cyclotest®mgWay Instructions for Use



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cyclotest[®] myWay is a fertility analysis device for determining the fertile and infertile days in a woman's cycle. The cycle computer serves as technical support when applying a natural contraception method and is no substitute for measures or means of preventing pregnancy.

Description

cyclotest[®] myWay works according to the temperature method for recording the basal temperature via a direct measuring mode (morning body temperature before getting up) in the female menstruation cycle. Optionally, the cycle computer can be used for symptothermal analysis, i.e. the additional evaluation of a further ovulation symptom is considered when calculating the fertile days. [see Ovulation symptoms, p. 48]

By measuring and storing the basal body temperature measured every day, the unit uses the temperature variations in °C and the stored data from previous cycles to pinpoint and display the highly fertile, fertile and infertile days. In the trying to conceive mode the highly fertile days are also displayed.

The unit is able to pinpoint dates with increasing accuracy as the amount of data collected increases. After 6 of temperature taking cyclotest[®] myWay has reached its greatest prediction reliability. The fertility date can be narrowed down even further with additional fertility data.

When using the trying to conceive mode:

When trying to get pregnant you should have sex in the highly fertile and fertile phases. The chances of getting pregnant are greatest on the highly fertile days. The unit offers numerous analysis and evaluation options to help you pinpoint the fertility date.

Please note:

- The simultaneous use of cyclotest[®] myWay and hormonal contraceptives is pointless. Hormonal contraceptives affect the natural course of the cycle and thus evaluation by cyclotest[®] myWay.
- cyclotest[®] myWay is not a contraceptive, but instead a fertility analysis device, which forms the foundation for hormone-free and natural contraception. Knowledge of the fertile and infertile days in the cycle makes contraception to suit requirements possible: If a pregnancy is to be avoided during fertile days, a suitable contraceptive should be used, for example a condom.
- The unit offers numerous analysis and evaluation options to help you pinpoint the fertility date.
- cyclotest[®] myWay is suitable for use by women who have completed puberty until the onset of the menopause. It should be used by women who sleep regular hours. Users of the unit are required to have full mental capacity and sufficient reading competence. Minors require the consent of their parents or guardian to use the unit.
- The unit is not suitable for women with changeable cycles (e.g. cycle lengths in excess of 45 days or postovulatory phase shorter than roughly 11 days) and who sleep irregular hours (shift work, time lags due to travelling).
- The unit does not actively intervene in the cycle; it evaluates temperature parameters and signals the current status in the cycle.
- The unit does not provide any protection against sexually transmitted diseases.
- Please note that possible disruptive factors such as unaccustomed alcohol consumption, stress and changes of environment can in individual cases affect the temperature.



Important technical information

- The unit must be used in accordance with the procedures contained in these instructions and must not be used for other purposes.
- The unit may only be operated with original spare parts and accessories. Damage caused by non-approved accessories is not covered by the warranty! Connecting the unit to an accessory that is not intended for the unit may result in personal injury or destruction of the unit.
- Do not under any circumstances open or modify the unit. This is a medical product and may only be opened by authorised specialists (excluding battery replacement). Any modification may result in personal injury or destruction of the unit.
- Please comply with the scheduled operating conditions for measurement. See Technical data, P. 51.
- Using the unit in the immediate vicinity of mobile phones, microwave appliances or other devices with strong electromagnetic fields may result in malfunctions. For operation, maintain a minimum distance of 3 metres to such devices.
- The unit contains sensitive parts and must be protected against strong temperature variations, air moisture, dust and direct sunlight.
- Make sure the connecting socket for the sensor and USB cable is always free of dust and debriss.
- The unit is not waterproof. Protect it from moisture and never immerse it in water. The sensor is waterproof.
- Suitable for indoor use only. Neither the device nor the method are designed for outdoor use.

- Do not expose the thermometer to extreme heat (blazing sun, heating, hot water, etc.). This could unnaturally affect the temperature measurement.
- The unit is not shockproof or impact-resistant. We recommend you have the unit checked for accuracy after bigger drops or impacts.
- The unit contains small parts that could be swallowed by children. For this reason, keep the unit out of reach of children. There is also the potential danger of strangulation by the measuring cable.
- Damage caused by children, pets or pest will inevitably result in the disruption of the cycle measurement series.
- Lithium polymer batteries can ignite if overcharged. For this reason, use only the supplied charger to charge the battery. Using other chargers increases the risk of the battery igniting or exploding!
- Check that tip of the thermometer is undamaged prior to measurement. A damaged thermometer sensor can cause injuries.
- Do not bite or excessively bend the sensor. This may result in damage and malfunctions.
- The plastic and the metal of the sensor comply with the biocompatibility requirements in accordance with ISO 10993-1. The golden coating on the measuring tip prevents a nickel allergy reaction. The plastic of the measurement sensor is free from latex and consists of bio-compatible TPE and ABS.
- Any serious incidents occuring in connection with the equipment should be reported to the manufacturer and the responsible authority in the EU member state in which the user is resident.

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Unit Description



saving Cancel or remove inputs

Back to the previous display without

cycle 1

01.01.2018

17.07.2018

14.07.2018

Cycle start

High level day

symptom

15:30 Wednesday 01.08.2018

+

X

28

17

14

- Confirm or save
- Back to the menu
 - Arrows for scrolling forward and back and for setting values

Inserting the battery



- Place the unit on a soft surface and open the battery compartment on the back of the unit.
- Connect the plug from the battery compartment to the battery plug. Make sure the cable colours are aligned.



• Slide the connected plug back into the designated compartment and insert the battery. Be sure the cable is not trapped or caught in any way.



Close the battery compartment.

Attention! Do not remove the foil wrapping from the battery.

Charging the battery

The battery is supplied partially charged. Charge the battery as described in the following before using the unit for the first time. The battery reaches its full performance capability only after several complete charging and discharging cycles. Use only the supplied battery.

- Connect the charging cable to the connecting socket on the unit and the charger plug to a suitable power socket. For safety reasons use only the supplied charger.
- A charging battery symbol appears during the charging process when the display is activated. When the charging process is finished, the charge status display will show 100 %.







• At the end of the charging process disconnect the unit from the mains power supply and detach the charging cable from the unit.

The unit is very economical in its power consumption. Initially, however, you will have to charge the battery more often due to more frequent display activities. The charging cycle is extended when you have fewer display activities.

Note: A full charge takes approximately 2 hours. The charging time is shorter for a partially uncharged battery.

Basic settings

Turn on the unit by pressing the ON/OFF button.



01 08 2018

Select your language.

Enter the current date and the time and confirm the input with the check (tick) symbol.

Your unit is ready for operation once you have acknowledged the liability disclaimer.



15:30 Wednesdu \1.08.201



To turn on the unit, briefly press the ON/OFF button. To turn off the unit, press and hold down the ON/ OFF button for approximately 2 seconds. The unit turns itself off automatically if it remains idle after 60 seconds.

To select menu symbols, to operate buttons on the screen, or to enter characters via the screen keypad, touch them with your finger.

Important user information

To ensure correct functioning of cyclotest[®] myWay, it is essential that you perform the morning measurements of wake-up temperature before getting up and before any activity without changing ambient conditions.

You should have slept for at least 5 hours and in the last hour prior to measurement you should not have gotten up. If you ascertain an atypical temperature rise due to illness/sickness, we recommend that you record the measurements for this time period as a disruption [see P. 29]

Using the unit outside the specified ambient conditions may give rise to inaccurate measurements or even mismeasurements.

Selecting the point of measurement

You can take your temperature orally, rectally or vaginally, but do not alternate you have chosen. Measuring under the arm (axillary) produces inaccurate results, it is therefore unsuitable for recording basal body temperature. Important: For accurate assessment there must be no inflammation at the selected point of measurement.

We recommend that you take the measurement under your tongue with your mouth closed. Place the sensor tip in one of the two heat pockets under your tongue to the left or right of the root of the tongue. The sensor must make strong contact with the tissue.

Close your mouth and breathe easily through your nose so that the measurement result is not compromised by inhaled air.

Measuring temperature

Once the cycle start has been successfully input (see P. 21), you can take your temperature measurements. Begin the morning after the cycle start before getting up. You may take your temperature while lying down.



Do not bite or excessively bend the sensor. This may result in damage and malfunctions.





Place the sensor tip on the selected point of measurement. When the sensor tip is resting steadily and comfortably, press the large Measurement button on the sensor briefly. This starts the temperature measurement. Please be patient during the measurement. The sensor must warm up first (from room temperature to body temperature).

The unit confirms successful measurement (duration approx. 60-90 seconds) with a long signal tone and indicates the completed temperature in the display. Be sure to wait for the signal tone to finish in order to ensure the accuracy of your temperature readings.

If you break off the measurement too early, the unit will alert you in the display and with a signal tone that it was unable to store a measurement result.



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In this case, please measure again and remove the sensor only when you have heard the signal tone. cvclotest[®] mvWav takes care of everything else in the background.

The measured temperature, your fertility status and much more information are then automatically displayed in your personal day chart [see below].

Note: If you believe that there might be irregularities regarding your temperature mesurements or if you would like to test them for accuracy, please perform a test temperature measurement [see P.35] or contact the cyclotest[®] service hotline.

Main menu



From the main menu you have access to all the functions and settings.

When you press the "i" icon the unit information such as serial number and software version are indicated in the display.

Daily Info



Completion of the temperature measurement and turning the unit on with the ON/OFF button brings up the daily info screen, summarizing the most important information at a glance.

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How to read the day chart:



Current day. Press the arrow to scroll through past davs.

Fertility status: Infertile





Fertility status: Fertile [Can be used in addition to a hormone-free contraceptive if you wish to prevent a pregnancy).



Fertility status: Highly fertile (only in Child wish mode). The probability of becoming pregnant is now at its highest.



Unusually long cycle [see P. 42]

Temperature

this day

l	36,54 °(
ſ	Cycle day

1

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You are on the 1st day of your current cycle.

Wake-up temperature measured on



Anticipated start of your next period and anticipated start of the next infertile phase.



Inactive cycle. [see P. 21] The display is grayed out.



Switch to the calendar view



Switch to the cycle curve



Switch to the Data menu



Switch to the main menu (without saving)



Help for the daily chart



Battery charge status



Date and time









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Possible display symbols in the day chart:



The alarm clock is activated.



The BMI function is activated. On this day a weight input is expected.



The skin care recommendation is activated.



It is now advisable to carry out an ovulation test in order to pinpoint ovulation even more exactly.



Calendar view

The PMS notice is activated [see P. 31]. On this day PMS-suitable preparations are recommended

On this day manual inputs are made, here e.g. protected sexual intercourse. Note: The prognostic details are in each case calculated currently on the basis of the stored cycle data and the cycle length average and can change in the course of the cycle due to new measured values and other data.

How to read the calendar view:



Selected month. You can scroll with the arrows to past or future months.



Fertility status: Infertile

Fertility status: Fertile



The current day is highlighted by a thicker border.







Fertility status: Highly fertile (only in

The PMS notice [see P. 31] is activated. On this day PMS-suitable preparations are recommended.



You can bring up the calendar via the menu or from the daily info screen.

When bringing this view up for the first time, please confirm once that your are aware that your prognosis data may change in the course of the cycle.

With one available active cycle your calendar shows a preview of a cycle.







Inactive cycle. [see P. 21] The display is grayed out.

Unusually long cycle [see P. 42]

the trying to conceive mode)









Cycle curve



How to read the cycle curve display:

- You can bring up the cycle curve via the menu or from the day chart.
- You can move the curve to the right or left by clicking and sliding.

Sexual intercourse. On this cycle day you marked unprotected sexual intercourse.



Cervical mucus. You recorded your mucus peak on this day.



LH value. You have entered a positive LH value for this day.

Note: If your temperature curve changes drastically or always shows the same values, we advise you to check the sensor [see Test measurement P. 35].

My Cycle



Your cycle data at a glance. A handy overview for yourself or for your next appointment with your gynaecologist:

Afterwards, the icon is no longer visible in the Cycle menu.

Current cycle day, last cycle day, shortest cycle, longest cycle, average cycle length, number of active cycles, peaks found.

Past Data





Fertility status: Fertile



Fertility status: Highly fertile (only in the trying to conceive mode)



Inactive cycle. [see P. 21] The display is grayed out.

Unusually long cycle [see P. 42]



Disruption (such as e.g. illness, see P. 29]: The temperature reading is not factored into the calculations.

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cvcle -1 Cycle start 28 01.07.2018 15 High level da 15.07.2018 15:30 Wednesda 01.08.201

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Your cycle curve in the selected cycle. Only the days you measured are displayed in the curve diagram.



Cycle start: The first day of menstruation

High level day: The first day with higher temperature measurement after ovulation

Symptom: the first day with positive LH, or the day on which the cervical mucus high-point is established.

On the right next to it you can see the corresponding cycle day. In the example above the cycle has a length of 28 days, the peak occurred on Day 15.

Note: If you backdate the begining of your cycle by more than 5 days, it is no longer possible to input past data. In this case, do not use the unit until the beginning of your next cycle.

Cycle History



On this display you can see the benchmark data of up to 12 of your last cycles in detail. Cycles will begin starting with cycle 01 and will increase consecutively. Manually input cycles can be recognised from a minus symbol before the number. From "cycle –1" (previous cycle) to "cycle –6" (oldest cycle).

Manually recording past cycles is possible up to until the 5th day of the first cycle using the device. This can be done from the main menu Past Data.

Cycle start: The first day of menstruation

High level day: The first day with higher temperature measurement after ovulation

Symptom: the first day with positive LH, or the day on which the cervical mucus high-point is established.

Inactive: The current and last cycles can be excluded. This data is then not factored into the calculations. Important: Inactive cycles cannot be reactivated.

Symptothermal: checked boxes show where the cycle was symptothermally evaluated.

Cycle Start



The cycle start should ideally be input on the first day of your period (menstruation). This data is not dependent on a measurement and can therefore be added in the afternoon or evening.

Note: cyclotest® myWay cannot store any measurement results the cycle has not been started.



Press "Cycle start" in the menu Cycle - Cycle start to start a new cycle and record the start of menstruation.

First select the date and the point of measurement (oral, vaginal, rectal) [see P. 12]. Press the right arrow button to go to the next menu item.

You can now define the measurement time window and activate the sensor light. Your cycle start is saved only when the check (tick) symbol is acknowledged **(see P. 22)**.

You can input your cycle start (1st day of menstruation) for up to 15 days after the actual start of menstruation. If your cycle start was more than 15 days ago, the cycle will become inactive automatically.

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Time Window for Measurement







By setting your desired time you define the measurement time window (+/- 2 hours) for this cycle. Temperatures taken outside this time are not recorded. We therefore recommend that you choose your first measurement time window to match your daily rhythm.

If for example you set the time to 7:00 am, you are reminded the next morning at this time by a signal tone (if the alarm clock was activated). During this cycle, it will be possible to take your temperature between 5:00 am to 9:00 am. Always take your temperature before getting out of bed.

Note: For optimal evaluation, temperature should be taken as close as possible to the same time each day.

The LED sensor light will be lit during the measurement time window if activated, allowing you to see if you are within your time window without looking at the clock.

Please note Your cycle start is registers only after confirming it with the check (tick) symbol.

Data



With cyclotest[®] myWay you can record the following data: period bleeding, sexual intercourse, cervical mucus, LH hormone, midpain, cervical position and disruption.

Adding this data is optional. cyclotest[®] myWay can be used without these details within the framework of the temperature method.

All data can be entered for the current day and the previous day.

How do you input data?

On the Daily Chart, press the pen icon and select the desired data (e.g. menstruation) and the corresponding day.

You can also add this infomation via the menu with the menu item Data.

Bleeding



Menstruation

The onset of your period (menstruation) is the start of your menstrual cycle. The day that you start your cycle is automatically recorded as the first menstruation day.









This data appears in the form of a shaded drop symbol on the daily info screen and on the calendar.

Important: Inputting menstruation is not a substitute for adding a cycle start [see P. 21]!

Intermenstrual Bleeding

Intermenstrual bleeding can occur as a result of fluctuating hormone levels throughout the cycle. Recording this bleeding is optional.



The input of intermenstrual bleeding appears in the form of a transparent drop in the day chart and on the calendar and has no bearing on calculations.

Sexual Intercourse



You can record sexual intercourse in your unit.

If you want to get pregnant: The most likely fertilisation date can be determined because of this data. If you fail to get pregnant in spite of the ideal available cycle data, this can help your doctor in diagnosing specific causes.

The data is displayed in the form of a heart symbol in the day chart and on the cycle curve.

Transparent heart = protected sex





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Cervical Mucus



During the first run, you will have the unique opportunity to decide whether the cervical mucus value should be used in your cycle evaluation. You will be able to decide whether cervical mucus is symptothermally evaluated. This means, that both basal temperature and cervical mucus condition should be taken into account when calculating your fertile period.

Cervical mucus is an indicator of the fertile phase; its consistency

changes during the course of a cycle. The cervical mucus is observed at the entrance to the vagina. Shortly before ovulation the consistency (spinnbarkeit - stretchability) of the cervical mucus changes.

A certain amount of experience is required to assess the cervical mucus, NFP (Natural Family Planning) advice centres can offer the necessary help learning to assess your cervical mucus.

The following cervical mucus consistencies can be recorded:

- Nothing seen, nothing felt Ø
- Nothing seen, dry feeling
- Moist feeling, no mucus visible
- Mucus is thick, white, yellow, lumpy or creamy S
- S+ Mucus is glassy, transparent, resembling raw egg white, flexible, thread-like, liguid, red or flows away like water, wet feeling and slippery vaginal introitus

S+H is the peak for cervical mucus. The characteristics correspond to those for S+. The input S+H is only possible on one day per cycle and only during the fertile days. This day is the last day with the best mucus quality (S+). S+H is determined retrospectively and therefore only recorded on the following day when the change to lower cervical mucus guality has taken place.

Please note: when using symptothermal methods, ovulation test (LH) results can no longer be calculated; the record is made purely for documentary purposes.







Cervical mucus (aka discharge) is a fluid produced in the cervix, which changes at certain times of a cycle in volume. Observing the cervical mucus is part of the symptothermal method (see page 48 "Ovulation symptoms") and can help to determine your fertility status. At the beginning of a cycle after menstruation, little mucus is secreted. The vagina feels rather dry and you usually feel little. After this phase, it feels more and more wet. The mucus is now usually whitish or yellowish as well as thick and creamy. When approaching ovulation, the amount of cervical mucus increases and the quality improves, i.e. it becomes more transparent and stretchable. Your vagina might then feel very wet. After ovulation, the conistency of the mucus changes again and becomes more sticky and non-transparent. The changes of the cervical mucus throughout a woman's cycle vary from woman to woman and the mucus cannot always be observed and felt the same way each cycle. It is important that you notice a deterioration of the mucus within a cycle. Observing your cervical mucus requires a lot of practice and only if you perform it on a regular basis, you can rely on the results. In case you decide to include cervical mucus into your evaluation, we suggest you obtain additional information on the subject. For example, you can find useful tips on the method in the book "Taking Charge of Your Fertility" by Tony Weschler.

LH Hormone Measurement



During the first run, please confirm that the LH entry is to be used for your cycle evaluation. Please note, that you should only submit your entries for calculation, if you already have experience of ovulation test results and their interpretation.



An increased concentration of the ovulation hormone LH in your urine indicates that ovulation is imminent. This can be verified using a cyclotest[®] Ovulation Test. To narrow down your ovulation date as much as possible, you can conduct ovulation tests on the highly fertile days.

If the test results are positive, enter the result on the corresponding day in the current cycle information. The LH entry affects cycle evaluation and is shown on the day chart and on the cycle curve. **Please note**, that you should either enter the cervical mucus high-point or the LH peak value. When selecting cervical mucus high-point, the LH entry is left uncalculated and is only shown for documentary purposes.

+ = positive test result

- = negative test result

It is only necessary to test LH hormone if you see the LH symbol in the day chart. cyclotest® Ovulation Tests are available in all well-sorted pharmacies (item no. 9035, PZN 01399381).

Midpain



Many women feel a dull pain in the lower abdomen around the time of ovulation. The manifestation of this midpain is individual for every woman and can go unnoticed or last several days. From a medical standpoint midpain cannot be precisely attributed to ovulation. Nevertheless many women like to record their midpain.

You can add midpain for the current day and the previo 😎 y. Inputting midpain has no bearing on the calculation of your fertility phase.



This data is displayed inon the daily info screen.



Cervical Position



Cervical observation provides a further indicator of fertility for pinpointing the fertile days. A high level of method knowledge and practise is required to be able to record cervical changes correctly. These changes are very inaccurate as a sole fertility indicator. nevertheless, observation is useful in helping women to understand their own cycles.

The input of cervical changes is recorded in your cycle data, but has no bearing on the calculation of your fertility phase.

The data is displayed as follows in the day chart:



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- Hard + closed, position high
- Hard + open, position low

Hard + open, position middle

- Hard + open, position high
- Soft + slightly open, position low Soft + slightly open, position middle Soft + slightly open, position high

- Hard + slightly open, position low
- Hard + slightly open, position middle
- Hard + slightly open, position high
- Soft + closed, position low 0
- 0 Soft + closed, position middle
- Soft + closed, position high
- Soft + open, position low
- Soft + open, position middle
- Soft + open, position high



Disruption



Certain circumstances in life can distort the basal body temperature data. Here it is possible to skip temperature measurement in individual cases so as not to load the cycle with incorrect data. Circumstances that might disrupt basel body temperature include: illness, a short or disrupted night sleep, going to bed unusually late, alcohol consumption, eating late at night, parties, stress and mental strain, change of environment or change of climate.

If these disruptive factors are only noticed after the morning measurement [the onset of a cold, for instance), this can be input retroactively. Disruptions can be recorded for the current day and the previous day.

If you record a disruption, the temperature of that day is not taken into account in the cycle evaluation.

This data is displayed on the Daily Info screen and in the Cycle Curve.



Display on the Daily Info Screen

Display in the Cycle Curve

Options





cyclotest[®] myWay features the following supplementary functions, which are summarised in the menu item Options: Skin care, PMS (Premenstrual Syndrome), BMI (Body Mass Index) Due date. PIN activation and deactivation and test measurement.



Skin Care





Many women are prone to skin changes caused by their cycle as the sebaceous skin glands react to the cyclic hormonal changes, particularly to testosterone. Increased amounts of sebum are produced and potentially cause skin issues.

Specific care can prevent or alleviate skin problems. cyclotest® myWay signals a skin care recommendation matched to the cycle phase.

Once the function is activated, the skin care recommendation is displayed on the Daily Info screen:



During the first half of the cycle, between menstruation and ovulation, many women find they have a smooth complexion. A blue jar of cream appears in the day chart advising you to use a regular moisturiser at this point.



During the second half of the cycle, after ovulation, many women notice a change in their complexion and a tendency towards skin blemishes. A green jar of cream appears in the day chart advising you to use a slightly antibacterial and oil-free moisturiser at this point.

PMS - Premenstrual Syndrome



Premenstrual syndrome is abbreviated to PMS. Many women suffer from PMS on the days prior to menstruation and the symptoms can persist up to the 3rd cycle day. PMS is caused by a drop in the oestrogen level and manifests itself in increased irritability.

Do you suffer from PMS?



When you activate this function via the menu item PMS, the unit reminds you on the Daily Info screen and in the calendar when alleviating measures (such as taking vitamins and doing sport or relaxation exercises) may be useful.

Due Date (only in the trying to conceive mode) cyclotest[®] myWay tells you the probable fertilisation date Due date and the expected due date if you get pregnant in the current cycle. \checkmark 20.02.2018 Have you done a pregnancy test with a positive result? If so, you can 14 Expected due date 13.11.2018 manually confirm the selection "Pregnant?". This data is displayed Planner once and is not saved. 15:30 Wednesday 01.08.2018







Basal body temperature is a reliable indicator of pregnancy. If cyclotest[®] myWay automatically determines that you may be pregnant through your temperature readings, the evaluation is save and adopted on the Daily Info screen, in the calendar and on the cycle curve.

Note: The due date is calculated based on your personal cycle data. The unit starts from your suspected last ovulation.



Plan the arrival of your baby with the due date planner

In the Planner submenu enter your desired due date and cyclotest[®] myWay calculates the ideal time for fertilisation on the basis of your cycle data.

BMI - Body Mass Index



Being underweight or overweight can have a negative impact on female fertility. With cyclotest[®] myWay you can calculate and chart your BMI. Also, in order to illustrate BMI progression, a graphical display of your BMI values in a historical comparison is possible.



The "Curve" submenu provides a graphical representation of your BMI values in a historical comparison in order to illustrate your BMI progression. You can move the curve to the right or left by clicking and sliding.

The "My BMI" submenu shows your current data at a glance. You may



15:30 Wednesday 01.08.2018 Height (cm)

Input rhyth

When the BMI function is activated you are reminded with the BMI icon on the Daily Info screen to enter your weight.

also consult the current BMI table.

your BMI calculated once a week or once a month.

You can activate and deactivate the BMI function in the "Settings"

submenu. Enter your height and select whether you wish to have

Image: Signal of the second second

BMI settings

170







PIN Activation and Deactivation

You can protect your personal data against unauthorised access by activating the PIN (Personal Identification Number).



Activating the PIN prompt

Enter and confirm a four-digit PIN to activate the PIN prompt. The prompt will now appear automatically when the unit is turned on.

The PIN you assign to the unit is also valid on the cyclotest $^{\circ}$ Software.



Deactivating the PIN prompt

You can deactivate the PIN prompt by entering the current PIN again.

Forgot your PIN?

Please call the cyclotest[®] service hotline and have the serial number of your unit on hand. The serial number is located on the inside of the battery compartment behind the battery.

👩 Test Measurement



This function allows you to perform a test temperature measurement. You can take a temperature reading for yourself or to demonstrate to others, without the value t

Position the sensor at the point of measurement and press "Start" in the display. The measurement proceeds like a normal temperature measurement (see P. 13).

Note: The data of a test measurement are neither saved nor factored into the calculations and have no bearing on the measurement time window. A test measurement is independent of the measurement time window.

Alarm Clock



You can activate, deactivate and set the alarm function via the Alarm Clock menu.

Activate the ararm function and set the desired wake-up time.

The alarm clock includes a dynamic alarm tion that allows you to select if you want to be woken only on days when temperature taking is relevant to your cycle evaluation, or every day.





When the dynamic alarm function is activated, the wake-up time can only be set within the current measurement time window. If you wish to be woken every day, wake-up time can be selected freely.

A clock icon in the day chart indicates when the alarm function is activated.



When the alarm rings, you can turn it off by pressing the white bar on the display.

Note: For optimal evaluation, temperature should be taken as close as possible to the same time each day.

Settings



This menu features the following functions: Date/Time. Mode, Measurement time window, Display, Tones, Help, Function test, Language.

It is essential to note: The measurement time window is automatically adjusted to the newly set time and cannot be changed within a cycle. The current cycle no longer becomes inactive automatically.

Mode



Here you can toggle the device from contraception mode to trying to conceive mode or vice versa. Please note that the displays and menus adapt to the relevant mode.

Attention: The relevant mode requires basic knowledge of natural methods. The natural methods include the temperature method a <u>sthe</u> symptothermal method. cyclotest[®] is not liable for currence or non-occurrence of a pregnancy.

Measurement Time Window



Date/Time



Set the date and time here.

Attention: Any change to the date or time can influence your cycle evaluation. Please note the information on the device.



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leasurement time window Measurement time window in this cycle 06:30 - 10:30 15:30 Wednesday 01.08.2018 Here you can select your desired measurer 100 time window (+/- 2 hours) for all temperature measurements in this cycle. We therefore recommend that you choose the time window appropriate for your daily routine.

Changes to the measurement time window are possible until the first valid measurement in this cycle. Taking your temperature outside the measurement time window is not possible.

The selected time is automatically set as the proposed wake-up time. You can change the wake-up time within the measurement time window via the Alarm Clock menu.

♥ Cvclotest[®]





Operating the Unit

Example: 8:30 am has been set as the wake up time. Your measurement time window for this cycle therefore extends from 6:30 am to 10:30 am.

Note: For optima	al evaluation, temperature should be taken as close as possible to the same time
each day. 🛛 💦	

The LED sensor light will be lit during the measurement time window if activated, giving you a visual indication of when to take your temperature without disturbing your partner.

Display



In this menu you can adjust the brightness of the display and calibrate the touch screen.

Note: The brighter the display, the shorter the battery running time.

Recalibrate the touch screen if precise operation is no longer possible. Calibration readjusts the touch screen to your finger clicks.

Calibration can be undertaken using mySoftware (Version 1.3 or later).

During the r recise. Alternatively, you can use the tip of the sensor.

Note: You need to press the marked dots on the display precisely during the recalibration process.

Tones



Help



When the Help function is activated, the Help button appears in the form of a question mark on all the menus. Here you can call up important and useful information on each respective function.

In this menu you can activate and deactivate the meas-

urement tone and the touch tone.

You can de the Help function by checking (ticking) "off".







Function Test



You can start the following unit and system tests via this menu.

Display

The unit displays a succession of differe mylours and patterns. Look out for unusual displays.





Touch Function

Here you can check whether the touch display is correctly adjusted. Click on anywhere in the display and a dot appears at this position.

If the point does not correspond to the printed area on the display. the display must be calibrated using the mySoftware cyclotest[®] for the given PC/Mac [see Page 45].





Sensor

The unit checks that the sensor is correctly connected to the unit and is functioning properly.





Battery

The unit checks the battery charge state, state of charge, and voltage.



Buttons

Here you can check the function of the ON/OFF button and the Measurement button on the sensor.



Tones

The unit plays a succession of test tones to check the acoustic output.







Language



Select your language here.



Ovarian Insufficiency (on

(only in the trying to conceive mode)

cyclotest[®] myWay indicates a possible ovarian insufficiency. Ovarian insufficiency is frequently the reason why couples fail to get pregnant. The egg is fertilised, but cannot implant itself in the uterus mucous membrane.

If the unit detects a possible ovarian insufficiency, a corresponding message appears in the display. Please arrange an appointment with your gynaecologist to discuss this.

Unusually long cycle

If cyclotest[®] myWay ascertains that you may be pregnant by reference to your temperature readings, this is indicated in the calendar and in the cycle curve by days highlighted in yellow. An egg symbol with a question mark is displayed on the Daily Info screen and a message appears in the display.



EN-42



The unit may think you are pregnant for a few different reasons:

- **1.** You are taking an extended break from temperature taking.
- **2.** You forgot to start a new cycle on the first day of menstruation (see P. 21). The unit interprets this as a missed period.
- **3.** If there is actually no menstruation, you may be pregnant. You are advised to take a pregnancy test.

Important: If within a cycle you observe inexplicable temperature measurements that deviate dramatically from your previous cycles, call the cyclotest $^{\circ}$ service hotline.

Reset Button

If the unit stops responding to inputs and can no longer be activated by pressing the ON/OFF button, you can restart the unit with the Reset button.

The Reset button is located in the battery compartment behind the battery and can be pressed with a thin pointed object.

The last measurement time window saved will still be valid. Your existing cycle data will still be saved.

Replacing the Battery

Open the battery compartment on the back of the unit and take out the battery.

Disconnect the battery from the unit by opening the black connector. To do so, hold both sides of the connector firmly to avoid damaging the connecting cables to the unit.

Now connect the connector of the new battery to the unit. Insert the battery in the battery compartment and close the cover (see also P. 10).

If the unit was disconnected from the power supply, the date and time must be re-entered. The last measurement time window will be saved and valid.

Note: The date should be identical to the last date saved in the unit.

Warning: Do not reuse the battery if it is clearly damaged. In this case, call the cyclotest[®] service hotline.

Charge the battery, when the battery symbol switches to yellow and starts flashing. A beep will sound periodically to remind you.

Connect the charging cable to the connecting socket on the unit and plug into a power socket.

A charging battery symbol appears during the charging process when the display is activated. The charging process is finished when the charge state display shows 100 %.

At the end of the charging process disconnect the unit from the power supply and detach the charging cable from the unit.

Note: It takes approximately 2 hours to charge a completely flat battery. The charging time is shorter for a partially discharged battery.

Note: If you will not be using the unit for an extended period, you should charge the battery roughly every 6 months to prolong its life.

Charging the Battery

The battery charge state is displayed in 5 stages in the bottom left corner of the display:

100 %	70 %	40 %	15 %	5 %

mySoftware

cyclotest[®] mySoftware is an additional software for transmission and depiction of cyclotest[®] computer cycle test data onto a PC. The link for downloading can be found on our website at "cyclotest[®] myWay" under the separate "cyclotest[®] mySoftware" menu point. Further information on cyclotest[®] mySoftware can be found separately in the user instructions.



Cleaning and Upkeep

The unit is not waterproof and must not be immersed in water! Clean the unit with a moistened cloth and a mild cleaning agent. The holder for the sensor can be cleaned with a cotton bud.

The sensor itself is waterproof and can therefore be immersed in lukewarm water for cleaning.

Our recommended frequency for cleaning the measuring sensor would be every 2-3 days or at least once a week.

Warning: Do not under any circumstances use hot water to clean the sensor, as high temperatures can damage the sensor (for brief periods max. 40-45 °C)!

If you feel the unit needs to be disinfected, use an ethyl alcohol solution or ethyl alcohol wipes (available in all good pharmacies).

Attention upon accidental contact with fluids! For example drink has been spilled over the device: Wipe device with a soft cloth, remove battery and charger, contact the cyclotest® service hotline.

Course of the Cycle



There are three distinct phases within the female cycle:

1. A relatively short infertile phase beginning with menstruation.

2. A fertile phase which ending shortly after ovulation.

3. A relatively long infertile phase after ovulation.

Regularity of the Cycle

Around 50 % of all cycles last between 26 and 29 days. Only around 10 % of all women exhibit a natural cycle length of exactly 28 days. Deviations of 5 days are considered to be within the normal standard range.

cyclotest[®] myWay displays a cycle length of 35 days in the cycle curve. For longer cycles you can move the curve by clicking and sliding.

In the event of irregular cycle lengths, a longer fertile phase is displayed.





Ovulation Symptoms

The following symptoms can be observed or verified in connection with imminent ovulation:

• Temperature rise

- Change in the cervix
- Increase in LH concentration in the urine
- Change in the cervical mucus consistency

e Midpain

The temperature rise is monitored and evaluated by cyclotest[®] myWay. The unit is also able to store other ovulation symptoms that you input. The combined evaluation of temperature and symptom-related information is known as the symptothermal method. The basis is the measurement of the basal body temperature. The presence of cervical mucus is used as a secondary sign of ovulation. (source: Federal Centre for Health Education [Ed.]: Be sure: contraception for you and him. Cologne 2013). If required, the LH value can be evaluated instead of cervical mucus consistency using cyclotest[®] myWay. All entries made in respect of the usual symptoms are only used for documentary purposes.

cyclotest[®] and Contraception

cyclotest[®] myWay is a fertility analysis device that functions on the basis of the symptothermal method and determines the infertile days in a woman's cycle. On these days, the use of an additional contraceptive, such as condoms, is not necessary. During the fertile phase, there is a risk of pregnancy and you should opt for a hormone-free contraceptive of your choice.

When and how often should I take my temperature?

You can start your daily temperature measurement the morning after your cycle begins. It is important that you slept for at least 5 hours and you did not get out of bed in the hour prior to measurement. You do not have to continue taking your daily temperature during the long infertile phase after ovulation. The current cycle is then concluded by the next cycle start. In the event of irregularities (e.g. not enough sleep, party, alcohol, stress, eating rich food late at night, use of temperature-altering medication, illness or fever), you should skip the temperature measurement or record it as a disruption [see P. 29].

What if I forgot to take my temperature?

If one or two temperature measurements were missed, it is not important. Simply carry on normally on the next day. If there are too few measurements for the cycle to be evaluated optimally, the unit will display a longer fertile phase than usual in order to be safe.

What if I have a fever?

An atypical increase in temperature is disregarded during the cycle recording. If there are not enough temperature values that can be accurately evaluated during a cycle, the fertile phase is extended. You can manually note this measurement as a disruption via the Input menu (see P. 29).

What happens if I travel and change time zones?

When travelling to a different time zone, you should pause your measurements until you have acclimatised to your destina-tion (at least 3 days for travel outside Europe). If you have any questions, please contact the cyclotest[®] service hotline.

What if I forgot my PIN?

If you enter an incorrect PIN three times, the unit will be automatically blocked. Please call the cyclotest[®] service hotline and have the serial number of your unit ready. The serial number is located on the base of the battery compartment.

How can I delete all the user data?

The stored data can be deleted using cyclotest $^{\circ}$ mySoftware. For information on cyclotest $^{\circ}$ mySoftware, see separate instructions for use.





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Customer Service

Should your unit show evidence of a fault, we ask you not attempt repairs yourself, but instead to send in the unit with a short description of the fault.

The unit may only be repaired by the manufacturer or by an expressly authorised organisation. Please contact:

UEBE Medical GmbH Zum Ottersberg 9 97877 Wertheim, Germany Phone: +49 [0] 9342/924040 Fax: +49 (0) 9342/924080 E-mail: info@cvclotest.de Internet: www.cyclotest.de

For returns from non-EU countries make sure you are in accordance with local laws.

Spare parts and accessories



Sensor Item no. 066002. PZN 10546651



Batterv Item no. 066003. PZN 10546674





Item no. 066095. PZN 10546668

Zip baq

6

PC software

For downloading at www.cyclotest.com





Calibrating the Measuring Accuracy

The unit is not subject to obligatory calibration. However, we do recommend the thermometer accuracy be checked and calibrated every 3 years.

This service may only be carried out by UEBE Medical GmbH or by a UEBE-authorised maintenance provider. Please call the cyclotest[®] service hotline for more details.

Technical data

Unit type:	Cycle temperature computer for recording basal body temperature
Method:	Symptothermal method modified on the basis of the recognised regula- tions of the WHO
Unit dimensions:	13.3 cm x 10.8 cm x 2.3 cm
Weight:	approx. 190 g
Housing material:	PVC-free, ABS-base plastic
Temperature sensor:	PVC free measurement sensor that is based on TPE and ABS.
Measurement cable:	Special cable with strain-relief device
Sensor:	Digital TSIC sensor
Display:	LCD display (liquid crystal display) 320 x 240 px
Temperature display:	Absolute in °C (non-extrapolating) from 33.8 to 38.0 °C
Evaluation range:	35.5 - 37.5 °C
Measuring accuracy:	± 0.1 °C at ambient temperature 10 °C to 35 °C and relative air humidity from 15 to 85 % (non-condensing)
Storage and transport conditions:	Ambient temperature -10 to 50 °C, relative air humidity from 15 to 93 % (non-condensing), protect against moisture/humidity

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Storage and transport conditions between uses:	If you are storing and or traveling with the device in the recommended zip bag, the standard condition recommendations apply. The ambient condition recommendation during use apply to storage and trans- port without the zip bag.
Ambient conditions during use:	Ambient temperature 10 to 35 °C, relative air humidity from 15 to 85 % (non-condensing), air pressure from 700 hPa to 1060 hPa.
Serial number:	The unit's serial number is located inside the battery compartment and is identified with SN. Please quote this number in the event of possible service enquiries.
Battery:	Lithium polymer battery, 3.7 V, 1700 mAh, 6.29 Wh. The battery may only be charged with the supplied charger model SW06-050E.
Calibration:	The unit does not have to be calibrated.
Protection class IP:	IP 22: Protection against solid foreign bodies with a diameter of more than 12.5 mm; protection against small amounts of liquid.
Minimum expected service life:	Unit: 5 years, power pack: 5 years, sensor: 3 years, battery: 500 charge/ discharge cycles

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data-processing equipment). Furthermore, all configurations shall comply with the normative requirements for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment is a system configurer and is therefore responsible for ensuring that the system complies with the normative requirements for systems. Please note that local laws take priority over the above-mentioned normative requirements. If in doubt, consult your local specialised dealer or the Technical Service department.

Error messages

Error	Meaning	Possible cause and remedy
н	Temperature too high	Display "H" when the measuring temperature is above 38 °C.
L	Temperature too low	Display "L" when the measuring temperature is below 34 °C. Measurement terminated too early.
	Measurement process terminated	Possible causes: 1. Measurement terminated too early 2. No valid temperature value determined 3. Sensor faulty A sensor function test should be carried out.
No data available	No cycle started	Cycle must be started via the Start Cycle menu.





Error	Meaning	Possible cause and remedy
Inputs not possible as no cycle started	No cycle started	Cycle must be started via the Start Cycle menu.
Wake-up time is not in the measurement time window	Wake-up time is not in the measurement time window	Select wake-up time within the set measure- ment time window or change wake-up mode to "Every day".
		If the battery discharges completely, the date/time must be reset after the battery is recharged and the unit is turned on.
Battery discharged due to long measurement break, date/time invalid, out-of- date cycle data.	Date/time incorrect, available cycle data unusable	If the unit has not been used for a long time (e.g. after a pregnancy), the battery discharg- es and the date/time must be reset after the battery is charged and the unit is turned on. The out-of-date cycle data should be deleted via cyclotest [®] mySoftware.

Explanation of Symbols



SN

This product complies with the Council Directive 93/42/EC from 5 September 2007 regard-ing medical devices and bears the mark CE 0123 (TÜV SÜD Product Service GmbH).





Manufacturer



∬~50 °C -10 °C

15%

Manufacturing date

Please observe instructions for use!

Storage and transport conditions:

Limit values for ambient temperature

Limit values for relative air humidity



Serial number of unit

Degree of protection against electric shock: TYPE BF

Keep dry



For indoor use only

Battery



Do not expose the battery to heat or fire. Do not store in direct sunlight.



The battery may not be machined, damaged or broken up.





Technical Information

Carger

The supplied charger (switched-mode power supply) is a component of the medical electrical device.



Protection class II (double insulation)



Internal fuse

Lithium polymer battery

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Disposal



Batteries and technical appliances must not be disposed of with domestic waste, but should be handed in at the appropriate collection and disposal points.



Recycling



Grüner Punkt [Green Dot]

When disposing of the unit at the end of its service life:

- If possible, delete data off the unit via your computer

- Remove battery and hand in at a battery collection point

The device has been manufactured and tested with great care. However, in the unlikely event of a defect being detected after delivery, your device is covered under warranty in accordance with the following terms and conditions:

During the warranty period of 2 years from the date of purchase we reserve the right either to repair any such defect at our expense [upon return of the unit to our factory] or to supply a perfect replacement unit. The warranty period for the battery is 6 months.

Excluded from the warranty are parts subject to normal wear and tear as well as damage caused by non-compliance with the instructions for use, improper handling [e.g. unsuitable power sources, breakages, leaking batteries) and/or disassembly of the unit by the purchaser. Furthermore, no claims for damages against us are substantiated by the warranty.

Warranty claims may only be made during the warranty period and by presenting proof of purchase. In the event of a warranty claim, the unit must be sent to the following address together with the proof of purchase and a description of the complaint:

> UFBF Medical GmbH Service-Center Zum Ottersberg 9 97877 Wertheim Germany

The cost of returning the unit to our factory shall be borne by the sender. UEBE shall refuse to accept return deliveries that were not paid for by the sender.

The statutory rights of the purchaser to claim against the seller (for example claims for defects, product liability) are not limited by the warranty.

Please note: In the event of a warranty claim it is essential to attach the proof of purchase.





The cyclotest[®] service hotline

Dear valued customer,

Please ensure you read the cyclotest $^{\circ}$ myWay instructions carefully and familiarised yourself with the device features.

Our description corresponds to the normal cycle response. While using your cyclotest[®] myWay you may notice initially some readings and information in the dialogue display that appear unfamiliar to you, or you may have questions about handling the unit.

In such cases you can call our cyclotest[®] service hotline, which is open from Mondays to Thursdays from 8.00 am to 5.00 pm and on Fridays until 4.30 pm.



Your team of cyclotest[®] advisers is looking forward to taking your call.



REF 0660 PZN 01221967

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UEBE Medical GmbH Zum Ottersberg 9 97877 Wertheim, Germany Phone: + 49 (0) 93 42 / 92 40 40 Fax: + 49 (0) 93 42 / 92 40 80 E-mail: info@uebe.com Internet: www.uebe.com 7 0660 203 GA 2018-07

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