

The pattern of cervical mucus development is very individual for every woman – some start with a very dry feeling at the beginning of the cycle and do not get beyond a thick consistency, others clearly recognize the clear mucus around ovulation. In any case, there is always a development and a high point that then subsides again.

You can start observing your cervical mucus first thing in the morning, as soon as you have removed your trackle. Pay attention to what you see and feel. Enter your observations directly into the trackle app. Now you can read off your current fertility status from the turquoise tab in the trackle app.

It is important to observe your cervical mucus multiple times a day because it may change over the course of the day.

Our tip: Before using the toilet, wipe your vaginal entrance with a clean finger or a sheet of toilet paper and check whether you find any cervical mucus. If you discover later in the day that the quality of your cervical mucus has improved, correct your entry in the app and then check your fertility status again.

### CERVICAL POSITION AND HARDNESS

The position of your cervix changes towards your fertile phase: At this time, the opening of the cervix is higher and becomes softer than at the beginning of your cycle. Therefore, in addition to the cervical mucus, you can feel the position of your cervix. To do this, you have to feel the cervix with the help of a finger. This can be lower than you may be used to when inserting a tampon, so it can be helpful to crouch when you feel it to make it easier to feel the cervix.

trackle only uses the temperatures and cervical mucus to evaluate your cycle.

### DISTURBANCES

Disturbances are circumstances that can affect your core body temperature although no ovulation has occurred. You can recognise a “disturbed” temperature value by the fact that your temperature suddenly rises for one or two days and then drops again. If a basal value is higher than expected and this increase may be due to one of the disturbances specified in the app, please select the corresponding disturbance for the day. The disturbed basal value will then not be included in the evaluation. However, not every cause of disturbance necessarily changes your temperature.

If you observe no effect on your measured values, do not select a cause of disturbance in the trackle app.

### IF YOU ARE TRYING TO CONCEIVE

If you are trying to conceive, the time when sex is most likely to lead to pregnancy is two days before ovulation. Because ovulation can only ever be definitively proven after it has taken place, you will, however, have to observe your ovulations over several cycles. The forecasts shown on the purple tab (calendar view) in the app will help you assess when you might next ovulate based on your ovulations recorded so far.

### IF YOU ARE TRYING TO PREVENT A PREGNANCY

trackle recalculates your current fertility status every day, with every item of information you enter and with every temperature transferred from the sensor. You should ideally have entered all your temperature readings and cervical mucus observations to date, and then check your fertility status on the status screen (turquoise tab) immediately before having sex. Only if the status reads “Today is not a fertile day” can you have sex without using additional contraceptives

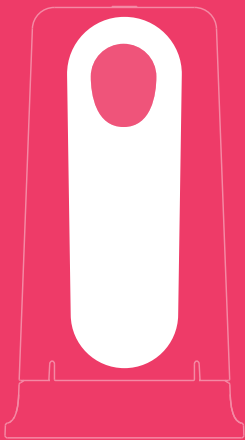
without falling pregnant. If the tab reads “Today is a fertile day”, you must use a contraceptive such as a condom or a diaphragm, or avoid having sex.

trackle is not a contraceptive in the sense that it interferes with your cycle. trackle supports you in determining your personal cycle status and can be used to ascertain your fertile and infertile days. If you do not want to get pregnant, no pre-ejaculate or semen should be put into the vagina on the days that have been determined to be fertile. During your fertile period, you must use a contraceptive of your choice. The contraceptive security depends on the contraceptive you use. It is safest if you have no vaginal intercourse during the fertile days.

trackle is not 100% certain when determining the infertile days. As with all methods of birth control there is some remaining risk of becoming pregnant from unprotected intercourse. In the event of an unintended pregnancy, please contact your doctor.

### INSTRUCTIONS FOR SAFE USE

- The trackle sensor was designed for use at home.
- The trackle sensor was manufactured and tested in accordance with the applicable legal regulations. It thus complies with the manufacturer's requirements to avoid health risks.
- trackle offers no protection against sexually transmitted diseases. Please make sure to protect yourself well using conventional methods.
- **PLEASE NOTE: IF YOU USE HORMONAL CONTRACEPTIVES SUCH AS THE PILL, TRACKLE IS WITHOUT ANY STATEMENT TO YOU, BECAUSE THESE CONTRACEPTIVES SUPPRESS YOUR OVULATION. NO OVULATION – NO TEMPERATURE INCREASE – NO TRACKLE RESULTS.**



- **IF YOU STOP TAKING HORMONAL CONTRACEPTIVES OR HAVE GIVEN BIRTH, YOU MUST WAIT UNTIL YOUR FIRST PERIOD BEFORE YOU CAN START USING TRACKLE.**
- The sensor can remain in your vagina for several days, but should only be worn overnight and removed in the morning.
- Before inserting it into the vagina, you have to check the sensor: Is the outer material intact and clean? Only insert the sensor if it is clean and undamaged.
- If you are in pain when wearing the trackle sensor, remove it and contact your gynaecologist.
- Use the trackle sensor only in your vagina and not in other body openings to avoid injuries. Do not use any other tools to insert or remove it.
- The sensor must not come into contact with pointed or sharp objects.
- The sensor must not be subjected to strong impacts or high pressure. Normal falling does not pose a risk. If you are not sure whether your trackle has been damaged, do not use it and contact us.
- The sensor must not be changed or modified under any circumstances, otherwise safe operation can no longer be guaranteed.
- trackle is only certified for the European market and may only be used in the European time zones. If you are in a time zone outside Europe, you must use a different method of contraception.
- Do not use aggressive detergents, disinfectants or abrasive cleaning agents to clean the sensor. Cleaning it regularly with soap and lukewarm water is sufficient and ensures that the surface material of the device is not damaged.
- The sensor must not be cleaned or disinfected in a microwave or dishwasher. Under no circumstances should it be boiled or frozen.

- Store the sensor in the storage box when not in use to protect it from dirt and light (e.g. direct sunlight). If the sensor is dirty, you should wash it with clear water before use. Direct sunlight can affect the outer material of the sensor.
- Please make sure that the sensor is not damaged by pests, pets or children.
- The sensor must only be used by one person. Use by multiple people would render the data unusable and increase the risk of infection.
- Used sensors may not be passed on and used by other people. Only purchase trackle sensors directly from trackle or from reputable retailers. If you would like to purchase a trackle sensor elsewhere, we recommend that you request the serial number beforehand and contact our support staff at info@trackle.de so we can check for you that the sensor is unused.
- The sensor must be stored at temperatures of at least -10 °C and at most +60 °C. You should avoid storing the sensor in environments where there are permanent temperatures in the range of possible body temperatures (35 °C–42 °C). Always store the sensor in its box when you are not wearing it so that it cannot accidentally record temperatures that were not measured within your body. If the sensor has nonetheless accidentally recorded temperatures that were not measured inside your body and then used these temperatures to determine a basal value, you must mark this basal value as disturbed in the app.
- Before sexual intercourse you have to remove the sensor from your vagina.
- When using several different sensors in close proximity, you have to make sure that the devices do not influence each other.

- The sensor should only be operated at a distance of at least 30 cm from high-frequency communication devices. When operating in close proximity to such devices, you have to make sure that the sensor works properly (e.g. during data transmission).
- You need either an Android smartphone with Android version 5.0 or higher or an iPhone with iOS 10 or higher to use the trackle sensor system.

When the sensor reaches the end of its life, it will make this clear with a corresponding blink code (see list below) and switch itself off. Until the sensor switches itself off, it will always work and measure correctly, so you do not have to be afraid that it will be inaccurate or unreliable. In the event of a failure, the sensor will no longer transmit data.

### CONTRAINDICATIONS

If the sensor has visible defects, you must not use it. You cannot use the trackle sensor system if you take the pill or use other hormonal contraceptives, if your cycle is pathologically altered or if your cycle is affected by hormonal supplements in any other way. You must not wear the sensor if you are suffering from an acute or chronic vaginal infection or a vaginal yeast infection. Do not start using the sensor again until the infection has completely cleared, and make sure to clean the device properly (as described in the chapter “Hygiene and cleaning instructions”) before use. Do not use the sensor if your vaginal mucosa is severely damaged. Wait until your vaginal mucosa has fully healed before using the trackle sensor system. Do not wear the sensor when you pass through security gates, such as at airports. Before MRI, CT, PET and X-ray examinations, you have to remove the sensor.

If your trackle causes one of the following serious incidents, you must report this incident to us and to the responsible public authority for the member state in which you reside:

- A serious deterioration of your overall health
- A life-threatening illness or injury
- Any permanent impairment of a bodily function or permanent physical damage
- Any condition that requires medical or surgical intervention in order to prevent permanent impairment of a bodily function or permanent physical damage

### USE OF TRACKLE IN CASE OF DISEASES

Basically, anyone who has an undisturbed menstrual cycle including ovulation can use trackle. Different lengths of your cycles play no role in the determination of ovulation by trackle, unless they are caused by a disease.

There are diseases that can influence the cycle and/or body temperature, for example hormonal diseases such as hypothyroidism or hyperthyroidism, rheumatic diseases, PCO syndrome, type I diabetes but also mental illnesses.

In such cases, we recommend accompanying NFP advice at the beginning of the application. We would also be happy to make the appropriate contact.

### MANUFACTURER

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53111 Bonn · Germany  
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### EXPLANATION OF THE SYMBOLS USED ON THE NAMEPLATE AND PACKAGING

	Do not dispose with household waste		Please be sure to follow the instructions for use.
	Serial number, unique device identification (UDI)		Type B applied part (no direct application to the heart and no delivery of currents to the body).
	Manufacturer with address		Protected against penetration of solid foreign objects ≥1.0mm Ø and larger, protected against the effects of permanent immersion
	Date of manufacture with indication of month and year.		Medical device
	Can be used until the month and year up to which the sensor can be used.		For repeated use by a single patient
	Operation: -10 °C to +60 °C Storage: -10°C to + 60°C		

## TECHNICAL DESCRIPTION

### HOW THE SENSOR LED WORKS

Your sensor is equipped with a red LED indicating the correct functioning of the sensor:

- **SENSOR PLACED IN BOX AND LEFT THERE: LED EMITS THREE LONG AND THEN TWO SHORT FLASHES.** Meaning: The sensor has not yet been paired with an app. The sensor is now ready and can be paired with the trackle app.
- **SENSOR PLACED IN BOX AND LEFT THERE: LED EMITS TWO SHORT FLASHES.** Meaning: You have placed the sensor in the storage box. The sensor will now begin to transfer data to the app.
- **SENSOR REMOVED FROM BOX: LED EMITS THREE SHORT FLASHES.** Meaning: You have removed the sensor from the storage box, the sensor will now start to measure. You should insert the sensor now.
- **SENSOR REMOVED FROM BOX: LED LIGHTS UP ONCE AND FLASHES TWICE.** Meaning: The sensor's memory is full. You will have to transfer your data before taking the next measurements. Doing so will free up memory.
- **SENSOR REMOVED FROM BOX: LED FLASHES RAPIDLY AND REPEATEDLY.** Meaning: The sensor has reached the end of its life and must be replaced.

### SENSOR

Direct mode medical thermometer

**MODEL NAME:** Elsa

**DELIVERED FIRMWARE VERSION:** 1.0.2 (the firmware version will be updated automatically, information about the latest version can be found in the app)

**DIMENSIONS (WXHXL):** 23,3 mm x 20 mm x 66 mm

**WEIGHT SENSOR:** 29 grams

**DATA TRANSMISSION:** 2,4 GHz Bluetooth connection

**MEASUREMENT INTERVAL:** 1 minute

**MEASUREMENT ACCURACY:** +/- 0,1°C in the range of 35,00°C to 42.00°C

**TRANSITIONAL PERIOD FOR HEATING/COOLING:** 800 seconds

### BATTERY

trackle contains one non-removable lithium manganese dioxide (Li/MnO2) primary cell. The battery can only be removed by a qualified technician. Never attempt to remove the battery yourself.

### DISPOSAL

Never dispose of obsolete devices in your household waste. They can be disposed of at designated collection facilities. You can also return the device to us by post for proper disposal free of charge. If you have any questions about disposing of your trackle, please contact info@trackle.de.

### STORAGE CONDITIONS

**MAXIMUM STORAGE DURATION:** 2 years

**STORAGE TEMPERATURE:** -10°C to +60°C

### ENVIRONMENTAL CONDITIONS FOR OPERATION

**RELATIVE HUMIDITY:** 15% to 90%

**AIR PRESSURE:** 700 to 1060 hPa

**LIFE SPAN:** 30 months (2.5 years)

**YEAR OF MANUFACTURE:** see information on the packaging

**SERIAL NUMBER:** see name plate on the bottom of the storage box

trackle is a medical device and meets the requirements of the Medical Devices Directive 93/42 EEC and Germany's Medical Devices Act (Medizinproduktegesetz, MPG). You can find our declaration of conformity online at [www.trackle.de](http://www.trackle.de).



### APP

You can find the exact version number of the app in the menu item “System status” in the app itself.



DEAR TRACKLE USER,

Thank you for choosing trackle. trackle is a system that helps you to precisely determine your current cycle status. This gives you a reliable basis for making conscious and responsible decisions. If you want to have children, trackle helps you to find the most fertile days. If you don't want to get pregnant, trackle shows you on which days you have to use a contraceptive or to avoid vaginal intercourse. The trackle system consists of a **SENSOR**, a **STORAGE BOX** and an **APP** on your Android or iOS smartphone. Before you start using trackle, please read the user information and the safety instructions carefully. If you have any questions, please do not hesitate to contact us: **INFO@TRACKLE.DE**

CYCLE INFORMATION

The fertile phase of any menstrual cycle lasts a maximum of seven days. These seven days include both the ovulation phase of approximately 12–18 hours, during which the egg cell can be fertilised, and the five days before ovulation, as sperm remains viable within the female body for up to five days. This means that having unprotected sex up to five days before and approximately two days after ovulation, and thus during a total of around seven days per cycle, may lead to a pregnancy. If you know the precise day on which you ovulate, you also know when you can get pregnant. Ovulation is indicated by, among other things, a rise in body temperature of about 0.2–0.6 °C. If you can pinpoint this significant increase, you will know, depending on

what your life plan is, whether you need to use contraception or not.

FIRST INSTALLATION

After unpacking trackle, please check that everything is complete. The pack must contain:

- the sensor
- the storage box
- the user manual

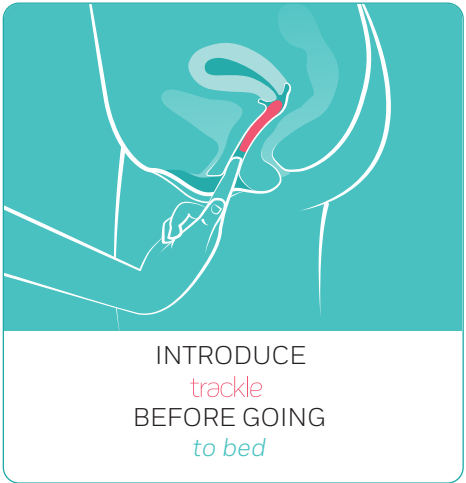
**BEFORE YOU PUT THE SENSOR INTO OPERATION,** download the trackle app from the Google Play Store or the Apple App Store. Now – guided by the app – you create a user account through which you can manage your data in the future. The app guides you through the registration process. Make sure that the Bluetooth function of your cell phone is activated and that your cell phone is connected to the Internet. As soon as your user account is set up, the app will ask you to add a sensor to your account. If you have an Android smartphone: Activate location services in addition to Bluetooth and your Internet and allow the trackle app to access your location. Is the Bluetooth function on your smartphone active? Then take the sensor out of its storage box, put it back in, and leave it there to connect the app and the sensor. Make sure that your cell phone and the sensor in the storage box are in close proximity. As soon as the sensor and app have found each other, you can pair the sensor in the app by pressing the corresponding button. The sensor is now successfully added to your account and ready for use. Further information on the app can be found in the chapter **“THE TRACKLE APP”** in this manual.

USE OF TRACKLE

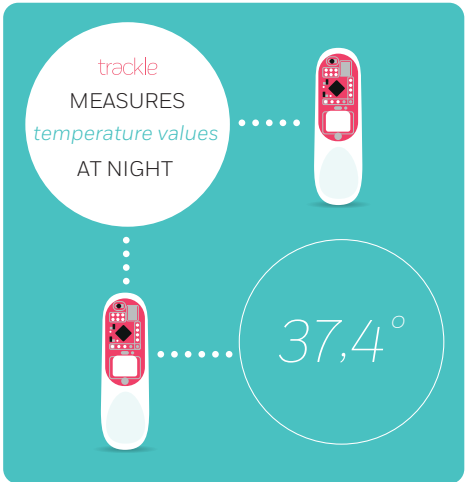
Your sensor is ready for use immediately after installation. It should be worn while sleeping or resting.

REMOVE THE SENSOR FROM THE STORAGE BOX AND INSERT IT INTO THE VAGINA

Before you insert the sensor for the first time, please clean it thoroughly with soap and water and rinse well. Before you insert the sensor into your vagina, please check carefully whether the sensor is undamaged. If the outer shell is deformed or damaged or if damage is visible inside the sensor, you must not use the sensor and must not insert it into your vagina.



Insert the sensor into the vagina like a tampon. When it has reached the right position, you should no longer be able to feel it.



Your sensor now recognizes from the uniform temperature values that it is in the body and begins to record your core body temperature at short intervals. As long as you wear the sensor, it only measures and does not transmit any data.

WEARING THE SENSOR

Wear the sensor while sleeping or resting. To successfully record your basal body temperature, i.e. the lowest value at rest, you should wear the sensor for at least four hours. This is important to give your body time to relax and reach its lowest temperature. You can also easily remove and re-insert the sensor at night, e.g. to have sex or go to the bathroom. Your sensor continues to measure normally after an interruption.

We recommend removing the sensor before going to the toilet as a precaution, to prevent it from accidentally falling in.

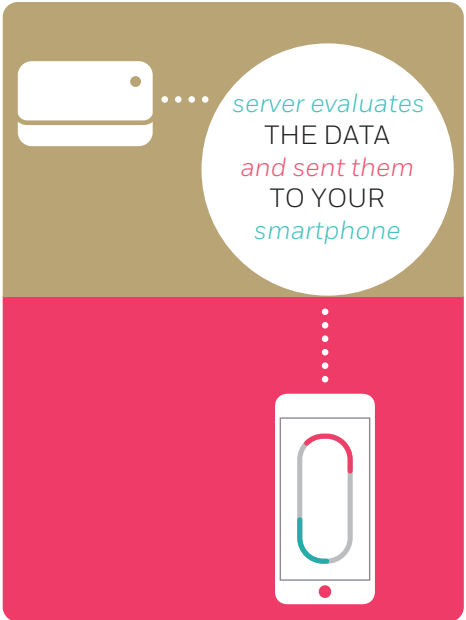
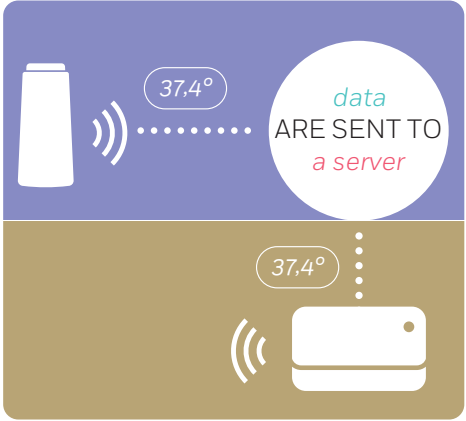
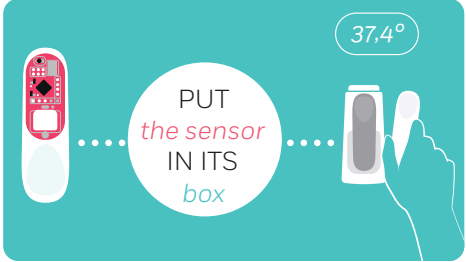
REMOVING THE SENSOR



After getting up in the morning you remove the sensor. To do this, insert two fingers (thumb and forefinger) into the vagina in the most comfortable position and grasp the sensor at the bottom of its web. If you cannot reach it, you can easily push it forward by exerting a little pressure on the pelvic floor (as with bowel movements). If you still find it difficult, try to squeeze a little in the squatting position and grab it. The sensor cannot get lost, slide up or cause damage – if it doesn't work right away, try again later. With practice, it's not a problem. Afterwards, clean it thoroughly with soap and water. That's all you have to do; your sensor is now clean enough to be reinserted the following evening.

DATA TRANSFER

Your sensor has measured your core body temperature during the night and saved it in its internal memory. In order for it to be evaluated, the data collected must be wirelessly transferred to your smartphone the next morning.



1. Make sure the Bluetooth function of your smartphone is activated so that a wireless connection to your sensor can be established.
2. Make sure your smartphone has an active internet connection.
3. Open the trackle app and go to the yellow "Sensor status" tab. If it says "Ready for synchronisation", the app is ready to receive data from your sensor.
4. Put the sensor in its storage box and leave it there. The sensor will flash twice briefly.

5. You can now track the progress of the data transfer on the yellow tab in your trackle app. Please leave the sensor in the box until the data transfer is complete and the app displays the "Ready for synchronisation" message again.

If the data status cannot be synchronized immediately, for example because the internet connection is not sufficient, the app will notify you. This is not a problem, because the sensor can store data over several days. As soon as it can set up the next connection, all data is being transferred.

HOW OFTEN DO YOU NEED TO WEAR TRACKLE?

At the beginning, you should wear the sensor every night if possible to collect a lot of meaningful data. trackle does not have to be worn during menstruation. Start your measurements when the bleeding has stopped, but at the latest on day 5 after the first day of menstruation. If you are still bleeding slightly, you can use your trackle in combination with a sanitary towel or period underwear, for example. Nothing can jam through the trackle sensor, the blood simply flows past the side.

HYGIENE AND CLEANING INSTRUCTIONS

Clean the sensor with soap and water before inserting and after removing it from your vagina. Make sure to wash your hands before re-inserting the sensor. If the sensor is very dirty or subject to increased contamination with bacteria or viruses, you can clean it using commercially available denture cleaning tabs or steriliser tablets. Wash it with soap and water afterwards to remove any residue.

In the event of a vaginal yeast infection, please do the following:

- You must not use the sensor for the duration of the yeast infection.
- Carefully clean the sensor and the storage box with 70% isopropyl alcohol and then wash both thoroughly with soap and water. When using isopropyl alcohol, please refer to the instructions for use of the product.
- Ensure that you have fully recovered from the yeast infection.
- After a yeast infection, we recommend that you repeat the process of disinfecting and then washing the sensor with soap and water before you start using it again.

DURABILITY AND STORAGE

You can use the sensor for 30 months from the first time you pair the sensor with the app. When there is no longer enough battery power for safe operation, the sensor turns itself off. The app informs you in good time before the end of life is reached so that you can order a new trackle if necessary. Before you pair it, you can store it for up to two years. You can find the date up to which the sensor can be used at least on the packaging. If you are not going to use the sensor for a long time, place it in its storage box, since it will then switch to stand-by mode and be protected from environmental influences.

REPLACING THE SENSOR

When the sensor has reached the end of its usability, it will flash rapidly multiple times when you take it out of its box. You can then send it back to us. We will delete

any data that may still be stored and dispose it properly for you.

RETURN ADDRESS:

trackle GmbH  
Bertha-von-Suttner-Platz 1–7 · 53111 Bonn · Germany  
Contact by E-Mail: info@trackle.de  
If you are replacing an old sensor with a new one, we recommend that you wait until the beginning of your next cycle before starting to measure with the new sensor. If you start using a new sensor in the middle of your cycle, be sure to observe whether the change in sensors results in higher temperature readings; if so, mark them "Thermometer change during cycle" to indicate that they are disturbed.

THE TRACKLE APP

To better protect your data, trackle uses a passphrase instead of a password. This phrase will be displayed when you create your account. **WITHOUT THIS PASS-PHRASE, NO ONE CAN ACCESS YOUR DATA – NOT EVEN WE CAN. PLEASE NOTE IT CAREFULLY AND PUT IT IN A SAFE PLACE.**

USE OF THE APP

BASICS

The app shows you your menstrual data (red), the fertile phase (turquoise) and ovulation (yellow). As long as the data are forecasted, the colour is pale – if they have been confirmed by measurements and information you entered, they will be strong. For a correct evaluation, you should start measuring on the 5th day of your cycle, **MEASURE EVERY NIGHT AND ALSO MEASURE YOUR CERVICAL MUCUS**

**EVERY DAY.** You will only get a correct evaluation with these two parameters. Because trackle recalculates your cycle with every temperature reading, any information you enter and every new day, you must check your current fertility status on the status screen (turquoise tab) of the app after every entry. If the system does not detect ovulation, you will continue to be shown for safety reasons that you are fertile – until you regain menstruation.

THE FIRST CYCLE

After the first pairing with the sensor, the app is ready for your entries. If you still have the data on hand, enter your last menstruation on the relevant day by entering the bleeding intensity. The first trackle cycle begins with the entry of menstrual data. As soon as this has been completed and the system has received the first data from you, trackle will display forecasts for future days. The more cycles are recorded, the more accurate these forecasts become. **PLEASE NOTE:** The forecasts in the calendar must not be used for contraceptive purposes! The duration of the fertile phase changes depending on the data situation, usage behaviour and cycle. The rules of the symptothermal method apply. If you have any questions, please contact info@trackle.de at any time.

ENTERING THE OTHER PARAMETERS CERVICAL MUCUS

It is very important for correct data evaluation that you record your cervical mucus in addition to the temperature. You are most likely to know cervical mucus in the form of discharge. This mucus is secreted from the cervix to

close the opening in your cervix and prevent bacteria from spreading too far into your cervical canal. This mucus liquefies around your fertile phase in order to better allow sperm to pass through and thus facilitate fertilization. Accordingly, if you observe the consistency of your cervical mucus, you can draw conclusions about how far you are in your cycle. The closer to ovulation, the more mucus is formed and the clearer, more stretchable, slippery and "egg-white" it becomes. Sometimes it even reminds of water at this stage.

CERVICAL MUCUS CATEGORIES

**DRY; DRY, ROUGH, ITCHY, UNPLEASANT FEELING:** And nothing visible, no cervical mucus in the outer part of the vagina ► **SIGN: t**  
**NOTHING NOTICEABLE, NO DAMPNES, NOTHING FELT IN THE OUTER PART OF THE VAGINA:** And nothing visible, no cervical mucus in the outer part of the vagina ► **SIGN: ø**  
**DAMP:** But nothing visible, no cervical mucus in the outer part of the vagina ► **SIGN: f**  
**DAMP OR NOTHING NOTICEABLE:** And thick, whitish, cloudy, creamy, lumpy, yellowish, sticky, milky, not stretchy or viscous ► **SIGN: s**  
**DAMP OR NOTHING NOTICEABLE:** And clear, transparent, opaque, like raw egg whites (clear streaked with white threads), stretchy or spinnable, stringy, liquid, so runny that it "flows like water", reddish, reddish brown, yellowy red ► **SIGN: S+**  
**WET, SLIPPERY, SLICK, SLIMY, AS IF OILED, SMOOTH:** And/or clear, transparent, opaque, like raw egg whites (clear streaked with white threads), stretchy or spinnable, stringy, liquid, so runny that it "flows like water", reddish, reddish brown, yellowy red ► **SIGN: S+**