

GvulaRing



USER MANUAL

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

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:

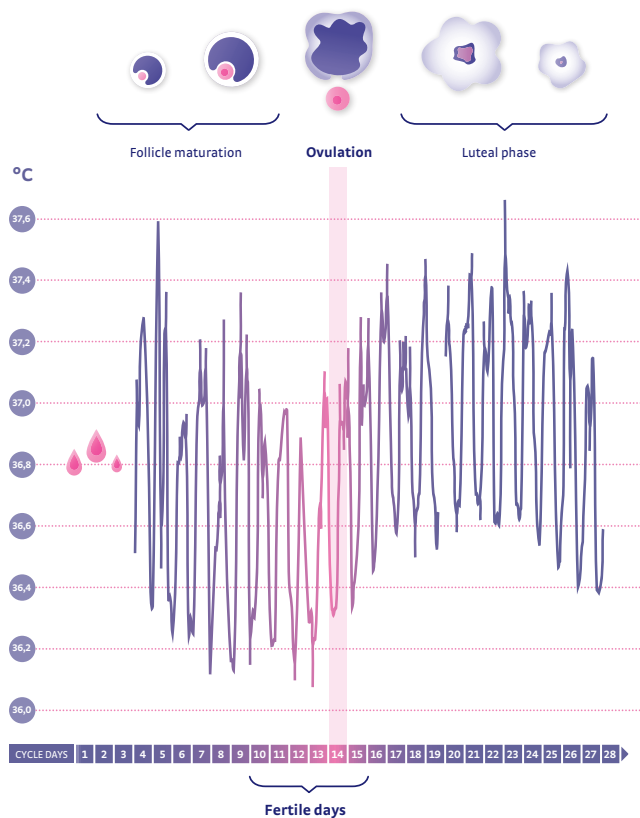
Web: ovularing.com/service

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 how your cycle works

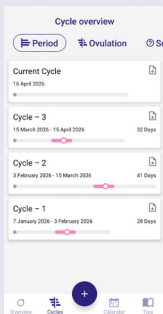
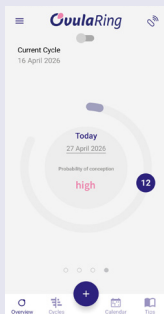
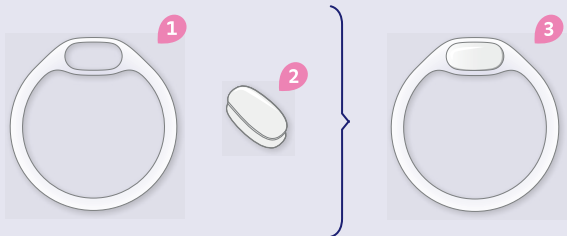
There are only 6 days per cycle on which sexual intercourse can result in a pregnancy. This fertile phase includes the 4 days before ovulation, the day of ovulation itself and the day after. The chances of conceiving are greatest 2 days before ovulation.

However, the day of ovulation is different for each woman and may vary from cycle to cycle. After ovulation, the body's core temperature rises by 0.2–0.5 °C due to the simultaneous release of the hormone progesterone and remains elevated until the end of the cycle. If you measure your basal body temperature in the morning, you would not detect ovulation until it has already occurred.

Thanks to the automatic and high-resolution measurement with OvulaRing, the smallest changes are recognized even before ovulation. Without the need for manual temperature tracking OvulaRing shows 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.**

Product Overview



- 1 Medical plastic ring
- 2 Biosensor (core body temperature)
- 3 OvulaRing, comprising a medical plastic ring with clicked-in biosensor
- 4 Mobile app (iPhone und Android)
- 5 Web software available at myovularing.com/en



Cycle monitoring with OvulaRing

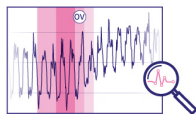
1. Wearing OvulaRing



2. Update 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 12. 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 a daily data upload 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:

- **Before your fertile days** – Your fertile window has likely not yet begun. However, conception cannot be completely ruled out.
- **Low** – Your fertile window has begun; there is a low chance of conception.
- **Medium** – There is a medium likelihood of conception.
- **High** – The likelihood of conception is now at its highest.
- **Conception unlikely** – The fertile window for this cycle has likely ended.

Your daily probability of conception is based on changes in your temperature curve. To do this, it uses your current temperature data and also takes into account typical patterns from your previous cycles.

Your temperature doesn't always follow the pattern “low – medium – high – medium – fertile phase over,” but can vary from person to person. You can verify the displayed estimates based on your temperature curve.

If the status message “Conception unlikely” appears with the explanation “The fertile phase is over for this cycle,” you no longer need to check OvulaRing daily. You can then wear it continuously until your next period begins.

After finishing the 3rd cycle and 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. We recommend always comparing the results of the forecast with the daily updated probability of conception.

Pregnancy test and calculation of due date

The OvulaRing app includes a built-in pregnancy test that uses your body temperature readings. Once a pregnancy has been confirmed, you can also calculate the exact expected due date.

Further functions

You can also use the OvulaRing app or web software as a cycle tracker and enter various additional markers, such as sexual intercourse, exercise, stress, illness or medication. This information is subjective and is therefore not included in the analysis performed by the OvulaRing algorithm.

Note: Following each removal of the biosensor from the body it is sufficient to clean the sensor with mild, ph-neutral soap under running, lukewarm water. Following this, rinse the biosensor well with clear water and dry.

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

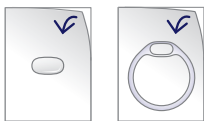
Hygiene and cleaning instructions

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.

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 of the biosensor has a limited lifespan of approximately 6 months. Depending on the usage period you've chosen, you'll receive a replacement sensor when the battery runs low. To this end, the battery status is transmitted along with the data during each data transfer.

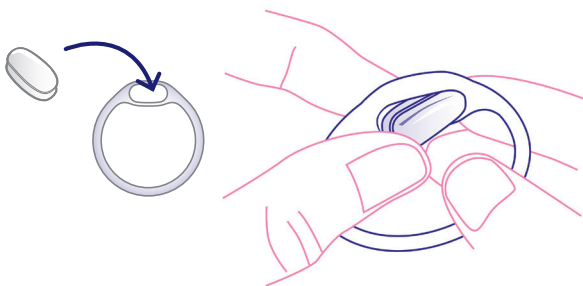
The usage period begins on the day the sensor records the first temperature reading, but no later than 4 weeks after the shipping date of your OvulaRing package. You should upload the data regularly, at least every 4 weeks. When the biosensor is not in your body, it does not record temperature readings. When you are not wearing the biosensor, store it in a dry place away from light so that the battery loses as little power as possible during this time.

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 OvulaRing app, you can easily analyse your temperature sensor data on the go. Data is transmitted from the sensor to the app via a Bluetooth connection. Once the sensor data has been successfully transferred to the secure OvulaRing web database, you can view your updated cycle analyses in the app.

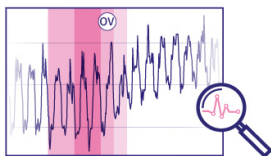


Follow these instructions for transferring the data:

1. Please make sure Bluetooth is activated on your smartphone and that it is connected to the internet. If you're using an Android smartphone, make sure to enable location services so that Bluetooth Low Energy (BLE) works.
2. Remove OvulaRing from the body and clean it according to the cleaning and hygiene instructions on page 8.
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. Then hold the sensor directly in bright light. 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.

OvulaRing webbased software - myovularing.com

You can view your cycle analyses not only in the app, but also on your laptop or PC via the web version at myovularing.com/en. The login credentials are the same as those for the app. In the web version, you'll also find your ovulation forecast and other evaluations.



The web version is particularly well-suited for viewing your cycle chart in detail at a higher resolution. This makes it easier to compare temperature trends with your daily routine and activities - for example, short-term spikes after exercise or typical drops during deep sleep phases.

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 switch to communication mode even after a brief period of darkness, the ambient light may be too dim. In this case, you can shine a light on the sensor—for example, using your smartphone's flashlight—for 3 seconds to activate Bluetooth communication mode.
- The sensor should be near your smartphone for data reading. To avoid interfering with the transmission, do not move the sensor or smartphone during the transfer.
- To stabilize the connection, you can temporarily turn off other connected Bluetooth devices (e.g., headphones, smartwatch).
- If too many devices are paired with your smartphone, please remove any that you do not use regularly.
- If the sensor flashes red after activating communication mode, there is a malfunction in the sensor. This must be checked by our technicians. In this case, please stop using the sensor and contact 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.

Website: ovularing.com/service

Email: info@ovularing.com

Intended purpose

Intended purpose OvulaRing - Cyclofertilography Measurement System

Cyclofertilography measurement system for the invasive measurement, recording, analysis, and graphical representation—based on algorithmic calculations—of the circadian temperature profile during the female menstrual cycle, for subsequent individualized diagnosis of cycle health and for determining the time of ovulation as well as fertile days using standard methods of natural family planning.

The OVU2 cyclofertilography measurement system consists of a medical plastic ring (KR) and a biosensor (BS), as well as an app and web-based software (SW).

Intended purpose of OVU-BS and OVU-KR

The vaginal ring sensor is used to record the circadian curve of a woman's core body temperature. For this purpose, a medical plastic ring (KR) containing a biosensor (BS) in the form of a vaginal ring is placed in the vaginal vault. The vaginal ring cyclically measures the core body temperature curve and stores the respective measurement value in an internal memory. The data can then be retrieved via a Bluetooth interface.

The vaginal ring sensor measures the circadian pattern of core body temperature for use as a biomarker for later evaluation. Measurement of vital physical parameters, even in the sense of a thermometer, is not intended.

Intended purpose of OVU-SW

myovularing Software (OVU-SW) for cyclofertilography Evaluation and graphical representation based on algorithmic calculations of the circadian temperature profile during the female menstrual cycle, for subsequent individual assessment of cycle health and for determining

the time of ovulation as well as fertile days using common methods of natural family planning.

In this process, circadian curves of a woman's core body temperature are evaluated using mathematical algorithms, and the results are presented in the form of probability data for retrospective, real-time, and prognostic analysis.

The use of the myovularing software is not a form of contraception, as it does not interfere with bodily functions in a regulatory manner and cannot prevent the transmission of sperm or the fertilization of eggs. The calculated results provide information exclusively regarding the probability of conception and are not a substitute for individual measures or methods of contraception.

Intended purpose of the OVU-App

Reading data via Bluetooth and transferring it to the software (APP). Reading core body temperature data from the OVU-BS-2.4 via the Bluetooth interface using the OVU-APP and transferring it to the web-based software (OVU-SW).

Graphical representation of the results calculated by OVU SW. Mobile display of the results calculated in the web-based software (SW) for the user in the APP. No calculations or changes are made to the data in the app.

Entering daily events related to the cycle into a digital diary.



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 longterm 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 forecast is only a prediction and must be checked daily or regularly against the current probability of conception to support natural contraception.
- 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.

- The OvulaRing may cause irritation as a foreign object or disrupt the balance of the vaginal flora. If you experience any unusual symptoms, please remove the ring and contact your specialist.



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 an 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.
- Your smartphone or tablet is exempt from this distance rule: When transferring data, a shorter distance can actually be helpful. Hold or place the sensor close to the smartphone (about 10 cm away) – but not directly against the device.
- When using the OvulaRing in combination with mechanical contraceptives (e.g. condoms), care should be taken to ensure that the contraceptive is not damaged. In this case, we recommend removing the OvulaRing during sexual intercourse.
- The OvulaRing app and web software support three usage modes: getting pregnant, natural family planning and understanding your cycle. The results displayed depend on the selected usage mode. Therefore, select the usage mode in the app or web software that corresponds to your current needs.

Note:

Please report any serious incidents related to the product to the manufacturer and the relevant regulatory authority.

Target audience

The target group for this product consists primarily of women of reproductive age 18 years and older, who:

- Current desire to have children
- Unfulfilled desire to have children (>12 months)
- Irregular cycles / cycle disorders
- Users of natural family planning methods for support with natural contraception
- General interest in menstrual health (PCOS, PMS, menopause)

The target audience for clinical use includes physicians and specialists in gynecology and women's health as well as in reproductive medicine.



Please do not use OvulaRing if ...

- ... you're on your period. For hygiene reasons remove the OvulaRing during your period.
- ... you have an allergy to epoxy resins and EVA copolymer.
- ... you have inflammation in your genital area.
- ... you notice any visible defects or changes in the OvulaRing.
- ... you are pregnant.
- ... you pass through security barriers or areas, for example at airports.
- ... you are required to undergo an MRI, CT, PET or X-ray examination, or high-frequency surgery.

Disposal instructions:

Electrical and electronic equipment that has become waste is referred to as end-of-life equipment. Owners of end-of-life equipment must ensure that it is collected separately from unsorted municipal waste. In particular, end-of-life equipment does not belong in household trash but must be disposed of through special collection and return systems.

Owners of end-of-life equipment from private households may return such items free of charge to collection points operated by public waste management authorities or to take-back points established by manufacturers or distributors in accordance with the ElektroG.

Warning:

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

Explanation of symbols used

Warning notice / safety notice



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



The biosensor and plastic ring are BF-type components to protect against electric shock.



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



“Use by” indicates the best-before date



Indicates the product's serial number



LOT number refers to the packaging batch



Unique identifier for medical devices



Note instructions for use!



Please see instructions for use.



Permissible temperature range with minimum and maximum temperature.



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.



Is a medical device (medical device)



Order number (reference) of the manufacturer/packager



Authorized Representative in Switzerland

Technical Data

Biosensor

Model name: 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

Material: zirconium oxide ceramic

Power supply: internal

Humidity: 15% to 90%, non-condensing

Operating temperature: 35 °C to 42 °C

Storage temperature: 0 °C to 50 °C

Activation / reading:

via mobile app/software

Duration of recording:

max. 7 months without readout

Service life after activation:

max. 6 months

Measurement accuracy:

+/- 0.1 °C in the 35 °C - 42 °C range

IP protection class 58:

The biosensor is dust-tight and protected against ongoing submersion.

Year of development: 2019
Serial no.: 48-000000
UDI DI: 4260359940129

Medical plastic ring

Model name: OVU2
Type: KR/OVU-KR-2
Dimensions: 54 mm x 4 mm
Material: Medical-grade EVA copolymer
Storage temperature: 0 °C to 50 °C
Max. duration of use: 30 days
Year of development: 2012
Batch number: M-000000
UDI DI: 4260359940129

Web Software

Model Name: OVU-SW
Type/UDI PI: OVU-SW-5.xx
Current Version: see Web Software
www.myovularing.com
UDI DI: 4260359940136

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
Bluetooth-Profile: Custom-Profile
Frequency: 2.45 GHz

App

Modell: OVU-APP
Typ/UDI PI: OVU-APP-2.x.x
Supported platforms:
iOS, Android
UDI-DI: 4260359940167

Included items

Disinfectant wipes
Storage container

Information:

The medical devices OVU-BS-2.4 and OVU-KR-2 are Class IIa medical devices. OVU-SW is a Legacy Device according to MDR Art. 120. OVU-APP is a Class I medical device. 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 regarding immunity in the home care environment.

Manufacturer

VivoSensMedical GmbH
Limburgerstraße 74c | 04229 Leipzig
Email: info@ovularing.com

for biosensor and
medical plastic ring



for app and web
software



Status: April 2026

OvulaRing app and web software

for iPhone

ovularing.com/link/app_ios



for Android

ovularing.com/link/app_android



web software (browser)

ovularing.com/link/app_browser



