

Welcome to inne.

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Introduction

ABOUT THIS DOCUMENT

This SYSTEM MANUAL contains important information about how to use the inne MINILAB. Read it carefully prior to using the inne MINILAB for the first time and keep it for future reference. This manual describes the proper procedures for operation and maintenance. The inne MINILAB must not be used for any purpose other than that which is specified in this document.

Version: 6.0

Date: April 10th, 2024

NOTE Always check the inne APP to access the latest version of this manual.

INTENDED USE

The inne MINILAB is a fertility monitoring device that measures progesterone in saliva throughout the menstrual cycle. It is designed for self-testing by female laypersons at home.

ABOUT INNE

When we see the female reproductive system we see beauty and we see logic.

Our mission is to help women see the same and provide a way to get reliable information about their personal fertility. Our minilab combines science, technology and design to help women understand the rhythms of their bodies and how they influence fertility.

The rhythms of a woman's body are controlled by hormones. These hormones, oestrogen and progesterone in particular, regulate the menstrual cycle and trigger ovulation. By measuring progesterone levels at different times in the cycle, the inne MINILAB is able to identify the days in which a woman has a high chance of getting pregnant and provide insights into her fertility.

The inne MINILAB

Overview

ABOUT THE INNE MINILAB

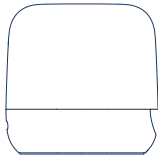
In order to use the inne MINILAB, you need to carry out a daily saliva collection using an inne Progesterone STRIP, perform a measurement using the inne READER, and finally review the results and view your fertility status in the inne APP.

Our system's algorithm calculates your fertility status by taking into account the progesterone concentration found in your saliva, the dates of your previous periods, the maximum lifespan of an unfertilised egg and the lifespan of sperm. The inne APP displays this fertility status by indicating whether you have a high or a low chance of pregnancy.

Since every woman's cycle is individual and each cycle can vary, the inne MINILAB has to be used consistently in order to accurately predict and monitor your fertility.



inne Progesterone
STRIP



inne READER

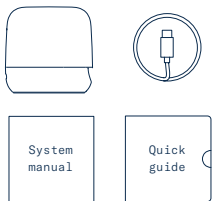


inne APP

COMPONENTS OF 'THE READER' BOX

The inne READER box includes the following components. If something is missing, please contact Feral GmbH.

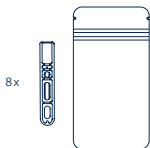
- inne READER
- USB-C Cable
- SYSTEM MANUAL
- Quick Guide



COMPONENTS OF 'THE STRIPS' POUCH

The inne Progesterone STRIP pouch includes the following components. If something is missing, please contact Feral GmbH.

- 8x inne Progesterone STRIP in a pouch



ADDITIONAL EQUIPMENT REQUIRED

In order to install the inne APP and connect to the inne READER.

- Apple iPhone (running IOS 13 or later)
- OR
- Android Devices (from version 7.0)
- 2.4 GHz Wi-Fi (in order to perform reader software updates)
- A Charging port with at least 0.5 A or 2.5W (5V)



Please download the free inne APP (latest software version) from Google Play or the Apple App Store.

When the inne MINILAB must not be used

Before using the inne MINILAB, make sure none of the following statements apply:

You are younger than 18 years of age

Your average menstrual cycles are shorter than 22 days or longer than 35 days

You are currently using or have used a hormonal treatment such as hormonal contraception (including progesterone-only, combined hormonal methods, or any other hormonal contraceptive program), fertility treatments or hormone replacement therapy. Since stopping the treatment, have not yet had 3 regular menstrual cycles.

You are currently using or have used a treatment which may affect their menstrual cycle (this would be mentioned in the patient information leaflet of the treatment). Since stopping the treatment, have not yet had 3 regular menstrual cycles.

You are pregnant or have recently been pregnant (including miscarriage or abortion), and have not yet had at least 3 regular cycles.

You are known to have polycystic ovarian syndrome or endometriosis.

Currently breastfeeding or have recently breastfed. After stopping breastfeeding, have not yet had 3 regular menstrual cycles.

Must avoid pregnancy at all costs.

Have or have had menopausal symptoms, including but not limited to hot flashes or night sweats.

Precautions

For in vitro diagnostic use

Not for internal use

For self-testing at home

Keep out of the reach of children

Read the SYSTEM MANUAL carefully before performing the test

Do not use the inne Progesterone STRIP after the expiration date printed on the pouch

Do not use the inne Progesterone STRIP if it is damaged

Use the inne Progesterone STRIP immediately after removing it from the pouch

Pay attention to collection time and the flow

indicator on the inne Progesterone STRIP

The inne Progesterone STRIP cannot be used if blood is detected on the inne Progesterone STRIP

The inne Progesterone STRIP is for single-use only and cannot be reused

The inne Progesterone STRIPs can only be read by the inne READER

The inne READER does only work with original inne Progesterone STRIPs

Test results may vary for different individuals

Use the test only for the purpose described in the SYSTEM MANUAL

Do not take any decision of medical relevance without first consulting the appropriate healthcare professional

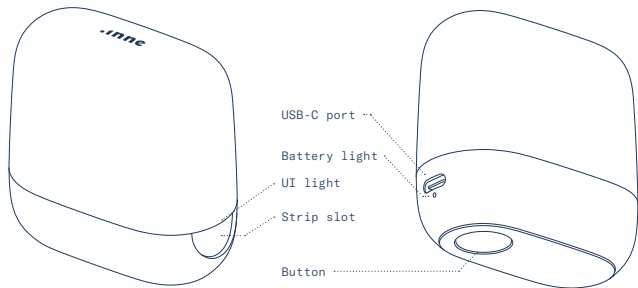
The inne MINILAB

Component names and functions











INNE READER

The inne READER is designed with Wi-Fi connectivity so it can integrate into a home environment and connect seamlessly with the inne APP. But we know that life today takes place

in more locations than at home. So we made sure the inne READER is also a perfect travel companion by giving it a compact form and the ability to connect via Bluetooth.



UI LIGHT

White breathing		Reading in progress - do not take out the inne Progesterone STRIP!
White solid		Task completed successfully: Measurement, Pairing or Data upload.
Red solid		Measurement error: the strip was taken out while analysing, the inne READER has encountered an error while analysing or the battery is too low to start a measurement. See App for details.
Red blinking		Hardware error, contact inne support
Green blinking		Sending measurement data to inne APP, please wait
Blue blinking		Setup mode, searching for available Bluetooth connection. The inne READER is not paired to an inne account
Blue solid		Setup mode, Bluetooth connected. The inne READER is not paired to an inne account. Follow the in-App instructions to pair the device.
Yellow blinking		Setup mode activated through long press: inne READER is trying to establish Bluetooth connection to inne APP.
Yellow solid		Active Setup mode : The inne READER has established a connection to the inne APP. To exit from this mode, wait until the light has turned off.
Yellow breathing		Firmware update in progress, please wait






STRIP SLOT

Slot for inne Progesterone STRIP	After collection insert the inne Progesterone STRIP by placing the rounded side inside the STRIP SLOT (see image on p.27) until you feel it is firmly in place.
----------------------------------	---

BUTTON

Short press	Wake up: inne READER attempts to send data to inne APP.
3-Second press long press	Setup mode: start the following actions from the inne APP. → Pairing or unpairing the inne READER from the inne account by following the on-screen instructions in the inne APP. → update the inne READER firmware by following the on-screen instructions in the inne APP. → setup Wi-Fi network by following the on-screen instructions in the inne APP.
10-Second press	Reset: inne READER will restart firmware.

BATTERY LIFE

Green solid		On – battery sufficiently charged.
Yellow solid		On – battery status low but sufficient for operation.
Red solid		On – battery status critically low, inne READER must be charged before an action.
Red blinking		Charging - please do not unplug. The READER can perform a measurement while charging.
Yellow blinking		Charging – battery charging in progress. Level sufficient for operation.

USB-C PORT

Battery charging port	Plug in the USB-C cable and connect to an adapter or computer.
-----------------------	--

IMPORTANT INFORMATION OF THE INNE READER

→ The inne READER is for indoor use only

→ Keep the inne READER dry

→ The equipment is supplied by protected and limited USB-C in compliance to IEC 61010-1

Limited-Energy- Circuit (LEC) or IEC 60950-1

Limited Power Supply (LPS)

Rated 3.5 V  4.4 V max.

Input 4.75 V  5.25 V max. 4w

→ inne READER dimensions:

Height: 67 mm

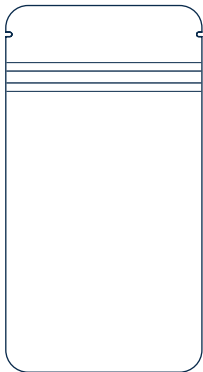
Width: 38 mm

Length: 68 mm

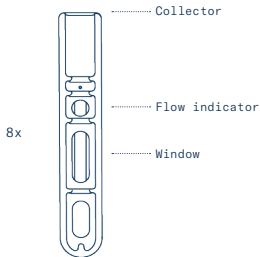
Weight: 73 g

INNE PROGESTERONE STRIP

The inne Progesterone STRIP is designed for single-use only. The inne Progesterone STRIP comes in a pouch of 8 inne Progesterone STRIPS. Make sure to close the zipper after taking a strip out in order to protect the remaining strips.



Pouch



inne Progesterone
STRIP

NAME	DESCRIPTION	INSTRUCTION
Collector	Saliva is deposited into the collection-side of the inne Progesterone STRIP.	See more details p.26 (Collect)
Flow Indicator	The flow indicator can be used to verify if saliva started moving through the inne Progesterone STRIP.	See more details p.27 (Collect)
Window	The window is used by the inne READER to analyse the progesterone level in your saliva and verify the quality control inherent of the inne Progesterone STRIP.	Make sure the inne Progesterone STRIP window is clean and is never covered by anything

STORAGE AND STABILITY OF THE INNE PROGESTERONE STRIP

- Store at 15°-30°C
- Stable in the sealed pouch up to the expiration date printed on the pouch
- Keep away from direct sunlight, moisture and heat
- CAUTION: DO NOT FREEZE

The inne MINILAB

General principles of the test

The inne MINILAB is based on measuring progesterone in saliva samples with a competitive lateral flow assay (the inne Progesterone STRIP) which is further analysed by the inne READER. By monitoring changes in the salivary levels of progesterone, the inne MINILAB identifies the days with a higher risk of pregnancy and the days with lower risk of pregnancy. The days with higher risk of pregnancy are around ovulation and take into account the lifespan of the egg and sperm. The rise of progesterone always occurs after ovulation has happened and characterizes the beginning of the luteal phase of the menstrual cycle. When a sustained elevation in the salivary progesterone is measurable between the follicular and luteal phases for at least 3 measurements, ovulation is confirmed, indicating the end of the fertile window and thus, the beginning of the non-fertile phase.

TEST PROCEDURE

For the saliva sample collection, please refer to p.26. Upon sample collection, the saliva fluid migrates through the capillary bed and initiates the reaction. The test result is displayed by a Test Line and a Control Line. For a competitive assay, the Test Line (TL) will show as a full colored line when the progesterone in the saliva sample is below the limit of detection. A colored line for the Control Line (CL) will demonstrate the test's validity.

CONTROL PROCEDURE

The inne MINILAB does not require the user to do any additional controls or use calibrators to assure the accuracy of the test. Therefore no controls and calibrators are provided.

BIOLOGICAL REFERENCE RANGE

Not applicable as no quantitative results are provided to the users.

BIBLIOGRAPHICAL REFERENCE

Regulation of the human menstrual cycle. Chabbert Buffet N, Djakoure C, Maitre SC, Bouchard P.,*Front Neuroendocrinol.* 1998 Jul;19(3):151-86. Review.

The Effect of Steroid Hormones on Ovarian Follicle Development. Chou CH, Chen MJ.,*Vitam Horm.* 2018;107:155-175. doi:10.1016/bs.vh.2018.01.013. Epub 2018 Feb 9. Review.

Saliva as a medium for investigating intra- and interindividual differences in sex hormone levels in premenopausal women. Gann PH, Giovanazzi S, Van Horn L, Branning A, Chatterton RT Jr.,*Cancer Epidemiol Biomarkers Prev.* 2001 Jan;10(1):59-64.

Salivary measurement of episodic progesterone release. O'Rourke MT, Ellison PT.,*Am J Phys Anthropol.* 1990 Mar;81(3):423-8.

Salivary steroids and natural variation in human ovarian function. Ellison PT.,*Ann N Y Acad Sci.* 1994 Feb 18;709:287-98. Review. No abstract available.

Characteristics of salivary profiles of oestradiol and progesterone in premenopausal women. Chatterton RT Jr, Mateo ET, Hou N, Rademaker AW, Acharya S, Jordan VC, Morrow M.,*J Endocrinol.* 2005 Jul;186(1):77-84 .

The inne MINILAB

Performance characteristics

LIMIT OF DETECTION

The Limit of Detection (LoD) is the lowest amount of analyte that can be detected in a saliva sample. The estimated LoD is 100.5 pg/mL.

DYNAMIC RANGE

The range of the assay is 100.5 – 1450 pg/mL.

ANALYTICAL SPECIFICITY

From the different substances evaluated for crossreactivity and interference, Caffeine and Ethanol have been identified as possible interferents. Respecting the saliva collection guidelines as explained in the section Daily Progesterone Test in the SYSTEM MANUAL on p. 24, mitigates the possible interference of caffeine and ethanol.

REPRODUCIBILITY

The variability between production lots is estimated above 20%, so it is important to use inne Progesterone STRIPS from the same lot throughout a menstrual cycle.

REPEATABILITY

Four levels of progesterone saliva samples were analyzed in duplicate determinations twice a day. A total of 160 assays, 40 per sample concentration, over a period of 10 non-consecutive days were run. Statistical analyses were performed to analyze repeatability, between-run, between-day components of variation as well as total variation to estimate within laboratory precision.

Repeatability is estimated to be below 6% CV, while total variation within laboratory precision is estimated to be below 7% CV.

CLINICAL SENSITIVITY & SPECIFICITY

An at-home real-life context clinical evaluation was conducted comparing the ovulation confirmed by the inne MINILAB to the ovulation determination via commercial LH urinary tests.

Sixteen voluntary testers used the inne MINILAB and the LH test according to the respective instructions for use and recorded the results of the positive LH test via the inne APP. Thus, the data collected corresponds to a total of 68 menstrual cycles.

Each menstrual cycle was evaluated to determine the ability of the inne MINILAB to correctly identify the presence of the marker progesterone within the different phases of the menstrual cycle. The results were compared against the menstrual cycle phases classification according to the positive LH test results logged by the users in the inne APP. Clinical sensitivity and specificity have been calculated accordingly.

This study has found a that the inne MINILAB detected a progesterone rise compatible with the ovulation in 94.3% of the cycles, with a Clinical Sensitivity of 91.5%, meaning that the inne MINILAB correctly identifies the luteal phase in 91.5% of the analyzed menstrual cycles, and a clinical specificity of 88.7%, meaning that the inne MINILAB correctly identifies the follicular phase

in 88.7% of the analyzed menstrual cycles.

Both clinical sensitivity and specificity are aligned with what previous studies have found for other fertility monitor systems based on a progesterone metabolite, pregnanediol 3-glycuronide (PDG).

BIBLIOGRAPHICAL REFERENCE

Use of Urinary Pregnanediol 3-Glucuronide to Confirm Ovulation. Ecochard, R., R. Leiva, T. Bouchard, H. Boehringer, A. Direito, A. Mariani, and R. Fehring. *Steroids* 78, no. 10 (2013): 1035–40. <https://doi.org/10.1016/j.steroids.2013.06.006>.

Setup

DOWNLOAD THE INNE APP AND CREATE AN INNE ACCOUNT

Prior to the first use, download and install the free inne APP from the Apple App Store or Google Play Store on your mobile device. Follow the on-screen instructions to sign in with your existing inne account or create a new inne account.

PAIR AND LINK YOUR INNE READER

In order to use the inne APP, the inne READER must be paired with a smartphone and linked with



TIP Open the Camera app on your smartphone and hold your device so that the QR code appears in the viewfinder in the Camera app. Tap the pop-up notification to download the inne APP.

an inne account. The inne READER is designed for use by a single user and therefore can only be linked to one account at a time. After setting up an account, the inne APP will automatically lead through the pairing process.

SETUP WI-FI

The inne READER can function with just a Bluetooth connection, but we highly recommend to set it up with your home Wi-Fi for more seamless and convenient use. The Wi-Fi communication will allow the inne READER to send readings to your inne APP even when you are not in proximity to the device. The inne READER also needs to be connected to a Wi-Fi to update its firmware.

We recommend to set up the Wi-Fi during the set up process of your inne READER. But you can set up and manage different Wi-Fis from the inne APP Settings at any time.

Daily Test

Daily progesterone test

The inne MINILAB requires a daily saliva test to understand the progesterone level in the body. In order to guarantee accurate results, the inne MINILAB only takes readings into account which are taken within your 4-hour testing window.

RULES

In order to record accurate progesterone levels, it is important to ensure two key things:

→ Take the test inside your set daily 4-hour testing window.

→ No foreign substances have been in your mouth since 30 minutes prior to testing.

OR

→ Rinse your mouth thoroughly with water and wait 10 minutes before taking the test.

NOTE If you taste blood in your mouth, you can rinse your mouth with clean water and wait for another 10 minutes before doing the test.

SET UP YOUR DAILY ALARM WITHIN THE TESTING WINDOW

To ensure accurate test results, the inne Progesterone STRIP should be used every day within the same 4-hour testing window which can be set between 5:00 am - 2:00 pm. The inne MINILAB will only take into account the first successful reading which is made within the testing window.

→ For ease of use, we recommend using the daily alarm as a reminder.

→ The daily alarm and the testing window are set up during the sign-up process. Both can be modified in the 'settings' tab.

→ Warning: measurements taken outside the 4-hour window are not recorded by the inne APP.

NOTE It is especially important to always measure on days that are marked as 'important measurements' in the APP for the algorithm to detect your ovulation.

STEPS OF THE DAILY PROGESTERONE TEST

In order to make it easy to remember the process of daily testing, we have divided it into three consecutive steps. Each step will be explained in detail in the next pages.

1

Collect

2

Measure

3

Review

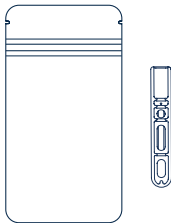
1

Collect

In order to collect a saliva sample accurately with an inne Progesterone STRIP, please follow these steps

TAKE A NEW INNE PROGESTERONE STRIP

The inne Progesterone STRIPS come in a pouch with 8 single strips. Make sure to close the pouch after taking one out to protect the remaining ones.

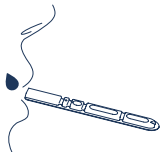


1

COLLECT SALIVA

Collect a pea-sized amount of saliva in your mouth and deposit it gently into the collector.

CAUTION If the inne Progesterone STRIP is damaged it cannot be used. Please take another one.

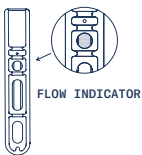


2

OBSERVE THE FLOW INDICATOR

The flow indicator temporarily turns light red when saliva starts flowing through the strip.

CAUTION If saliva is not starting to flow through the inne Progesterone STRIP within 20 seconds please refer to the help section in the inne APP.



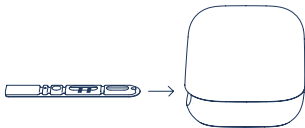
3

PLACE THE STRIP IN THE READER

Make sure to insert the rounded side into the reader.

CAUTION Make sure there is no blood in the collector.

CAUTION The inne Progesterone STRIP needs to be inserted into the inne READER right after the sample collection to ensure accurate results.



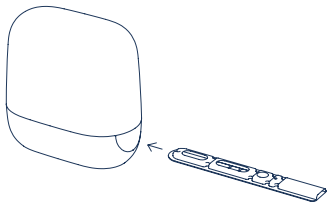
4

Insert the inne Progesterone STRIP into the inne Reader to start the measurement

START READING

Reading automatically starts when an inne Progesterone STRIP is inserted into the inne READER as shown below.

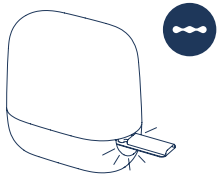
TIP Make sure to insert the rounded side of the inne Progesterone STRIP first as shown and check that nothing is covering the strip window.



READING IN PROGRESS

The white pulsating UI light indicates the reading is in progress.

CAUTION Do not take the inne Progesterone STRIP out of the inne READER while the measurement is in progress.



READING SUCCESSFUL

When the measurement is done, the UI light will turn solid white. The result is automatically sent to the inne APP. The inne READER will go to deep sleep, which is indicated by the UI light turning off.

TIP If you are connected via Bluetooth, make sure your phone is in the same room (10-meter reach) and has the inne APP running.

RECEIVE RESULTS

You can review the results in the inne APP. See next page.

CAUTION - DISCARD USED INNE PROGESTERONE STRIP

The inne Progesterone STRIPS are made for single-use only. After the measurement has been done, the inne Progesterone STRIP can be removed from the inne READER and discarded in the residual waste.



Review your progesterone results in the inne App.

THE SCIENCE BEHIND THE INNE MINILAB

The inne MINILAB enables women to understand their hormones, specifically progesterone. These hormones are secreted by the pituitary gland in the brain and ovaries. Progesterone influences many aspects of the body in a cyclic pattern. Along with informing the body about when to ovulate and when to menstruate these hormones also influence the cervical fluid pattern.

REVIEW PROGESTERONE RESULTS

The measurement results are charted in the graph in the inne APP showing the daily changes in progesterone levels throughout the cycle. The progesterone interpretation provides information about the progesterone trend and the occurrence of ovulation. It is updated every time a new measurement comes in.

THE FERTILITY STATUS

Based on the progesterone measurements, the inne APP identifies the fertile window and displays it as different fertility statuses such as:

You have a **high chance** of pregnancy today

You have a **low chance** of pregnancy today

In order for the algorithm to more precisely predict ovulation, it is important to be consistent with the progesterone measurements. The longer the inne MINILAB is used regularly, the shorter the fertile window can become.

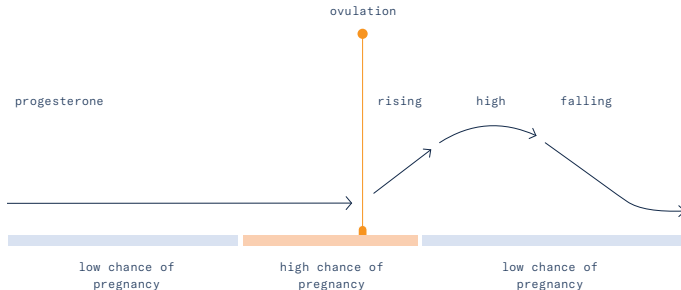
THE BEHAVIOR OF PROGESTERONE

→ Low: Progesterone level is low in the follicular phase and stays low until ovulation occurs

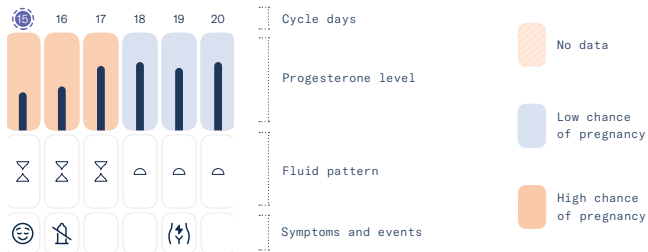
→ Rising: Progesterone rise can be seen right after ovulation and when entering the luteal phase

→ High: Progesterone level is high during the luteal phase. Ovulation has taken place

→ Falling: Progesterone level decreases as the cycle ends



The graph in detail



Cycle days

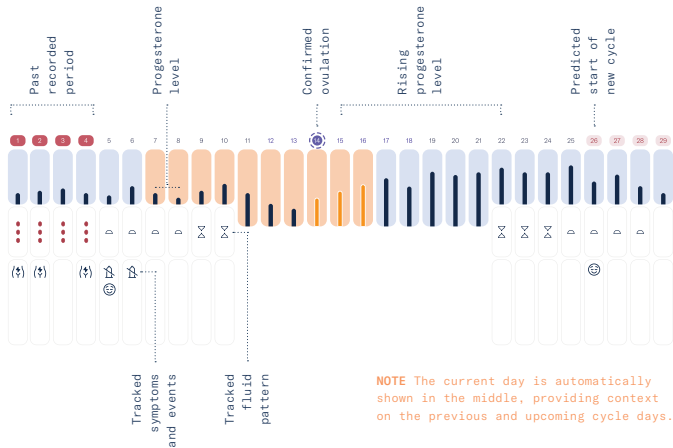
The timeline of the graph is structured in cycle days.
20 the current day 19 past days 21 future days
1 predicted start of a new cycle

Ovulation

■ Predicted ovulation is displayed based on data from previous cycles.
⦿ Ovulation is displayed once it has been confirmed based on the progesterone trend.

Progesterone level

■ Displays the levels throughout the cycle.
■ Rising progesterone is highlighted in orange color.



Fluid pattern

You can track stages of cervical fluids and period in the inne APP.



Symptoms and events

You can track multiple symptoms and events in the inne APP.

Your cycles

START A NEW CYCLE

Set the start of each menstrual cycle in your inne APP. Do this on cycle day 1, which is the first day of your period. The first day of your period is the first day of blood flow – spotting should not be logged as period.

You can start a new cycle by logging the fluid 'period' on the day the cycle begins. To do so, tap the fluid button on the APP's home screen, select 'period' and save the change.

IF YOU FORGET TO START A NEW CYCLE

A new cycle can be started anytime by logging 'period' as your current fluid. Select the day your period started by scrolling through your cycle graph. Then tap the fluid button, select 'period' and save the change.

CAUTION It is important to remember the day your period started and track it in the inne APP. The inne MINILAB takes the first day of your cycle into account for your fertility prediction. Not tracking a new cycle will result in inaccurate fertility information.

VIEW, EDIT AND DELETE PAST CYCLES

The section 'Past Cycles' in the inne APP gives an overview of previous cycles, their start date, duration, progesterone levels and detected ovulations. You can open 'Past Cycles' by tapping the calendar symbol in the top right corner of the inne APP.

The inne APP differentiates between cycles which have been added manually and those which were recorded while using the inne MINILAB.

→ Change the start date of a past cycle:

Tap 'edit period dates', set the correct start date of your period within the calendar view and save the changes.

→ Delete a cycle:

In the 'Past Cycles' overview, swipe the cycle to the left to see the option 'delete'. When pressing 'delete' the cycle will be removed and the days will be added to the previous cycle. Your measurements will not be lost.

TIP You can view and edit all cycles in the 'Past Cycles' section in the inne APP.

Maintenance

Troubleshooting

The troubleshooting guide in this chapter is applicable to both the inne READER and the inne APP.

The described troubleshooting is only for problems which can be solved by you, the user. If any other problems or defects occur with the inne READER, you should immediately contact customer care (see p.38) and ship the inne READER to the manufacturer for servicing.

There is no maintenance or service procedure to be performed by you, the user.

Cleaning of the inne READER is not recommended – if you want to clean the outer shell, you must use a dry cloth and no chemical detergents.

You can find the most up to date information in the inne Help Center.

I HAVE MISSED MY 4-HOUR TESTING WINDOW

If you have missed taking your reading within the 4-hour testing window, you cannot take a measurement for that day.

MY INNE READER IS SHOWING A RED UI LIGHT

→ If the inne READER shows a **solid red UI light**, it means the device has encountered an error. The error could either be a too low battery level or an error when analysing your saliva sample. In order to identify the error type please check the inne READER's battery level. Press the button on the inne READER briefly and check the battery LED below the USB-C charging port. A red light indicates that the READER needs to be charged before performing the next measurement.

→ If the inne READER shows you a **blinking red light** and goes off afterwards, it means that it has encountered a system error. Please contact customer service by sending an email to support@inne.io

MY READINGS HAVE NOT SYNCHRONISED WITH MY INNE APP

If you have done your daily saliva test and the inne APP does not display your readings, short-press the inne READER button. If the inne READER shows a green UI light, it means that it has stored unsynchronised measurements due to a lack of connection to your inne APP.

DATA SYNCHRONISATION

To transfer unsynchronised results make sure that the READER is within reach, that Bluetooth is enabled on your smartphone and that the inne APP is launched. Then, press the button on the inne READER briefly.

The inne READER sends the results automatically via Bluetooth to the inne APP. If results cannot be sent, the inne READER has the capacity to store the 10 most recent measurements.

When the inne READER has over 10 unsynchronised measurements in memory, it will overwrite the oldest with the latest one.

WARNING Not synchronising the test results daily will prevent you from using the inne MINILAB for its intended use of fertility monitoring.

SOFTWARE UPDATES – INNE APP

Once a new update is available, it will be shown automatically upon launch of the inne APP. All updates are made available on the Apple App Store & Google Play.

FIRMWARE UPDATES – INNE READER

If a firmware update for the inne READER is available, it will be shown through a notification in the inne APP. You can also go to the 'settings' tab → about the reader.

WHAT IS NEEDED TO UPDATE THE INNE READER FIRMWARE?

→ The inne APP on your smartphone with connection to the internet

→ The inne READER with connection to an active Wi-Fi and sufficiently charged or connected to a charging point.

TIP With an established internet connection and a sufficient battery level the inne READER will automatically receive and update the firmware overnight.

Maintenance

General Information

READER REPAIR

Your inne READER contains no user-serviceable parts. Don't attempt to open or disassemble your inne READER or remove, crush, or puncture the battery in your inne READER, expose it to high temperatures or liquids. Disassembling your inne READER may damage it or cause injury to you.

WARRANTY INFORMATION

Feral GmbH warrants the inne READER, and only the inne READER, against defects in materials and workmanship under normal use for a period of three years from the date of purchase by the original purchaser. Defects discovered within the warranty period should be reported to Feral GmbH. Feral GmbH reserves the right to a period of investigation to establish the cause of the defect and may exercise its discretion in determining whether or not to replace free of charge. This warranty does not cover cosmetic deterioration or damage caused by general wear and tear, physical or natural destruction, accident, misuse, neglect or other external

causes. Any attempt to take the READER apart will invalidate this warranty. Any warranty claims must be supported with reasonable evidence, including proof of date of purchase, alongside these warranty conditions. In the event that Feral decides to provide a replacement, any replacement will not extend the life of this warranty.

CUSTOMER CARE

If you have any questions or require assistance with your inne READER, inne Progesterone STRIP, inne APP, inne account, if you need support with your inne order, or if you want to share some feedback or complaints with us, please contact:

- Via email: support@inne.io
- Via WhatsApp: +49 170 28 84 276
- Via post: Feral GmbH, Skalitzer Straße 85-86, TR B, 10997 Berlin, Germany

RETURN AUTHORISATION

All returns must be preapproved by Feral GmbH before sending the device.

REGIONAL DISPOSAL AND RECYCLING INFORMATION



The symbol above indicates that the inne READER and/or its battery should not be disposed of with household waste. When you decide to dispose of the inne READER and/ or its battery, do so in accordance with local environmental laws and guidelines.

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MANUFACTURER DETAILS



FERAL GmbH
Skalitzer Straße 85-86, TR B
10997 Berlin
GERMANY

WEEE-REG.-NR. DE40321321

REGULATORY COMPLIANCE INFORMATION

This system was developed in compliance with the following standards:

ISO 13485:2016
IVD Directive 98/79/EC (IVDD)
ISO 14971:2007
IEC 62366-1:2015
IEC 62304:2006+A1:2015
IEC 61010-1:2010
IEC 61010-1-2010/AMD1:2016
IEC 61010-2-101:2018
ISO 18113-1:2016
ISO 18113-4:2016
ISO 18113-5:2016

REPORTING

Any serious incident occurring in relation to this device should be reported to Feral GmbH and to the competent authority of the EU Member State in which the user is established.



Legend



Consult the SYSTEM MANUAL for important information such as warnings and precautions



Keep dry



Do not use if package is damaged



Serial Number



Batch code



Date of Manufacture



Do not reuse



Manufacturer



Temperature limit to which the inner Progesterone STRIP can be safely exposed



In vitro diagnostic Medical device