discover if you are ovulating or if there is an indication of a hormonal cycle disorder. In addition, you can view your daily conception probability in real time and view a forecast for ovulation in the subsequent cycle.

Please read the user manual carefully before unpacking and use! If you have any questions, please contact our team of experts at any time:

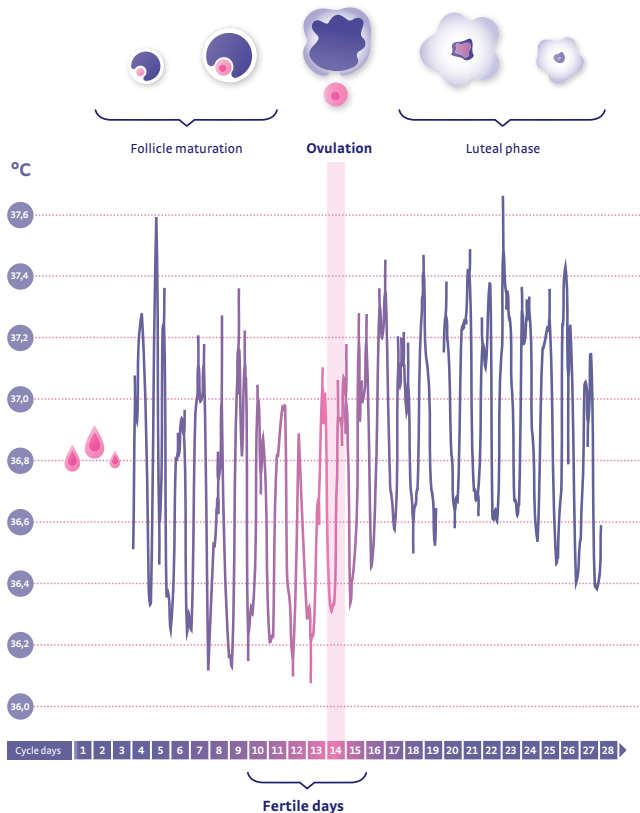
Telephon: + 49 (0) 341 3558 2099

E-mail: info@ovularing.com

We hope that you enjoy using this product.

Your OvulaRing team

Maturation phases of the egg cell and course of the core body temperature



OvulaRing shows you how your cycle works

There are only 6 days per cycle on which sexual intercourse can result in pregnancy. This fertile phase includes the 4 days before ovulation, the day of ovulation itself and the day after. The chances of pregnancy are greatest 2 days before ovulation.

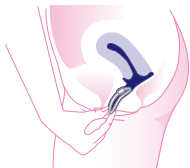
However, the timing point of ovulation is different for each woman and may vary from cycle to cycle. Body temperature rises after ovulation with the simultaneous release of the hormone progesterone, increasing by 0.2 - 0.5 °C. If the temperature remains elevated for 3 days, you can be sure that ovulation has occurred and that the fertile phase is complete.

The high resolution temperature measurement allows OvulaRing to detect the smallest changes in temperature even before ovulation and shows you your fertility window, without the need for morning temperature taking.

📖 **A wealth of further information regarding the female cycle can be found on our website www.ovularing.com.**

Cycle monitoring with OvulaRing

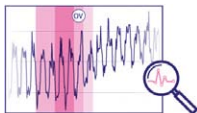
1. Wearing OvulaRing



2. Uploading data



3. Evaluating your cycle



In the 1st usage cycle, OvulaRing gets to know your individual cycle patterns. You will receive an evaluation for this first cycle when it has been completed. Then you will find out whether ovulation has occurred and if so when. You will also receive other important information about your cycle health. If ovulation has been detected, OvulaRing can now use your individual cycle pattern as the basis for evaluating the subsequent cycles. In the first cycle, we recommend that you remove and read out the sensor for the first time after 1-2 days. You can find detailed instructions on this under the section 'Removing OvulaRing from the vagina'. If the data transfer worked without any problems, you can put the ring back in and wear it until the beginning of the period.

In the 2nd usage cycle you can use the display of the current conception probability. This requires that OvulaRing is inserted at the latest on the 6th day of the cycle and recording gaps are smaller than 1 hour per day. In addition, new data must be uploaded. We recommend uploading data daily from approximately 1 to 2 days before the cycle day on which your fertile phase began in the 1st cycle.

The current conception probability is displayed with the following status reports:

- **Fertile phase has not yet begun**
- **Low** – There is a low likelihood of conception.
- **Medium** – There is a medium likelihood of conception.
- **High** – The likelihood of conception is highest on this day.
- **Unlikely, the fertile phase for this cycle has passed** – Conception is therefore unlikely.

If the status report “Unlikely, the fertile phase for this cycle has passed” appears, you no longer need to read out OvulaRing daily and can wear it without interruption until the beginning of the next menstruation.

From the 4th usage cycle onwards you receive an ovulation forecast for the following cycles. Prerequisite for this is that ovulation was recognised in the first 3 cycles. If ovulation fluctuates by more than 8 days in the subsequent cycles, no safe forecast can be provided. Please note that the forecast is an approximate value and is calculated on the basis of the last completed cycles. The findings for the current conception probability may vary from this, as they are based on more recent data. Therefore, we always recommend comparing the results of the prognosis with those of the daily probability of conception.

What do you need to pay attention to before and during use of OvulaRing?

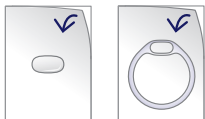
Hygiene and cleaning instructions

A



Great emphasis should be placed on hygiene during use. Please wash your hands each time before inserting or removing OvulaRing.

B



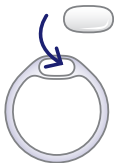
Biosensor and medical plastic ring are supplied separate from each other in a hygienic, clean condition. Please only remove the biosensor and plastic ring from the packaging directly prior to insertion.

C



Disinfect the biosensor and plastic ring thoroughly with the enclosed disinfectant wipes prior to each insertion.

D



Place the biosensor in the plastic ring and insert it into the vagina.

Note:

Following each removal of the biosensor from the body it is sufficient to clean the sensor with mild, ph-neutral soap under running, luke-warm water. Following this, rinse the biosensor well with clear water and dry. Please also clean the sensor holder and the cap of the reading device regularly in the same way.

Service life and storage of biosensor and medical plastic ring

On the packaging of the biosensor and plastic ring you will find the packing date and the maximum storage date, which states the date until which the biosensor and plastic ring may be used.

Medical plastic ring: The plastic ring may remain in the vagina for a maximum continuous period of 30 days at a time and must be replaced at the latest after this time. Naturally, you may remove it for reading and insert it again as often as you like.

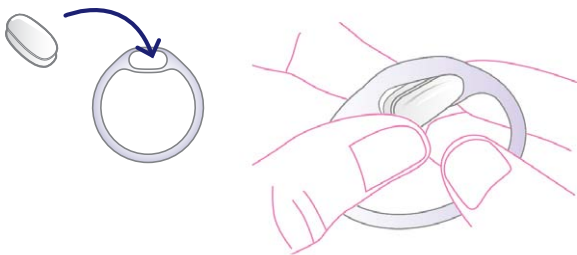
Biosensor: The battery life of the biosensor is approximately 6 months. The battery status of your sensor is communicated with each data upload. If the battery is running low, we will send you a replacement sensor automatically. The booked application time starts on the day on which the first temperature value is recorded with the sensor, at the latest 4 weeks after the date of sending of your OvulaRing package. The internal memory of the biosensor can record data for up to 3 months. If the memory is full, no new temperature values can be saved. Therefore, the biosensor should be read out at least every 4 weeks. When the biosensor is not located in the vagina, no temperature value is recorded. During this time store the biosensor in a dry, light-protected location in the storage box supplied.

How to use OvulaRing

OvulaRing is inserted into the vagina following the end of menstruation, or at the latest on the 6th day of the cycle. The first day of the cycle is the first day of the period. Prior to inserting OvulaRing make sure that the biosensor is correctly clicked into place in the plastic ring.

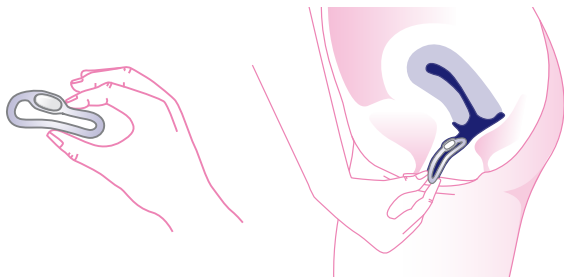
Inserting the biosensor into the plastic ring

Wash your hands, the plastic ring and the biosensor as described under the hygiene and cleaning instructions. Take the clean biosensor and press it into the hollow space of the plastic ring. Place the biosensor into the plastic ring above a soft surface (e.g. a towel). This can prevent damage to the sensor in the event of it falling down. The biosensor should lock in securely via the groove in the plastic ring. The biosensor should not slip out of the groove when the ring is twisted and bent! Please check this carefully. If this occurs, the biosensor has been inserted incorrectly and must be removed and inserted again.



Inserting OvulaRing into the vagina

Press OvulaRing together lightly with thumb and index finger. Now insert the compressed ring with the sensor in front deep into the vagina. Raising one leg may aid this. Some women find it easier to insert the ring whilst squatting or lying down. It is a good idea to try various positions until you find the one you are most comfortable with.

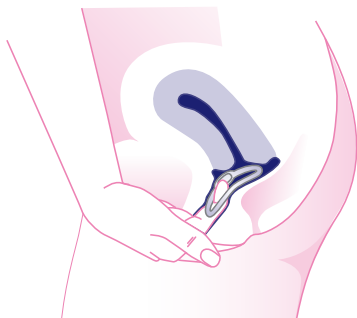


After releasing, OvulaRing automatically resumes its original ring form. Now use your middle or index finger to push OvulaRing to the deepest point of the vagina. The ring slides into the correct position and is no longer noticeable.



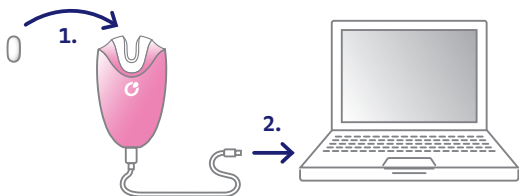
Removing OvulaRing from the vagina

To remove OvulaRing from the vagina grip it with the index or middle finger and draw it out. Then remove the biosensor from the plastic ring, clean it with a mild, ph-neutral soap and rinse it well under running lukewarm water. If you now wish to place the biosensor into the reading device or store it in the box during the time of menstruation, dab it dry beforehand with a clean, soft cloth or place it on a clean surface for a number of minutes until it is dry.



Data upload

With the aid of the OvulaRing reading device you can upload the data of the biosensor simply and unassisted. In this process the device generates and saves a file that is identified with sensor number, date and time of reading (in Greenwich Mean Time). After successful read out, the reading device can be accessed like a USB stick. You can upload the current file to our secure web database via www.myovularing.com.



Read out is performed as follows:

1. Clean the biosensor before reading, in accordance with the hygiene and cleaning instructions. The sensor holder may be removed from the reading device for cleaning purposes.
2. Plug the sensor into the reading device and ensure that it does not fall out.
3. Connect the reading device with sensor to your computer via the USB port.
4. The transfer of data now begins automatically. The data is transferred from the sensor to the reading device. This is indicated by a rapid flashing of the LED and may take up to 30 seconds, depending on file size.
5. Following successful reading the file is deposited on the USB memory of the reading device and the sensor memory is deleted. The reading device now switches to mass storage mode, indicated by a slow, gentle flashing of the LED. If the LED is illuminated constantly again after the reading process, no data has been transferred. In this case repeat the read out of the sensor in a different position in the reading device.
6. Log in to www.myovularing.com with your access data and select the option 'Upload data' on the start screen. Further information

regarding the web software can be found in the sub-section 'Using the myovularing software'.

7. Select the drive of the reading device in the upload dialogue and select the current file in the DATA folder. The file name is coded as follows: Sensor number_Date_Time of reading; e.g. 32-012345_200215_0947.ovu.
8. After successful uploading a message appears that your data have been saved in the database. Now the results of the current likelihood of conception are displayed to you or you can view your cycle curve.

Note:

It is also possible to connect the reading device to the computer first in order to read out the sensor. With this option, the time until the sensor is plugged into the reading device may not exceed 30 seconds. If you do not insert a sensor into the reading device within these 30 seconds after connecting the reading device to the computer, it switches to mass storage mode (USB stick). This is indicated by the slow, gentle flashing of the status LED on the top of the reading device and your computer recognises the reading device as a drive. This enables you to see old files without reading the sensor, for example. If you wish to read out the sensor again, eject the reading device (as with a USB stick), remove it from the computer and connect it again with the sensor inserted.

Using the myovularing software

Launch the software www.myovularing.com in your web browser. Username and first password for the web software can be found on the back of these instructions. Be sure to keep these in a safe place. When you log into the software for the first time you will be asked to change your password. This is a security measure to ensure that only you know your password. When logging in for the first time you

can also add your e-mail address to reset your password, if you have forgotten it. You cannot change your username, this should be noted or memorised.

After successfully logging in to www.myovularing.com the start screen appears, containing an overview of the most important software information. Using the 'Upload data' button you can access the OvulaRing reading device, select a file and update your data. For clear allocation of the cycles please state the first day of the most recent menstrual period (enter beginning of cycle). After uploading the data you can view your cycle curve and use further functions of the software.

Overview of the individual functions

1st Cycle - learning cycle and retrospective analysis

Your first OvulaRing cycle is a learning cycle. Here the algorithms get to know your individual cycle pattern in order to compare this with the patterns in the following cycles. At the end of the cycle you learn if you have ovulated, when your fertile phase was and if the second half of the cycle was sufficiently long.

2nd cycle - daily conception probability

From OvulaRing cycle two it is possible to identify your daily fertility status. This requires that you insert OvulaRing at the latest on the 6th day of your cycle and avoid recording gaps of more than one hour. Following this, each time the data is uploaded your conception probability will be stated as low, medium and high. The system also shows you if your fertile phase is completed.

From cycle 4 - ovulation forecast

After three recorded OvulaRing cycles with ovulation the software is generally able to give you a forecast for ovulation and fertile phase in the following cycles. This requires an ovulation in each of the

first three cycles. If ovulation fluctuates by more than 8 days in the subsequent cycles, no safe forecast can be provided. Please note that the forecast is an approximate value and is calculated on the basis of the last completed cycles. The findings for the current likelihood of conception may vary from this, as they are based on more recent data.

Pregnancy test and calculation of due date

The OvulaRing software has an integrated, free pregnancy test. If a pregnancy is identified, you can also precisely calculate a provisional due date.

Further functions

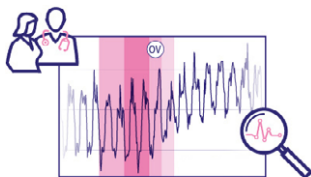
You can also use the OvulaRing software as a cycle diary and enter various additional markers such as sexual intercourse, sport, stress, illness or medication taken. In addition, you can also look at an overview of all recorded cycles in the statistics.

A detailed explanation of the software can be found in the software operating instructions, you can view and download these at www.myovularing.com or www.ovularing.com.

For questions regarding use of the software and evaluation of your data please go to www.myovularing.com or contact our team of experts in confidence:

Telephone: +49 (0) 341 3558 2099

E-mail: info@ovularing.com





General safety information

- OvulaRing has been produced and tested in accordance with the applicable statutory requirements and thereby complies with all possibilities open to the manufacturer to avoid health risks.
- OvulaRing provides support in the diagnosis of female cycle health and can be used to determine fertile phases, i.e. fertile days. OvulaRing is not a replacement for individual contraception measures and means (e.g. condoms). If you do not wish to become pregnant, you must use a contraceptive method of your choice.
- Infections, high stress, high levels of sporting activity or long-term pressure as well as a lack of sleep, particularly where this occurs or increases abruptly, influence the hormonal cycle and can inhibit the evaluation of the software. In these cases please update your data regularly, at least every 2 days, and take note of all evaluations. In case of doubt, please contact our customer service.
- The plastic ring may remain in the body for a total of 30 days at a time. After this it should be disposed of in the household waste.
- OvulaRing should be examined for any visible defects and changes on removal from the body. OvulaRing may not continue to be used after the use-by date.
- If you experience pain following insertion of OvulaRing, please remove it and consult your medical specialist.
- OvulaRing can be swallowed. Please keep out of reach of children.
- OvulaRing is not a thermometer and is not suitable for direct temperature measurement (e.g. in the manner of a clinical thermometer).

- If you are taking medication over an extended period of time that affect the body temperature (e.g. progesterone), this may affect the results of OvulaRing.
- Do not use any other aids for insertion and removal of the ring.



Information for safe use

- Do not use any aggressive disinfectant or cleaning agents, scouring powder or hard brushes for cleaning. Do not use chemicals or hot water.
- Do not clean the plastic ring and biosensor in boiling water.
- Do not store the biosensor in a disinfection cloth or in a disinfection solution.
- Do not clean or disinfect the plastic ring and biosensor with the aid of a microwave. Do not clean the plastic ring and biosensor in the dishwasher.
- If you are using vaginal therapeutics such as vaginal creams or suppositories at the same time this may inhibit the material of the plastic ring and the ring may break in rare cases. Please check the plastic ring regularly where used in parallel with vaginal therapeutics and change the plastic ring promptly in the event of defect or breakage.
- The biosensor should only be used together with the medical plastic ring.
- OvulaRing should not be inserted into more than one person. Multiple use is only permissible with one and the same person.

- OvulaRing should not come into contact with pointed or sharp objects.
- OvulaRing should be protected against knocks and impacts. Protect OvulaRing against high and low temperatures and avoid direct sunlight.
- Do not place OvulaRing on the radiator, in the oven or in the microwave to dry. Do not place it in the freezer.
- The ring may slip out of place during sexual intercourse or during bowel movements. Please check the correct position regularly to avoid loss of OvulaRing.
- OvulaRing is designed for domestic use, please do not use it in other medical environments, such as in emergency medicine.
- Please only use the USB cable supplied.
- Please use and store OvulaRing with a minimum distance of 30cm to other electronic devices with radio-control functions, as these may affect safe use of OvulaRing.
- Please do not use the OvulaRing reading device in the vicinity of water and splashing water.
- Only IEC 60950-tested computers may be used as power source for the reading device.

Send back to manufacturer in case of malfunctions.

Warning:

Technical alterations to the OvulaRing biosensor, plastic ring or reading device are not permitted.



Please do not use OvulaRing if you...

- ... have your menstrual bleeding. Remove OvulaRing for hygiene reasons during menstruation.
- ... are allergic to epoxy resins and EVA copolymers.
- ... have inflammation in the genital area.
- ... find visible defects or changes in OvulaRing.
- ... are pregnant.
- ... pass through security barriers or areas, for example at airports.
- ... are required to undergo an MRI, CT, PET or X-ray examination, or high-frequency surgery.

Explanation of symbols used

Warning notice / safety notice



Identifies potential damage or danger for the user that may result from improper use.



Identifies the name and address of the manufacturer of the product.



Biosensor and plastic ring are type BF application parts for protection against electrical shock.



Note instructions for use!



Permissible temperature range with minimum and maximum temperature.



Please see instructions for use.



Disposal: Biosensor and reading device may not be disposed off in the household waste.



Recycling: The plastic ring can be disposed off in the household waste.

Technical data

Biosensor

Model designation: OVU-BS
Type: OVU-BS-2.2
Battery type: RENATA SR 626W (376)
Battery category: Silver oxide
Battery voltage: 2 x 1,55 V / 20 mAh
Dimensions (W x H x D):
20.7 mm x 10 mm x 10 mm
Power supply: internal
Humidity: 15% to 90%, non-condensing
Operating temperature: 35 °C to 42 °C
Activation / reading:
via software and reading device
Duration of recording:
max. 3 months without readout
Storage temperature: 0 °C to 50 °C
Service life after activation: max. 6 months
Measurement accuracy:
+/- 0.1 °C in the 35 °C - 42 °C range

IP protection class 58:
BS is dust protected and protected
against ongoing submersion
Year of development: 2012
Serial no.: 32-000000

Plastic ring

Exactly: Flexible ring pessary
Model designation: OV-KR
Type: OVU-KR-2
Dimensions: 54 mm x 4 mm
Storage temperature: 0 °C to 50 °C
Max. duration of use: 30 days
Year of development: 2012
Batch number: M-000000

Software

Model designation: OVU-SW
Type: OVU-SW-4.xx
Current version: see website
www.myovularing.com

Reading device

Model designation: OVU-LG
Type: LG/OVU-LG-2.2
Power supply:
external via USB, 5V, 100mA
Storage temperature range:
0 °C to 50 °C
Storage humidity:
15% to 90%, non-condensing
Operating temperature: 5 °C to 40 °C
Operating humidity:
15% to 90%, non-condensing
IP protection class 20:
The reading device is protected
against
solid foreign bodies with a
diameter \geq 12.5 mm
Service life: 10 years
Year of development: 2012
Serial no.: 32-L-000000

Accessories

USB cable < 0.5 m
Sensor holder for reading device
Disinfection cloths
Storage box

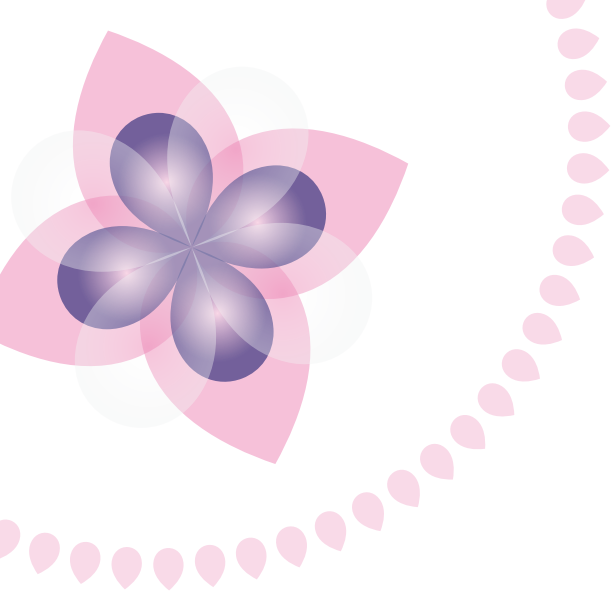
OVU-BS-2.2 and OVU-KR-2 are medical products class IIa. OVU-SW-4.x.x and OVU-LG-2.2 are medical products class I. OVU-BS-2.2 correspond to the requirements of CISPR 11 as well as DIN EN ISO 60601-1, DIN EN ISO 60601-1-11 and DIN EN ISO 60601-1-2.

Manufacturer

VivoSensMedical GmbH
Limburgerstraße 74C | 04229 Leipzig
Telephone: + 49 (0) 431 3558 2099
E-mail: info@ovularing.com



Status: May 2020



www.myovularing.com

Zugangsdaten für die Auswertung
Login-in data for the evaluation