

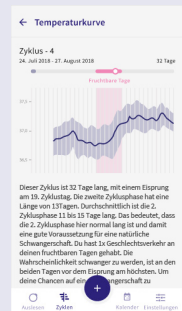
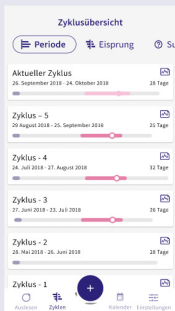
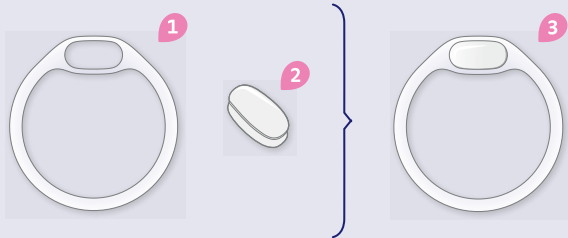
GvulaRing



USER MANUAL - EN

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

Product overview



- 1 Medical plastic ring
- 2 Biosensor
- 3 OvulaRing, comprising a Medical plastic ring with clicked-in biosensor
- 4 Mobile App (iPhone and Android)
- 5 OvulaRing webbased software 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, sports 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 likelihood of conceiving in real time and view a forecast for ovulation in the subsequent cycle.

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

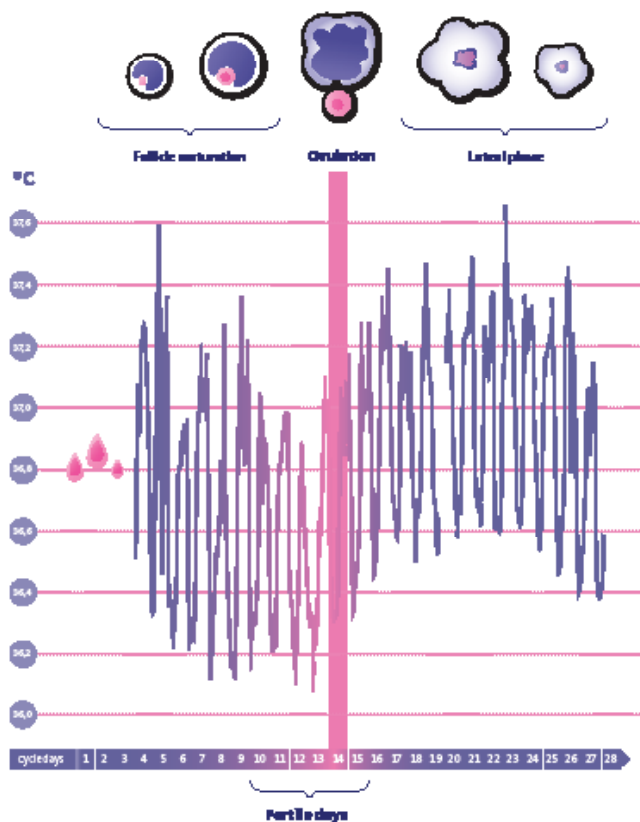
Telephon: + 49 (0) 341 3558 2099

E-mail: info@ovularing.com

We hope that you enjoy using this product.

Your OvulaRing team

The female cycle 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 a pregnancy. This fertile phase includes the 4 days before ovulation, the day of ovulation itself and the day after. The chances of conceiving are greatest 2 days before ovulation.

However, the day 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 and remains elevated until the end of the cycle.

Thanks to the automatic and high-resolution measurement with OvulaRing, the smallest changes are recognized even before ovulation. Without taking a morning measurement, OvulaRing shows you your fertility window and gives you detailed information on your individual cycle health.

➤ You can find more detailed information on the female cycle on our website at [ovularing.com](https://www.ovularing.com).

Cycle monitoring with OvulaRing

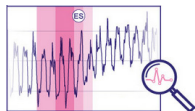
1. Wearing OvulaRing



2. Uploading data



3. Evaluating your cycle



In the 1st cycle OvulaRing gets to know your individual cycle patterns. You will receive an evaluation of this cycle once it has been completed. Then you will find out if and when an ovulation has occurred. Additionally you will receive further important information on your individual cycle health. If an ovulation has been detected, OvulaRing can now use your individual cycle pattern as a basis for evaluating subsequent cycles. In the first cycle, we recommend that you upload the sensor data into the OvulaRing App after 1-2 days for the first time. For detailed information please see chapter 'Removing OvulaRing from the vagina' on page 32. If the data transfer has worked without any problems, you can now wear OvulaRing until your next period starts.

From the 2nd cycle you can use the display of the current likelihood of conception. Prerequisite for the calculation of the current likelihood of conception is that the 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 one daily data upload from approximately 1 to 2 days before the cycle day on which your fertile phase began in the 1st cycle.

The current likelihood of conceiving 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 now at its highest.
- **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 scan the OvulaRing daily and can wear it without interruption until the begin of the next menstruation.

From the 4th cycle onwards you receive an ovulation forecast for the next cycle. Prerequisite for this is that ovulation was recognized 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 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 see your complete cycle statistics.

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

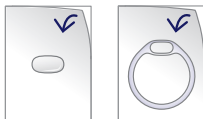
Hygiene and cleaning instructions

A



Please pay special attention on hygiene during use and wash your hands each time before inserting or removing the OvulaRing.

B



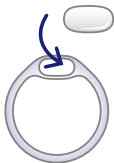
Biosensor and medical plastic ring are supplied separate from each other in a hygienic, clean condition. Please only remove the biosensor and medical plastic ring from the packaging directly prior to insertion.

C



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

D



Place the biosensor in the medical 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.

Service life and storage of biosensor and medical plastic ring

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

Medical plastic ring: The 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. But of course, you may remove it for data upload and insert it again as often as you like.

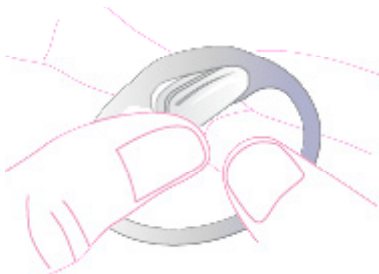
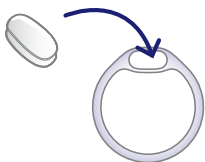
Biosensor: The battery life of the biosensor is approximately 6 months. The battery status of your sensor is communicated with each data upload. If the battery is running low, we will send you a replacement sensor automatically. Your booked time of application commences on the day on which the first temperature value is recorded with the sensor, or at the latest 4 weeks after the shipping date 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 data of the biosensor should be uploaded 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

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

Inserting the biosensor into the medical plastic ring

Wash your hands, the medical plastic ring and the biosensor as described in the chapter hygiene and cleaning instructions. Take the clean biosensor and press it into the hollow space of the medical plastic ring. Place the biosensor into the medical 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 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 the 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, the OvulaRing automatically resumes its original ring form. Now use your middle or index finger to push the ring 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 medical plastic ring, clean it with a mild, ph-neutral soap and rinse it well under running lukewarm water. If you now wish to 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 until it is dry.



Using the OvulaRing App

Download the OvulaRing app free of charge from the App Store or Google Play onto your smartphone. To log in to your personal account, we have set up a username and an initial password for you. You will find your login data on the back page of this manual. Be sure to keep it. The first time you log in to the app, you will be asked to change your password. This is a security measure to ensure that only you know your password. You cannot change your username. After successfully logging into the app, you will get an overview of the functions and will be able to personalize your account settings.

For clear allocation of the cycles please state the first day of your last period (enter beginning of cycle). The app now needs data to analyze your cycle. Wear OvulaRing and start recording data. After transferring the sensor data to the app, you can see your cycle curve and your current fertility status.

Data transfer from OvulaRing

With the help of the OvulaRing app, you can easily analyze your cycle. The data is transferred from the sensor to the app using a Bluetooth connection. After the successful data transfer, you can view your cycle analysis in the app.

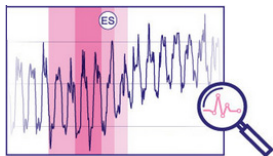
Follow these instructions for transferring the data:

1. Please make sure that Bluetooth is turned on on your smartphone and that it is connected to the internet.
2. Remove OvulaRing from the body and clean it according to the cleaning and hygiene instructions in the user manual.
3. Log in to the OvulaRing app with your username and password.
4. In the app, tap on „Upload“ or on the the upload data icon in the upper right corner of the home screen and follow the instructions in the app.
5. You activate the data connection in the biosensor by darkening it for 3 seconds. To do this, enclose the sensor with your hands and count to 3. Make sure not to darken the sensor longer than 6 seconds. If communication modus is active, the sensor flashes green.
6. After the message „Data upload successful“ appears in the app, you can continue wearing the sensor. You can now view the updated evaluation of your cycle. Depending on the quality of your internet connection, it may take a few seconds until the new results are available.



Web-based software myovularing.com

You can also view your cycle analysis on the computer in the web-based software at myovularing.com. The access data for the web software and the app are identical.



Storing the Bluetooth Sensor

Store your sensor in the included storage box when you are not wearing it in your body. Your Bluetooth sensor should always be stored in the dark so that it cannot accidentally switch into communication mode. This will also save the sensor's battery and prevent it from discharging prematurely.

Notes on the use of the Bluetooth sensor

- If the packaging of your sensor has not yet been opened, it is still in sleep mode to save energy. The sensor is activated when the packaging is opened and the sensor flashes green for approx. 30 seconds.
- The biosensor automatically detects the brightness of its environment. If the sensor is inside the body, Bluetooth communication is not possible. If the sensor is outside the body, no temperature values can be recorded.
- Only by removing the ring and sensor from the body and with the associated difference in brightness the sensor can switch to communication mode. If the sensor is darkened and exposed to ambient light again after a few seconds, the communication mode is started.

- The sensor indicates the communication mode by flashing green several times. The sensor also flashes green while uploading data.
- If the sensor is no longer in communication mode, you can activate it again by darkening it for 3 seconds, e.g. with your hand. If you expose the sensor to the light again it switches back to communication mode..
- If the sensor does not flash after removal from the body, the Bluetooth communication mode is not yet active. The ambient light may be too dark to detect the brightness difference. In this case, you can illuminate the sensor with your smartphone flashlight for 3 seconds to activate the Bluetooth communication mode.
- During the data upload the sensor should be placed close to the smartphone. To avoid disturbing the transmission, the sensor and smartphone should not be moved.
- If the sensor flashes red after activating the communication mode, there is a fault in the sensor. In this case, please stop using the sensor and contact the OvulaRing customer service.

For questions regarding the use of the OvulaRing app and evaluation of your data please visit 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 the fertility window. 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 activities 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 medical 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 the 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).

- Taking medication affecting the body temperature (e.g. progesterone) over an extended period of time, may affect the evaluations 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 medical 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 medical plastic ring and biosensor with the aid of a microwave. Do not clean the medical 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 medical plastic ring and the ring may break in rare cases. Please check the ring regularly when used in parallel with vaginal therapies and change the ring promptly in the event of defect or breakage.
- The biosensor should only be used with the medical plastic ring.
- The same OvulaRing should not be used by 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 a radiator, in a oven or in a 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 the OvulaRing.
- OvulaRing is designed for domestic use, please do not use it in other medical environments, such as in emergency medicine.
- 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.

Warning:

Technical alterations to the OvulaRing biosensor or medical plastic ring are not permitted.



Please do not use OvulaRing if you...

- ... have your period. Remove the OvulaRing for hygiene reasons during menstruation.
- ... are allergic to epoxy resins and EVA copolymers.
- ... have inflammation in the vaginal area.
- ... find visible defects or changes in the 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 medical 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: OvulaRing Biosensor may not be disposed off in the household waste.



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

Technical Data

Biosensor

Model designation: OVU2

Type: OVU-BS-2.4

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 mobile app/software

Duration of recording:

max. 7 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 68:

The TS/BS is dust-tight and protected against ongoing submersion

Year of development: 2019

Serial no.: 32-000000

Medical plastic ring

Model designation: OVU2

Type: KR/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

Web-based Software

Model designation: OVU-002

Type: OVU-SW-4.xx

Current version: see website

www.myovularing.com

Bluetooth data transfer

Data transfer: via Bluetooth Low Energy

Start Connection:

Sensor light-trigger-event

Brightness threshold (trigger):

,light' > 100 LUX

,dark' < 10 LUX

Advertising: BLE-Advertising via

Bluetooth-beacon-signal

BT-Profile: Custom-Profil

Frequency: 2,45-GHz

App

Model: OVU-APP

Type: OVU-APP-1.x.x

supported platforms:

iOS, Android

Accessories

Disinfection cloths

Storage box

Information Medical Device

OVU-BS-2.4 and OVU-KR-2 are medical devices of class IIa. OVU-SW-4.x.x and OVU-APP-1.x.x are medical devices of class I.

OVU-BS-2.4 complies with the requirements of CISPR 11 and DIN EN ISO 60601-1, DIN EN ISO 60601-1-11, DIN EN ISO 60601-1-2 and IEC 60601-1-2:2014 according to Immunity in the home care environment concur.

Manufacturer

VivoSensMedical GmbH

Limburgerstraße 74C | 04229 Leipzig

Telephone: + 49 (0) 431 3558 2099

E-mail: info@ovularing.com



Status: June 2021

