

SYSTEM MANUAL 4.1

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1. 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: 4.1

Date: November 14th 2022

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

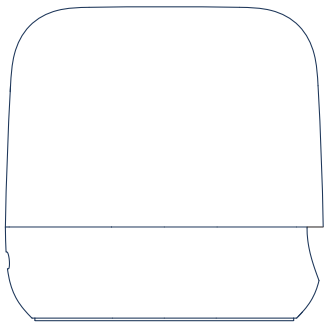
When we see the female reproductive system we see beauty and we see logic.

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.

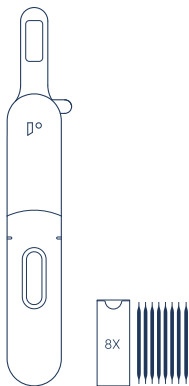
The rhythms of a woman's body are controlled by hormones. These hormones, oestrogen and progesterone in particular, regulate the menstrual cycle and trigger ovulation. By measuring progesterone levels at different times in the cycle, the inne MINILAB is able to identify the days in which a woman has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

ABOUT THE INNE MINILAB

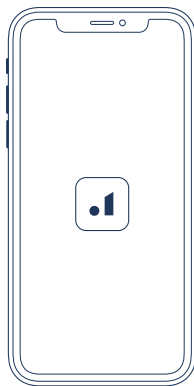
In order to use the inne MINILAB, you need to carry out a daily saliva collection using an inne STRIP, perform a measurement using the inne READER, and finally review the results and view your fertility status on your inne APP. Our system's algorithm calculates your fertility status by taking into account 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 every day in order to accurately predict and monitor your fertility.



inne READER to measure the
progesterone level in your saliva by
reading the inne STRIPS



inne STRIPS (Pack of 8) for collecting and analysing your saliva sample (one inne STRIP per day)



inne APP for viewing your data measured by the inne READER and your fertility status

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.

Additionally, we recommend observing cervical fluid as a secondary sign of fertility. The primary function of the cervical fluid is to support and transport sperm as you approach ovulation. Around ovulation, the cervix will release large amounts of runny and stretchy fluid that assists sperm to fertilize the egg. Once ovulation has taken place your fluids will reduce in quantity until the next cycle begins. (More information about cervical fluids and how to identify them can be found in the 'resources' tab of the inne APP).

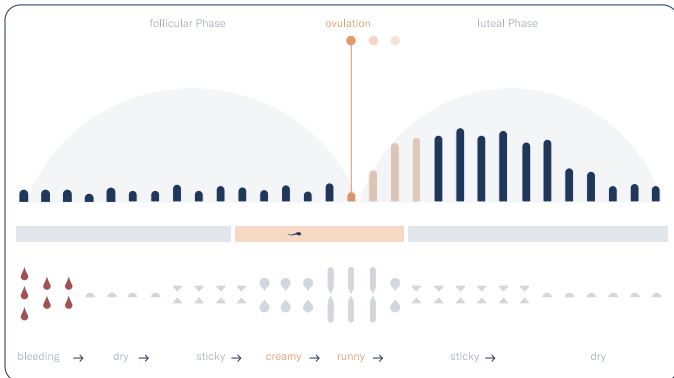
Understanding these signs – i.e. the progesterone hormone and the cervical fluid - provides valuable insight into the female body.

MENSTRUAL PHASES

PROGESTERONE
LEVEL

CHANCE OF
PREGNANCY

CERVICAL
FLUIDS



WHEN THE INNE MINILAB MUST NOT BE USED

Before using the inne MINILAB for fertility monitoring, make sure none of the following statements applies:

You are younger than 18 years of age

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

You are undergoing hormone treatment such as hormonal contraception, fertility treatments or hormone replacement therapy

You are in or have recently undergone a treatment which may affect your menstrual cycle (this would be mentioned in the patient information leaflet of the treatment)

You suffer from polycystic ovarian syndrome or endometriosis

You must avoid pregnancy at all costs

You are currently or have recently been pregnant (until after the third consecutive period, even if the pregnancy was not carried to term)

You are breastfeeding or have recently breastfed

You have had or have menopausal symptoms such as 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 STRIP after the expiration date printed on the pouch

Do not use the inne STRIP if the pouch is punctured or damaged

Use the inne STRIP immediately after removing it from the pouch

Pay attention to collection time and procedure of activation of the inne STRIP

The inne STRIP cannot be used if blood is detected on the inne STRIP as it interferes with the result

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

The inne STRIPs can only be read by the inne READER

The inne reader does only work with original inne STRIPs

Test results may vary for different individuals

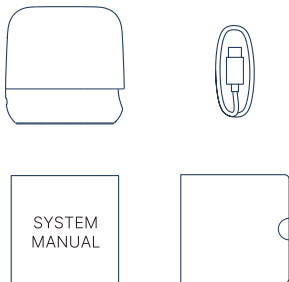
Use the test only for the purpose described in the SYSTEM MANUAL

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

2. The inne MINILAB – Overview

COMPONENTS OF 'THE READER' BOX

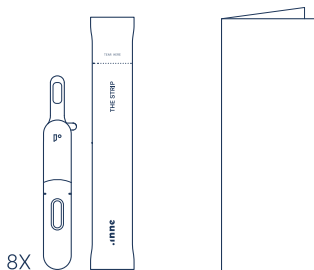
The inne READER box includes the following components. If something is missing, please contact Feral GmbH .



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

COMPONENTS OF 'THE STRIPS' BOX

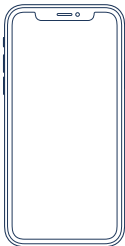
The inne STRIP box includes the following components. If something is missing, please contact Feral GmbH.



- 8x inne STRIP in single pouches
- 'How to use' instructions

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 6.0)
- 2.4 GHz Wi-Fi (in order to perform reader software updates)

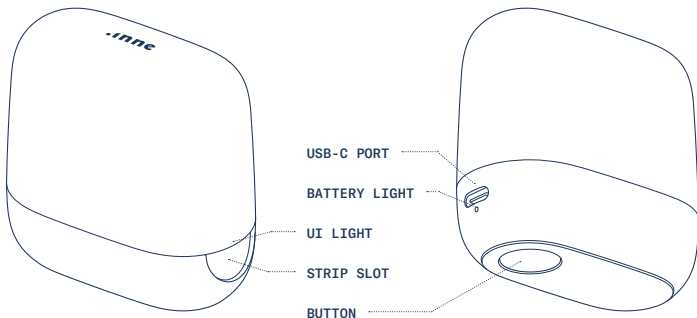
Please download the free inne APP (latest software version) from Google Play or the Apple App Store.

2. 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 STRIP!
White solid		Reading successfully done
Red solid		Measurement error: the inne READER battery is too low or has encountered an error while analysing your daily reading. For more information see p.73
Green blinking		Unable to send the reading to the inne APP - caused by a connection error. Make sure to have an established connection via Bluetooth and open the APP to retrieve data. See how to retrieve data from the inne READER on p.74
Blue blinking		Searching for Bluetooth connection The inne READER is searching for an available Bluetooth connection.
Blue solid		Bluetooth connected The inne READER has established a Bluetooth connection to the inne APP.
Yellow blinking		Setup mode: searching for connection The inne READER is trying to establish a connection to the inne APP.
Yellow solid		Setup mode: connected 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		Setup mode: inne READER software update in progress. Do not press the inne READER button or insert an inne STRIP during this process.
STRIP SLOT		
Slot for inne STRIP		Insert the activated inne STRIP by placing the window side inside the STRIP SLOT (see image on p.54) until you feel it is firmly in place.

BUTTON

Short Press	Wake up: inne READER attempts to send data
3-Second press long press	Setup mode: start the following actions from the inne APP → unlink the inne READER from the inne account by following the on-screen instructions in the inne APP → update the inne READER software by following the on-screen instructions in the inne APP
10-Second press	Reset: inne READER will revert to factory default settings

BATTERY LIFE

Green Solid		On - battery sufficiently charged
Yellow Solid		On - battery status low (below 20%)
Red Solid		On - battery status critically low (below 10%) inne READER cannot measure an inne STRIP due to insufficient battery level
Red blinking		Charging - battery level critically low (below 10%) wait until battery light turns yellow (above 10%) to measure an inne STRIP
Yellow blinking		Charging - battery level above 10%

USB-C PORT

Battery charging port	Connect a USB-C cable to this USB-C-port, and connect the other end of the cable to the Adaptor or Computer.
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IMPORTANT INFORMATION OF THE INNE READER

→ The inne READER is for indoor use only

→ 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.

Inout 4.75 V  5.25 V max.

4w

→ inne READER dimensions:

Height: 67mm

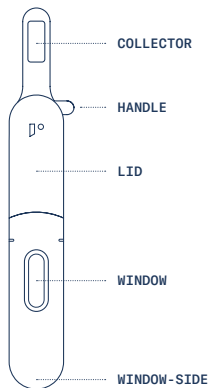
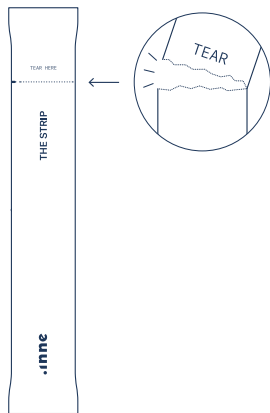
Width: 38mm

Length: 68mm

Weight: 86g

INNE STRIP

The inne STRIP is designed for single-use only. Each inne STRIP is packaged in a pouch. To take out the inne STRIP, tear open the pouch by pinching and pulling firmly where indicated.



NAME	DESCRIPTION	INSTRUCTION
Collector	The collector holds a collector pad to retrieve a saliva sample.	Use the collector to collect a saliva sample by holding it in your mouth for 30 seconds. See more details p.50 (Collect).
Handle	The handle is used to fold the collector before activating the inne STRIP.	Use the handle to fold in the collector after you have collected a sample. See more details p.53 (Activate).
Lid	The lid starts the development of the inne STRIP by releasing the saliva.	Open the lid before folding in the collector and close it back afterwards to activate the inne STRIP. See more details in p.53 (Activate).
Window	The window is used by the inne READER to analyse the progesterone concentration in your saliva and verify the quality control inherent of the inne STRIP.	Make sure the inne STRIP window is clean and is never covered by anything.
Window side	This side of the inne STRIP marks the side which goes into the inne READER.	Only insert activated inne STRIP inside the inne READER. See more details on p.54 (Measure).

STORAGE AND STABILITY OF THE INNE STRIP

Store at 15°-30°C

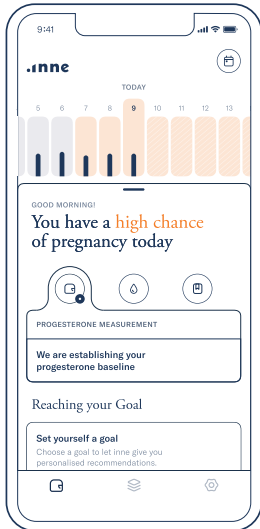
Stable in the sealed pouch up to the expiration date printed on the pouch

Keep away from direct sunlight, moisture and heat.

CAUTION: DO NOT FREEZE

INNE APP

The inne APP is structured in three main tabs:
'lab', 'resources' and 'settings'.



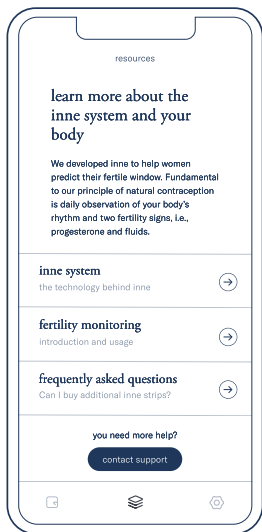
LAB → Follow the daily testing process

→ View progesterone reading and fertility status

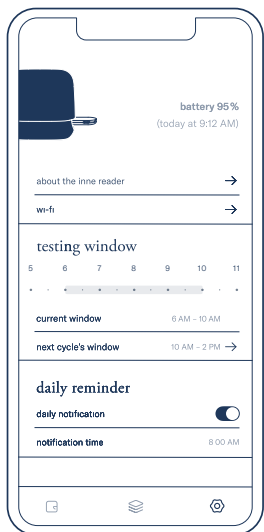
→ Track cervical fluids

→ View the current cycle

→ Access past menstrual cycles

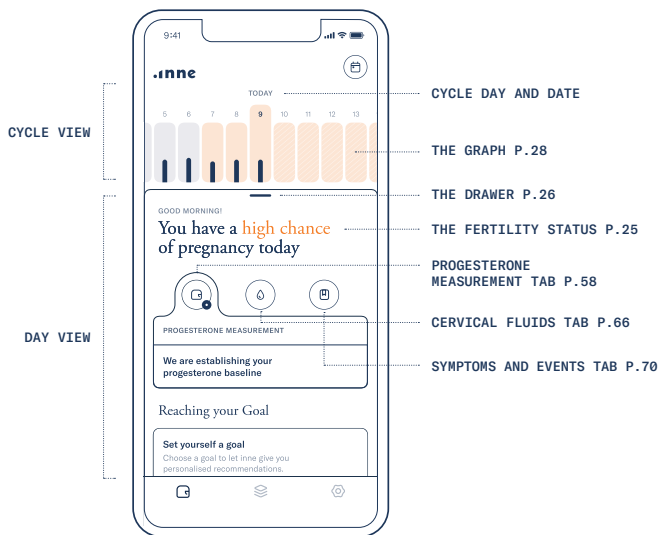


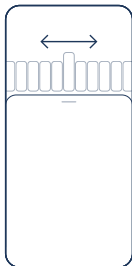
RESOURCES → Access educational content about fertility monitoring
 → Access information on how to use the inne MINILAB and FAQs
 → Contact the inne support team



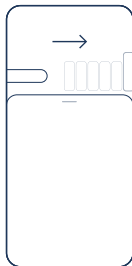
SETTINGS → Information and maintenance of your inne READER
 → Set alarm and testing window
 → Access account details and legal information

THE 'LAB' TAB IN DETAIL





Access past and future days of the cycle by swiping on the 'cycle view'.



Access 'past cycles' by swiping all the way to the left on the 'cycle view'.

THE FERTILITY STATUS

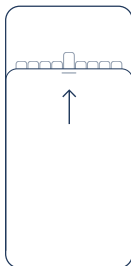
Based on the progesterone measurements, the inne APP identifies the fertility window and displays it as different fertility statuses such as:

you have a high
chance of pregnancy for today

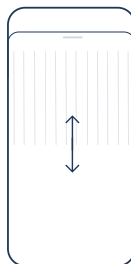
you have a low
chance of pregnancy for today

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.

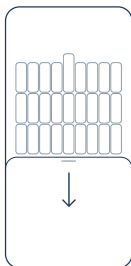
THE DRAWER



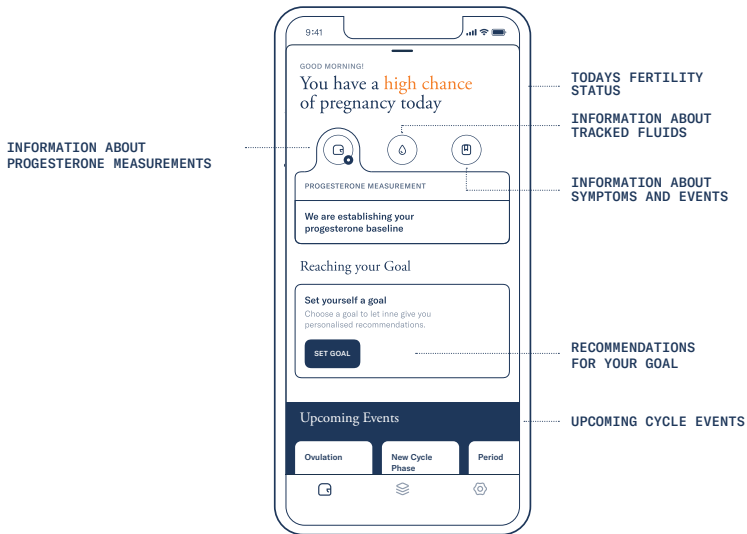
Access more information about the current cycle by dragging the 'drawer' up.



Swipe up or down to see all information available in the 'drawer'.

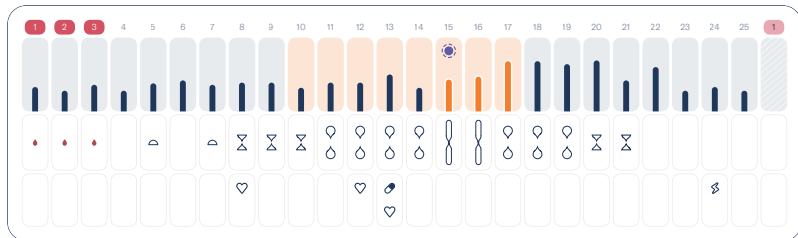
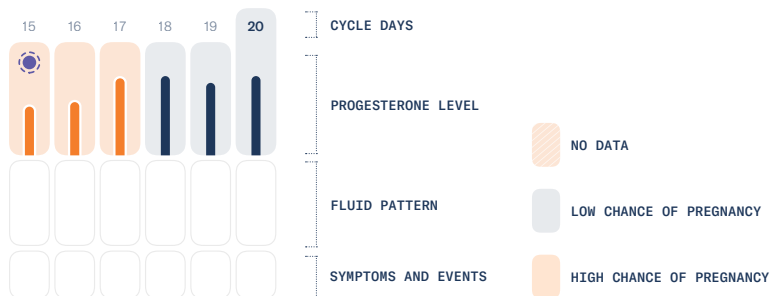


Drag the 'drawer' down to minimise it and see the extended 'graph' in the 'cycle view'.



THE GRAPH

The current day is automatically shown in the middle, providing context on the previous and upcoming cycle days.



CYCLE DAYS	<p>The timeline of the graph is structured in cycle days.</p> <p>20 the current day 19 past days</p> <p>21 future days 1 predicted start of a new cycle</p>
PREDICTED OVULATION	<p>🕒 Predicted ovulation is displayed based on data from your previous cycles.</p>
CONFIRMED OVULATION	<p>🌙 Ovulation is displayed once it has been confirmed based on the progesterone trend.</p>
PROGESTERONE LEVEL	<p>📊 Displays the levels throughout the cycle.</p> <p>🟠 Rising progesterone is highlighted in orange color.</p>
FLUID PATTERN	<p>Tracked stages of cervical fluids. See more on how to track cervical fluids on p.66</p> <div> </div> <p>period dry sticky creamy runny</p>
SYMPTOMS AND EVENTS	<p>Summary of tracked symptoms and events. See more on how to log symptoms and events on p.70.</p>

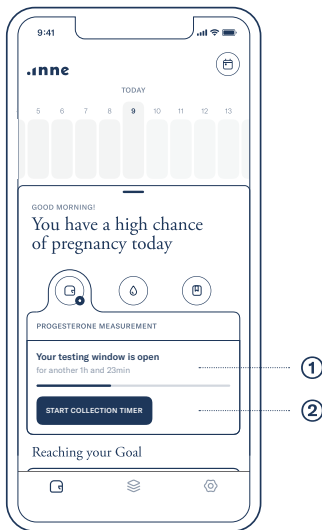
TESTING WINDOW AND TIMER

To ensure accurate results, the daily progesterone test should be done during the same 4-hour testing window which can be set between 5:00 am - 2:00 pm (see more information on page 46).

The window will be displayed while open and until a successful reading has been done.

The timer can be used to ensure that the saliva sample is collected for 30 seconds (see page 50).

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

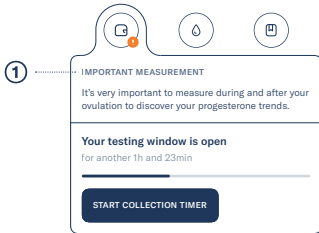


NOTE It is especially important to always measure on days that are marked as 'important measurements' in the APP for the algorithm to be able to detect your ovulation.

Once the testing window is open, it is displayed in the 'progesterone measurements tab' ① in the inne APP showing how much time is left to perform the test. The timer ② can be started while the testing window is open.

IMPORTANT MEASUREMENTS

The inne app displays 'important measurements' as an orange symbol on the 'progesterone measurement tab' on days where they are essential to help pinpoint your progesterone trend and day of ovulation.



-
- ① On Important Days we will show you why we need a measurement on that day.
-



-
- ② On days that are not important we show you when the next important measurement is.
-

2. 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 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.46. Upon sample collection and strip activation, 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.

2. 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 cross-reactivity 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. 48, 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 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 or the absence 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 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 the 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-glucuronide (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>.

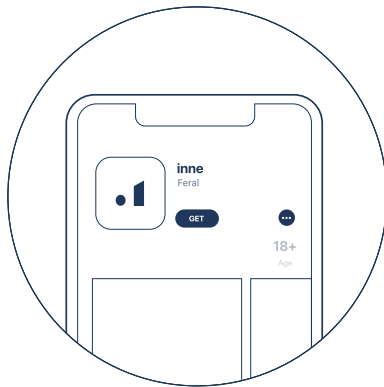
3. Setup

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 on your mobile device. Follow the on-screen instructions to sign in with your existing inne account or create a new inne account.

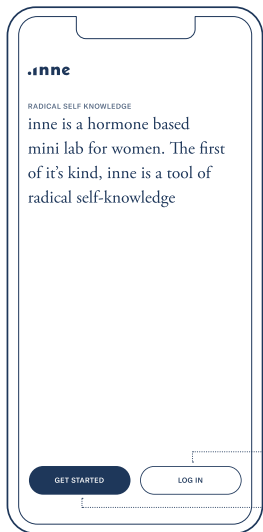


TIP Open the Camera app on your smartphone and hold your device so that the QR code appears in the viewfinder in the Camera app. Tap the pop-up notification to download the inne APP.



The inne APP on the Apple App Store & Google Play

When launching the inne APP for the first time, it is possible to:



1 Log in

Click 'log in' to log in with your existing inne account

2 Get started

Click 'get started' and follow the on-screen instructions to create a new inne account. For the account creation you need to enter the following information and set a password.

→ First and last name

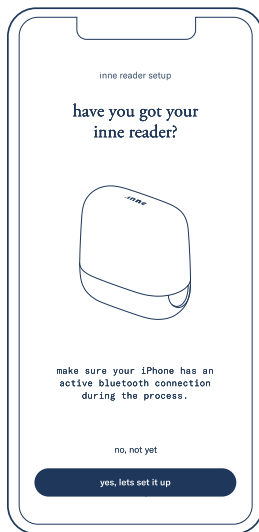
→ E-mail

→ Date of birth

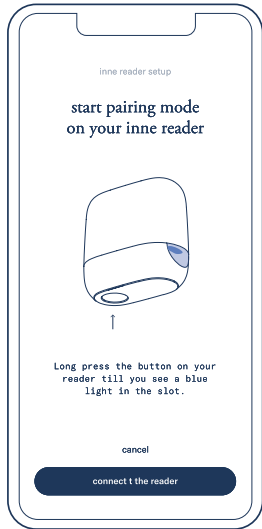
Sign in / Sign up screen

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 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 to the following steps:



Click 'yes, let's set it up' to start the 'inne reader setup'. Make sure the smartphone has Bluetooth connectivity turned on.



Long press (3 seconds) the button on the inne READER until the UI light starts blinking blue. Tap 'connect reader' to establish a connection between the smartphone and the inne READER.

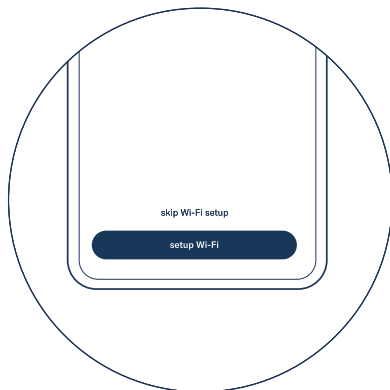


Once pairing is complete the inne READER will automatically be linked to the inne account.

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 and notifications 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:

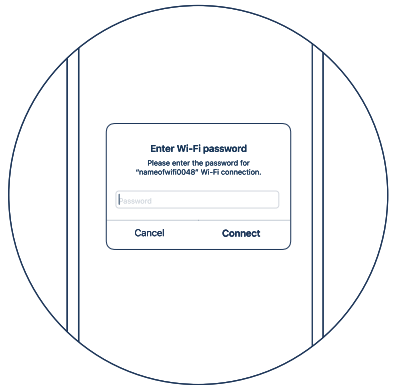


Setup a Wi-Fi connection for the inne READER after successfully pairing it with the inne account. Tap 'set up Wi-Fi' to start the process.



The inne READER is searching for a compatible Wi-Fi.

IMPORTANT: The inne READER can only connect to secure Wi-Fi networks which work on 2.4 GHz (not to open hotspots)



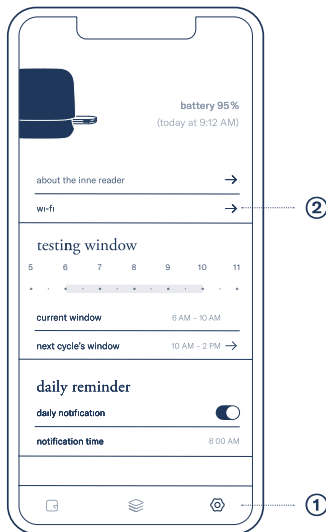
Select the Wi-Fi you want the inne READER to pair with and fill in the Wi-Fi password.



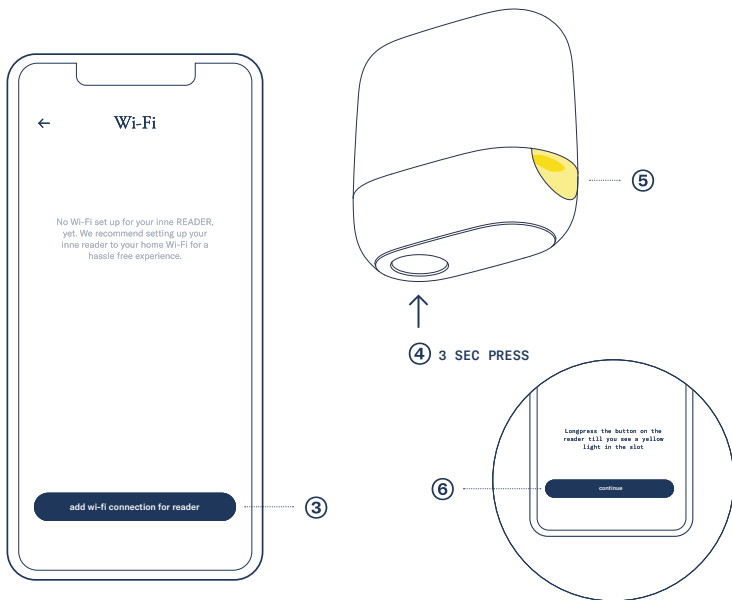
A Wi-Fi has been successfully set up for the inne READER.

ADD WI-FI

The inne READER can be setup with several Wi-Fi networks. To add an additional Wi-Fi, go to the 'settings' -> 'wi-fi' -> 'add wi-fi connection for reader'.



Go to the 'settings' ① tab of the inne APP
and click on 'wi-fi' ②



Tap 'add wi-fi connection for reader' ③

Long press the button ④ on your Inne READER until the UI light is blinking yellow ⑤. Tap 'continue' ⑥ and follow the on-screen instructions.

SET UP YOUR DAILY ALARM WITHIN THE TESTING WINDOW

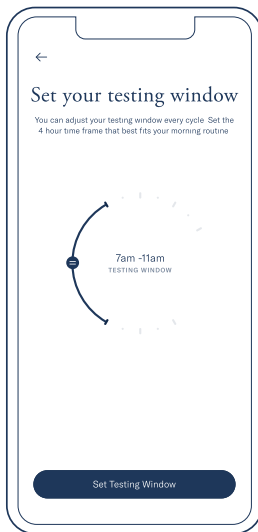
To ensure accurate test results, the inne STRIP should be used every day within the same 4-hour testing window which can be set between 5:00 am - 2:00 pm. The inne MINILAB will only take into account the first successful reading which is made within the testing window.

More information about daily use of the testing window can be found on page 30.

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. In addition, the daily alarm can be modified in the 'settings' tab.

WARNING: measurements taken outside the 4-hour window are not recorded by the inne APP



Choose the testing window during the setup process.



To set the daily alarm, go to the settings tab, turn on the daily notification ① and select the preferred notification time ②.

4. Fertility monitoring – 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 done within your 4-hour testing window every day.

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.

DAILY ALARM

You will receive the daily alarm by the inne APP, within the set 4-hour testing window when it is time for the test. Click on the alarm to launch the inne APP on your smartphone.

FOUR STEPS OF THE DAILY PROGESTERONE TEST

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

① COLLECT

② ACTIVATE

③ MEASURE

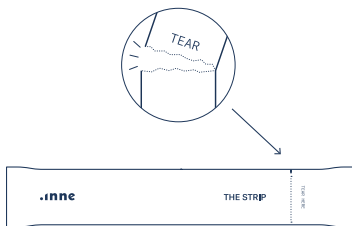
④ REVIEW

COLLECT

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

Take a new inne STRIP

Make sure the pouch is intact before using the inne STRIP, then tear the pouch by pinching and pulling to open it.



CAUTION If the pouch is damaged this inne STRIP cannot be used. Please take another one.

Start the timer

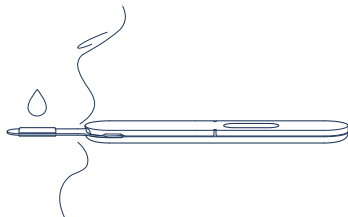
Use the timer in the inne APP to collect saliva for 30 seconds or more if needed.



TIP The timer is accessible on the 'lab' screen while the testing window is open.

Collect saliva

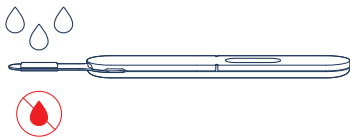
Place the collector in your mouth and move it freely over your tongue until the pad is fully soaked.



CAUTION Make sure to not bite or suck the collector.

Check collected sample

Make sure the collector pad is fully soaked after taking it out of the mouth.



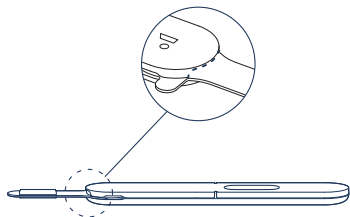
CAUTION Make sure there is no blood on the collector pad.

ACTIVATE

The inne STRIP must be activated after saliva collection in order to develop a test result.

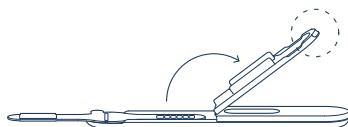
Start here

To open the lid locate the inne symbol on the strip.



Open Lid

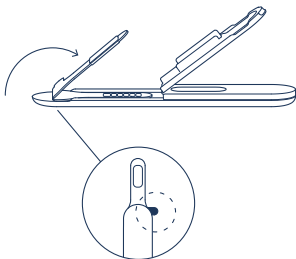
Grab the front of the lid to pull it open as shown below:



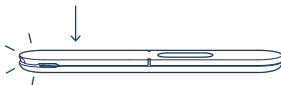
CAUTION Make sure not to touch the collector pad with your fingers during the activation process.

Fold

Use the handle to fold in the collector as seen below:

**Activate**

Close the lid again and press until it 'clicks', indicating that the inne STRIP is activated.



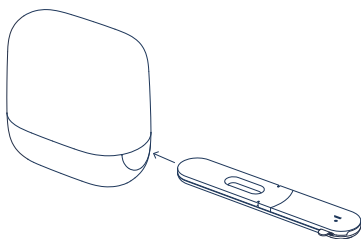
CAUTION The inne STRIP needs to be inserted into the inne READER right after activation. See p.54.

MEASURE

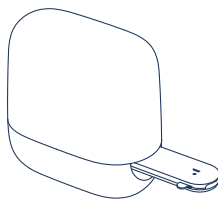
Insert the activated inne STRIP into the inne READER to start measurement of the collected sample.

Start Reading

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



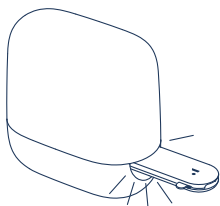
TIP Make sure to insert the window side of the inne STRIP first as shown and check that nothing is covering the strip window.



CAUTION The inne STRIP needs to be inserted into the inne READER right after it has been activated to ensure accurate results.

Reading in progress

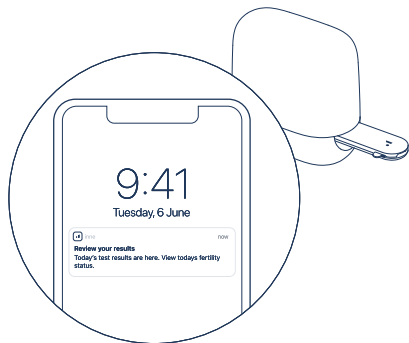
The white pulsating UI light indicates the reading is in process.



CAUTION Do not take the inne 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 is in the same room (10-meter reach) and has the inne APP running.

Receive Results

Launch the inne APP by clicking on the notification on your informing about a successful reading.



Review the results on home screen

- ① Today's progesterone reading shown on the graph.
- ② Explanation of today's progesterone measurement.
- ③ Today's 'fertility status', taking today's reading into account.



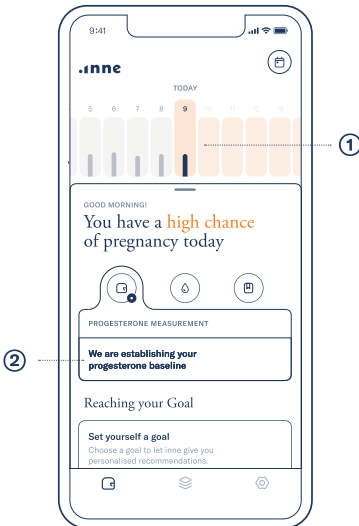
DISCARD USED INNE STRIP

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

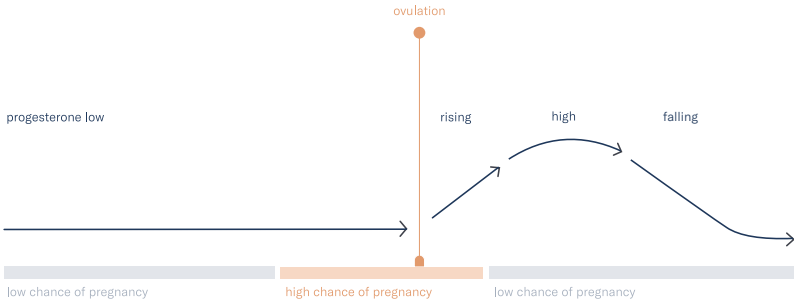
4. Fertility monitoring – Interpret progesterone results

The measurement results ① are charted in the graph on the 'lab' tab showing the daily changes in progesterone levels throughout the cycle.

The progesterone interpretation ② provides information about the progesterone trend and the occurrence of ovulation. It is updated every time a new measurement comes in.



The behavior of progesterone throughout the menstrual cycle is displayed below in a simplified graph.

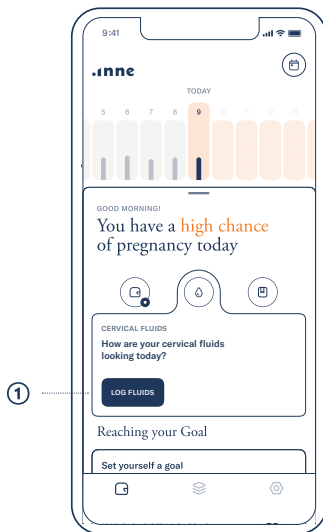


Low	Progesterone level is low in the follicular phase and stays low until ovulation occurs
Rising	Progesterone rise can be seen right after ovulation and when entering the luteal phase
High	Progesterone level is high during the luteal phase. Ovulation has taken place
Falling	Progesterone level decreases as the cycle ends

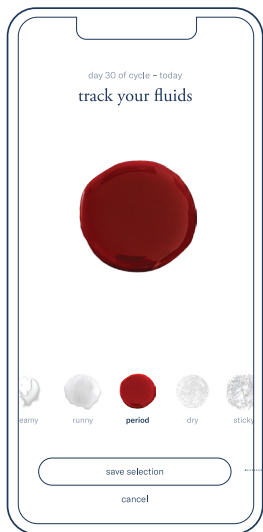
4. Fertility monitoring – Cycle

START A NEW CYCLE

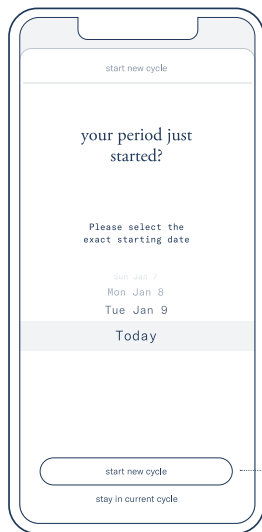
Set the start of a new cycle for each menstrual cycle. Do this on day 1, which is the first day of your period. The first day of your period is the first day of blood flow – spotting should not be logged as period.



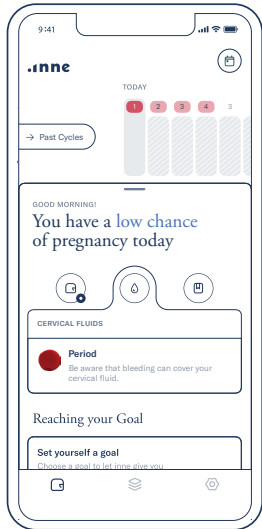
Click on 'log fluids' ① on the day the cycle has started.



Select 'period' in the fluid menu ② and click 'save selection' ③.



Confirm by tapping on 'start new cycle' ④.



A new cycle has been started.

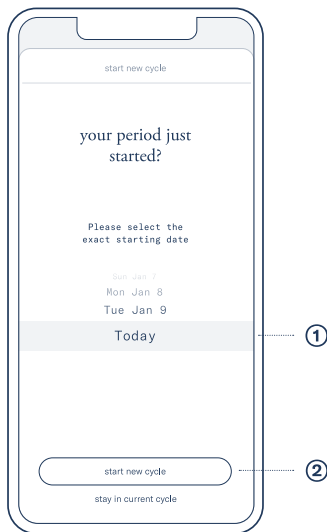
IF YOU FORGET TO START A NEW CYCLE

A new cycle can always be started by logging period as your current fluid. The App will open a window which allows you to select and confirm the start date of a new cycle.

STEPS

- ① Set the correct start date
- ② Click 'start new cycle' to confirm

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 your fertility calculation. Not tracking a new cycle will result in inaccurate fertility information.



YOUR CYCLES

'Past cycles' gives an overview of previous cycles, their start date, duration, progesterone measured and ovulation detected. The inne APP differentiates between the cycles which have been manually put in and the ones which are recorded while using the inne MINILAB.

GO TO YOUR CYCLES

- 1 Scroll to the left of your current cycle on the 'graph' and tap on 'past cycles' OR tap the calendar to view and add past cycles.

VIEW AND ADD PAST CYCLES

- 2 Current and past cycles recorded with the inne MINILAB

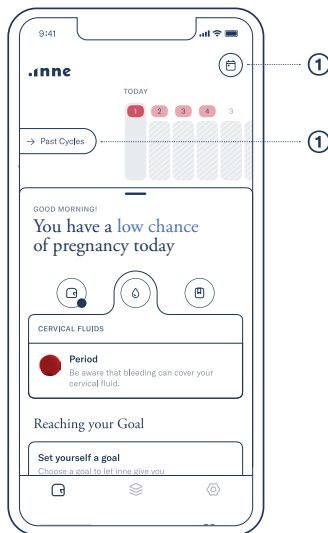
- 3 Past cycles input by you, the user

- 4 Add missing cycle:

Tap 'add a missing past cycle'

- 5 View cycle details:

Click on the arrow of a past cycle to view it in detail



EDIT AND DELETE PAST CYCLES

⑥

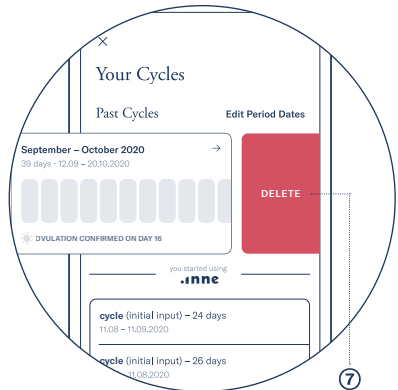
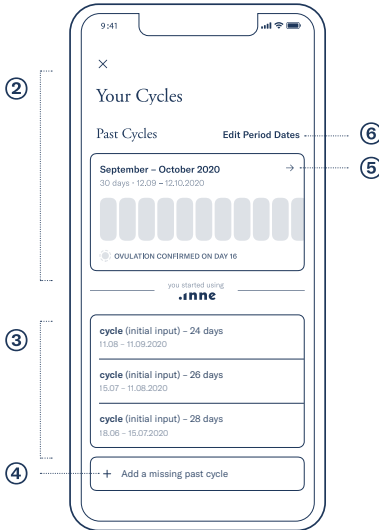
→ Change start date of past cycle:

Tap 'edit period dates' to change past period dates within the calendar view.

⑦

→ Delete cycle :

Swipe the cycle to the left to see the option 'delete' as shown below. When pressing 'delete' the cycle will be removed and the days of this cycle will be added to the previous cycle. Your measurements will not be lost.



4. Fertility monitoring – Tracking cervical fluids

Tracking cervical fluids is an additional parameter for fertility monitoring with the inne MINILAB. Cervical fluids provide information about where you are at in your menstrual cycle and inform how long sperm will survive in your vagina.

HOW TO OBSERVE AND CLASSIFY CERVICAL FLUIDS

The inne APP contains instructions on three different methods on how to observe and classify cervical fluids

1. The toilet paper method
2. The insertion method
3. The touch method

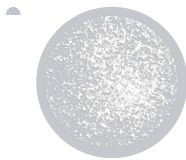
Read these instructions in the inne APP by going to the 'resources' tab, 'fertility monitoring' and open 'tracking fluids'

CERVICAL FLUID IN THE INNE MINILAB

The inne MINILAB allows to track four different cervical fluid states (dry, sticky, creamy and runny) spotting, period bleeding and abnormal fluid.

In addition to the cervical fluid visuals the inne APP uses icons to represent the fluid pattern in the graph. Icons as in the cycle view.

DRY



STICKY



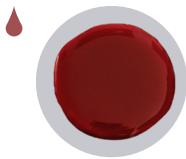
CREAMY



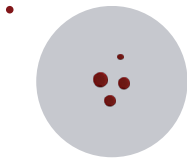
RUNNY



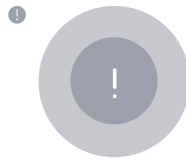
PERIOD



SPOTTING



ABNORMAL



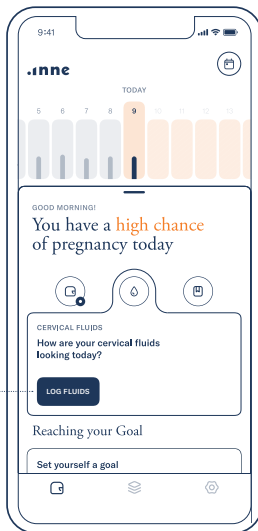
HOW TO TRACK CERVICAL FLUIDS IN THE INNE APP

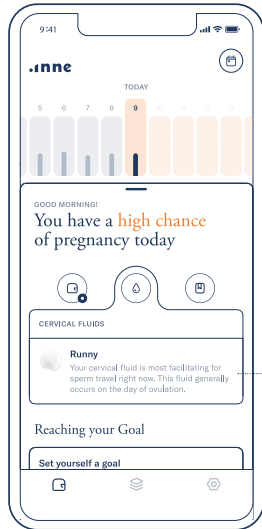
Once you have classified your cervical fluids you can track them on the 'cervical fluids tab' on the 'lab' screen of your inne APP.

STEPS

- ① Tap on the 'log fluids' button
 - ② Select the cervical fluid you have observed
- TIP** The short description underneath the fluid visual will help you to make sure you are selecting the right one.
- ③ Tap 'save selection'
 - ④ The cervical fluid will be shown on the 'day view' under the fluids tab.

①





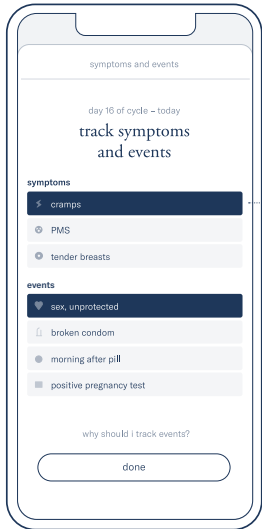
4. Fertility monitoring – Additional features

SYMPTOMS AND EVENTS

With the inne APP, it is possible to track different symptoms and events which are relevant when monitoring fertility.



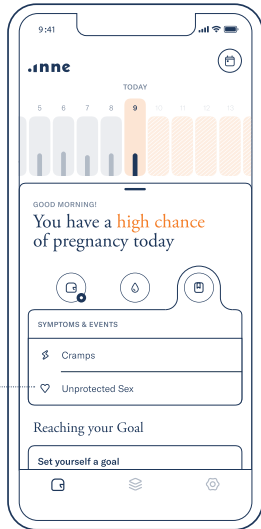
Click on the 'track symptoms & events' button ① on the 'day view'



②

③

Tap to select the symptoms or events to track ② and tap 'done'.



Selected items ③ will appear on the day view under the 'symptoms & events' tab

5. 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.76) 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

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.

I HAVE FORGOTTEN TO ACTIVATE THE INNE STRIP BEFORE STARTING A READING

If you started your reading before activating your inne STRIP, please follow the steps below

- Take out the inne STRIP from the inne READER
- Take a new inne STRIP and follow all the steps under Daily progesterone test (p.48) to take a new measurement

MY INNE READER IS SHOWING A RED UI LIGHT RED STATIC 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 follow the steps below

1. Check the inne READER's battery level:
Press the button on the inne READER shortly and check the battery light of the inne READER.

→ RED BATTERY LIGHT or NO BATTERY LIGHT:

Battery level is too low to take a measurement.

STEPS: Connect the inne READER to a charger and wait till the battery light changes from red to yellow. Then take a new inne STRIP and repeat the progesterone measurement.

→ YELLOW / GREEN BATTERY LIGHT:

Battery level is sufficient to do a reading. Problem with the collected sample or the inne STRIP.

STEPS: Repeat the test with a new inne STRIP to get the daily progesterone reading. Follow the steps outlined in p.48

RED BLINKING LIGHT

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 .

DATA SYNCHRONISATION

To transfer unsynchronised results make sure the is within reach, that Bluetooth connection is enabled and the inne APP is launched, when pressing the button on the inne READER.

The inne READER sends the results automatically via Wi-Fi or 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.

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 AppStore & Google Play.

INNE READER SOFTWARE

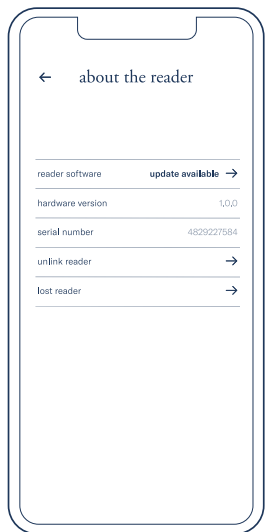
If a software update for the inne READER is available, it will be shown through a notification in the inne APP.

To see if new updates are available for the inne READER go to the 'settings' tab and tap on 'about the reader'.

What is needed to update the inne READER software?

- The inne APP on your with connection to the internet
- The inne READER with connection to an active Wi-Fi
- The inne READER, 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.



To update the inne READER software when an update is available, click on 'update' and follow the on-screen instructions.

5. 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 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
Skalitzerstrasse 85-86, TR B
10997 Berlin,
GERMANY

Return authorisation: All returns must be pre-approved 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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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 18113-1:2009
ISO 18113-4:2009
ISO 18113-5:2009

LEGEND



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



Do not use if package is damaged



Batch code



Do not reuse



Temperature limit to which the inner STRIP can be safely exposed



In vitro diagnostic Medical device

MANUFACTURER DETAILS

Designed and manufactured by

Feral GmbH

Skalitzerstrasse 85-86, TR B

10997, Berlin

GERMANY

CE
0483

