



INSTRUCTIONS FOR USE

MY OVU Ovulation Thermometer

Before use, please read these instructions carefully, as they contain important information regarding use.

What is the MY OVU ovulation thermometer and what is it made of?

The MY OVU ovulation thermometer is a medical device in the form of a flexible ring made of medical-grade silicone, intended to be placed in the vagina. The device is used for automatic measurement of basal body temperature (BBT) during night-time rest, with a measurement resolution of 0.01°C.

The device is intended for use by one user and works with a dedicated mobile application that enables analysis and monitoring of the ovulatory cycle. The device is not a contraceptive and does not replace medical diagnostics.

Intended use

The device is intended for use by adult women in the home environment to monitor fertility by measuring basal body temperature during sleep and analyzing the ovulatory cycle.

Indications

The device is indicated for use for:

- predicting and monitoring ovulation,
- determining the fertile period in the cycle to support reproduction,
- supporting diagnostic procedures related to ovulation disorders.

Target patient group

The target group consists of adult women of reproductive age interested in monitoring their ovulatory cycle and fertility, in particular:

- women planning pregnancy,
- women observing their menstrual cycle,
- women requiring support in the diagnosis of ovulation disorders.

The device is not intended for use in pregnant women.

Intended users

Adult women using the device independently in the home environment.

The device does not require the involvement of medical personnel for its use; however, the results may be used by physicians in the diagnostic process.

Contraindications

Do not use the device in the following cases:

- acute vaginal inflammation,
- recent injury or discomfort in the vaginal area,
- heavy menstrual bleeding,
- during sexual intercourse,
- use of vaginal medications,
- undergoing computed tomography or magnetic resonance imaging examinations,
- pregnancy (the device has not been studied in this population).

Warnings

- The device is intended solely for individual use – it must not be shared with other persons.
- If symptoms such as: pain, bleeding, vaginal discharge, fever, signs of infection, allergic reaction, or difficulty removing the device occur, discontinue use and consult a physician.
- Do not boil the device – this may damage it.
- Cutting, crushing, or biting may damage the device and cause loss of its leak-tightness.
- Keep the device out of reach of children and animals.
- Maintain appropriate hygiene – wash the device before and after each use.
- Do not use the device during MRI examinations or other procedures using strong electromagnetic fields or radiation (e.g. CT, PET, X-ray, diathermy). Remove the device before undergoing the procedure.

Operating principle

The MY OVU ovulation thermometer operates by continuous, automatic measurement of basal body temperature (BBT) during night-time rest, performed by means of a temperature sensor placed in an intravaginal ring made of medical-grade silicone.

After the device is placed in the vagina before sleep, it records the user's body temperature throughout the night, ensuring stable measurement conditions due to its internal location, which is less susceptible to the influence of environmental factors than surface measurements.

Recorded temperature data are stored in the device's internal memory (up to 5 nights) and then transmitted to the dedicated mobile application using wireless technology (Bluetooth).

The mobile application analyzes changes in basal body temperature over time, using the physiological phenomenon of a temperature rise after ovulation (related to the action of progesterone), which enables:

- identification of the time of ovulation,
- determination of the phases of the menstrual cycle,
- determination of the fertile period.

Regular use of the device allows observation of temperature trends in subsequent cycles, which supports fertility monitoring and may support the diagnosis of ovulation disorders.

The device does not interfere with the user's physiology – its operation is purely measurement and analytical in nature (non-invasive, passive).

Method of use

Preparation for use

Correct operation of the device requires installation of the compatible MY OVU application on an Android or iOS device from Google Play or the App Store. The list of compatible applications is available at my-ovu.com/app.

Scan the QR code to install the application



Scan the QR code
to install the app

After installing the application, register and synchronize the device according to the displayed instructions. Connecting the device to the application requires enabling Bluetooth on the phone, following the prompts in the application, and pressing the button on the device (Fig. 5). Keep the MY OVU thermometer close to your phone (maximum up to 0.5 m). Pressing the button once is required only during the first synchronization and during each data download. It is not necessary to click repeatedly during these activities.

Register in the application and pair the device before first use.

Inserting the MY OVU ring

1. Wash your hands and the ring under warm running water with soap or using a dedicated hygiene fluid.
2. Fold the ring with the thickened part facing forward as shown in Fig. 1.
3. Place the ring in the vagina; if necessary, lubricate it with lubricant (Fig. 2).
4. Assume a comfortable position. If necessary, squat and stand up so that it settles comfortably. The ring can be inserted in a squatting, sitting, or standing position. The choice of the most comfortable position depends on the user. The ring should be completely concealed inside the vaginal canal. Comfortable placement of the ring is individual. It is usually located above the pelvic floor muscles (Fig. 3).

Removing the MY OVU ring?

1. Wash your hands.
2. Relax.
3. In a comfortable position, reach for the ring with your index or ring finger. (Fig. 4).
4. Wash the ring with warm water and soap and dry it.
5. After downloading data to the mobile device, place the device in the box included in the packaging.
6. At least once a month, wash the box with soap and wipe it dry.



Fig. 1



Fig. 2

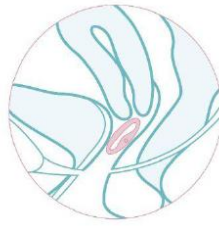


Fig. 3



Fig. 4



Fig. 5

Downloading data from the MY OVU device to the phone

1. Turn on Bluetooth on your phone.
2. Launch the MY OVU application on your phone and enter the data download options.
3. Hold the device close to the phone and, when you see the appropriate prompt in the application, press the button located on the thickened part (Fig. 5).

Perform the first data download after the first monitored night. Otherwise, MY OVU has not registered any measurements and a download error may occur.

Frequency of use

The device should be used daily during sleep to obtain reliable and repeatable results and to correctly interpret the ovulatory cycle.

To obtain the best information about your cycle, use MY OVU during sleep – every day, from the end of menstruation until at least four days after observed ovulation. MY OVU automatically monitors body temperature throughout the night. If you wake up or have night-time activity, there is no need to remove the ring to stop measurements. For optimal results, remember to download data to the application every day after removing the thermometer from the vagina. MY OVU is equipped with internal memory allowing storage of measurements from the last five nights if it is not possible to download them earlier.

Cleaning and maintenance

- The device should be washed before and after each use using warm water and soap or a dedicated agent.
- Do not boil the device or use methods that may damage its structure.
- The storage container should be cleaned regularly (at least once a month).

Period of use

The recommended period of use of the device is 12 months from first use.

Disposal

The device contains electronic components and, after the end of use, should be disposed of in accordance with applicable regulations regarding waste electrical and electronic equipment.

Medical incidents

Any serious incident related to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient resides.

Reporting problems

In the event of an error, failure, or malfunction of the application, or lack of connection between the device and the application, report the problem to: office@my-ovu.com

Technical specifications

Normal conditions of use:

Storage temperature: 0–50 °C

Relative humidity: ≤90% non-condensing

Power supply: non-replaceable Renata V393 silver batteries

Dimensions: diameter 48 mm

Device weight (with battery): 10 g

Displayed temperature increment: 0.01°C

Measurement range: 34–42 °C

Measurement accuracy: 0.1°C

Memory: 32 KB

Device usage time: up to 18 months from first activation

Ingress protection rating: IP68

Electromagnetic compatibility (EMC)

The MY OVU device meets the requirements of IEC 60601-1-2 in the field of electromagnetic compatibility (EMC).

The device should be used in the electromagnetic environment specified below.

Operating environment

The device is intended for use in:

- home environment
- typical outpatient conditions

It is not intended for use in:

- environments with a high level of electromagnetic interference (e.g. operating rooms, MRI rooms)

Warnings and precautions

- Do not use the device directly next to or stacked with other devices.
- If such use is necessary, observe its operation.
- Portable and mobile RF communication equipment (e.g. mobile phones, routers, Bluetooth devices) may affect the operation of the device.
- Do not use the device near strong sources of electromagnetic fields.
- Use only accessories recommended by the manufacturer.

RF emissions (CISPR 11)

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The device uses RF energy only for internal functions
RF emissions CISPR 11	Class B	The device is suitable for use in the home environment

Immunity

Test	Test level	Compliance
Electrostatic discharge (ESD)	±8 kV / ±15 kV	Complies
RF electromagnetic field	10 V/m	Complies
Conducted RF disturbances	3 Vrms	Complies
Fast transients	±2 kV	Complies
Electrical surges	±0.5 kV	Complies
Power frequency magnetic field	30 A/m	Complies

A minimum distance of 30 cm should be maintained between the device and portable RF communication equipment.

The device uses Bluetooth Low Energy (BLE) technology in the 2.4 GHz band. Tests have shown that wireless transmission does not adversely affect the safety and operation of the device.

Symbols used by the manufacturer in informational materials

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Unique device identifier
	Date of manufacture		Consult the instructions for use before using the device
	Ingress protection rating		Medical device
	The device contains electrical or electronic components and, after the end of use, should be taken to an appropriate collection point for waste electrical and electronic equipment, in accordance with applicable legal regulations. (WEEE)		Batch number



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