

# Welcome to inne MINILAB.

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System Manual 7.3

**.inne**



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# Introduction

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## 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: 7.3

Date: April 2nd, 2025

**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

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### ABOUT THE INNE MINILAB

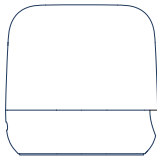
In order to use the inne MINILAB, you need to carry out a daily saliva collection using an inne Progesterone STRIP, perform a measurement using the inne READER, and finally review the results and view your fertility status in the inne APP.

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

## WHEN YOU HAVE RECEIVED YOUR inne MINILAB SHIPPING BOX

Unpack the inne MINILAB and check for completeness according to the components listed on this spread. Inspect the package for damage from shipping.

Follow the set-up process steps described in the Quick Guide instructions included within the inne READER packaging (charging and pairing). Confirm the function of the inne READER through successful pairing with your smartphone device.

## CONTENTS OF THE 'SHIPPING' BOX

- inne READER box
- inne Progesterone STRIP pouches (3X)
- inne Demo STRIP pouch (1X)
- SYSTEM MANUAL



## CONTENTS OF 'INNE READER' BOX

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

- inne READER
- USB-C Cable
- Quick Guide



## CONTENTS OF 'INNE PROGESTERONE STRIP' POUCH

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

- 8x inne Progesterone STRIPS in a pouch





## CONTENTS OF 'INNE DEMO STRIP' POUCH

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

→ 2x inne Demo STRIPs in a pouch



**NOTE** inne Demo STRIPs are non-functional strips for you to learn how to collect a saliva sample before using inne Progesterone STRIPs.

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## 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 - Contraindications

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

You are younger than 18 years of age

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

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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.

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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.

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

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You are known to have polycystic ovarian syndrome or endometriosis.

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

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Must avoid pregnancy at all costs.

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

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You are menopausal or post-menopausal.

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# Warnings and Precautions

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**CAUTION** Use of inne READER in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results.

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**CAUTION** The inne MINILAB is designed for use in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the inne READER and the source of the interference.

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**CAUTION** Ensure that saliva is only deposited into the collector to prevent invalidating the test.

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**CAUTION** Women to women differences and natural hormonal fluctuations during a cycle could influence the test and lead to false results of progesterone level and fertility detection.

---

**CAUTION** Only use inne Progesterone STRIPS from the same lot throughout a menstrual cycle.

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**CAUTION** Only use for self-testing at home.

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**CAUTION** Keep out of the reach of children.

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**CAUTION** Read SYSTEM MANUAL carefully before performing the test.

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**CAUTION** Use the inne Progesterone STRIP immediately after removing it from the pouch.

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**CAUTION** Pay attention to collection time and the flow indicator on the inne Progesterone STRIP.

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**CAUTION** Use the inne Progesterone STRIP only with the inne READER.

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**CAUTION** Use the inne READER only with original inne Progesterone STRIPS.

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**CAUTION** Use the test only for the purpose described in the SYSTEM MANUAL.

---

**CAUTION** Store and use between 15°C-30°C.

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**CAUTION** Keep pouch closed and store in a dry place. Make sure to close the zipper after taking a strip out in order to protect the remaining strips.

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**CAUTION** Keep the inne READER dry.

---

**CAUTION** The inne READER is for indoor use only.

---

**CAUTION** Make sure the inne Progesterone STRIP read-out window is clean and is never covered by anything.

---

**CAUTION** Make sure that the inne Progesterone STRIP barcode is never covered by dust, hair or saliva as it will not be scannable by the inne READER.

---

**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.

---

**CAUTION** Keep the inne Progesterone STRIP horizontal after collection until the strip has been inserted into the reader.

---

**CAUTION** If saliva is not starting to flow through the inne Progesterone STRIP within 30 seconds please refer to the help section in the inne APP.

---

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

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**CAUTION** The inne READER shall remain still and upright on a flat surface until the measurement has ended.

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**CAUTION - DISCARD USED INNE PROGESTERONE STRIP** The inne Progesterone STRIPS are made for single-use only. After the measurement has ended, the inne Progesterone STRIP can be removed from the inne READER and should be discarded as residual waste.

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

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**CAUTION** Do not use the inne READER in proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

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**CAUTION** Do not use if inne Progesterone STRIP is damaged. Please take another one.

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

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**CAUTION** Do not use the inne Progesterone STRIP with blood in saliva.

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

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**CAUTION** Do not fill more saliva than the amount indicated below can lead to inaccurate results. If you collected too much saliva repeat the test with a new inne Progesterone STRIP.

---

**CAUTION** Your inne READER contains no user-serviceable parts. There is danger of explosion if the battery is mishandled or incorrectly replaced. Do not 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.

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

---

**CAUTION** Do not test if foreign substances have been in your mouth since 30 minutes prior to testing. Rinse your mouth thoroughly with water and wait 10 minutes before taking the test.

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**CAUTION** Do not collect samples when oral diseases, inflammation or lesions exist.

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**CAUTION** Please be aware of a general residual risk of potentially infectious materials from non-human origin that cannot be completely excluded by the excessive testing.

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**CAUTION** Failure to follow these cybersecurity recommendations may lead to data loss, unauthorized access, or improper device functionality.

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**NOTE** The inne MINILAB does not protect you from sexually transmitted infections.

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**NOTE** The inne MINILAB can help you achieve your pregnancy goal by providing you with personalized information about your most fertile days based on your progesterone levels and aided by our algorithm. However, there are many factors that can impact fertility, we cannot guarantee a positive pregnancy outcome.

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**NOTE** It can take healthy couples several months to achieve a pregnancy. You should consult with your doctor if you are younger than 35 years and have been trying to get pregnant for more than 12 months, if you are older than 35 years and have been trying to get pregnant for more than 6 months, or if you are more than 40 years old.

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**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.

---

**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.

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

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

---

**NOTE** Measurements taken outside the 4-hour window are not recorded by the inne APP.

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**NOTE** inne Demo STRIPs are non-functional strips for you to learn how to collect a saliva sample before using inne Progesterone STRIPs.

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# The inne MINILAB

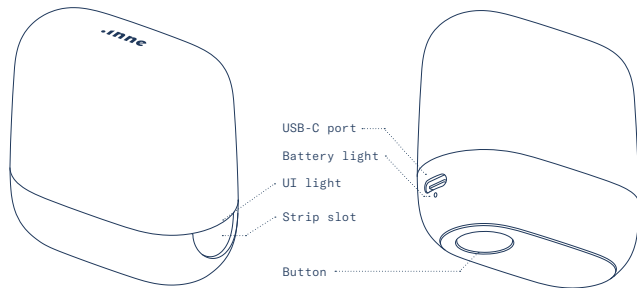
## Component names and functions

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### 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.32) until you feel it is firmly in place.
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## 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.
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## IMPORTANT INFORMATION OF THE INNE READER

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

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

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Limited Power Supply (LPS)

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Rated 3.5 V  4.4 V max.

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Input 4.75 V  5.25 V max. 4W

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→ Maximum altitude 3000 meters

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→ inne READER dimensions:

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Height: 67 mm

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Width: 38 mm

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Length: 68 mm

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Weight: 73 g

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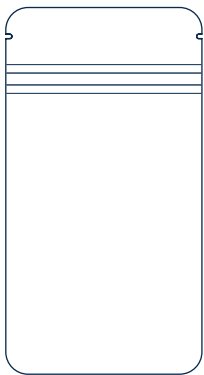
**CAUTION** Store and use between 15°C-30°C.

**CAUTION** The inne READER is for indoor use only.

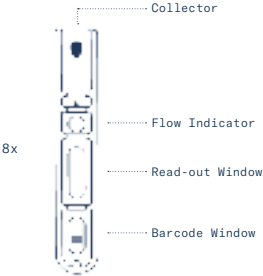
**CAUTION** Keep the inne READER dry.

**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 collector of the inne Progesterone STRIP.	See more details p.30 (Collect)
Flow Indicator	The flow indicator can be used to verify if saliva started moving through the inne Progesterone STRIP.	See more details p.31 (Collect)
Read-out Window	The read-out 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 read-out window is clean and is never covered by anything.
Barcode Window	The barcode is used by the inne READER to identify the LOT to confirm that the same LOT of strips is used within each cycle for accurate results.	Make sure that the inne Progesterone STRIP barcode is never covered by dust, hair or saliva as it will not be scannable by the inne READER.

**CAUTION** Store and use between 15°C-30°C.

**CAUTION** Keep pouch closed and store in a dry place. Make sure to close the zipper after taking a strip out in order to protect the remaining strips.

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

# The inne MINILAB

## General principles of the test

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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 chance of pregnancy and the days with lower chance of pregnancy. The days with higher chance 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.30. 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.

### ACTIVE INGREDIENTS

Each inne Progesterone STRIP contains 5.78 ng of anti-Progesterone antibody.

### **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

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### 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 92.2 pg/mL, determined consistent with the guidelines in CLSI document EP17 based on the proportions of false positives ( $\alpha$ ) less than 5% and false negatives ( $\beta$ ) less than 5%.

### DYNAMIC RANGE

The range of the assay is 92.2 – 1920 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. 28, 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 9.18% CV, while total variation within laboratory precision is estimated to be below 13.62% CV.

→ **CAUTION** only use inne Progesterone STRIPs from the same lot throughout a menstrual cycle.

## 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 92.4% 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-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>.

# The inne MINILAB

## Setup

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### 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.



## CHOOSE YOUR GOAL

You will be guided to select the goal for which you'd like to use the inne MINILAB:

1. Understand my cycle
2. Get pregnant

You can always easily change your goal in the profile section of your inne APP.



# 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 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 NOTIFICATION 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 notification as a reminder.

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

**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.

**NOTE** Measurements taken outside the 4-hour window are not recorded by the inne APP.

## 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

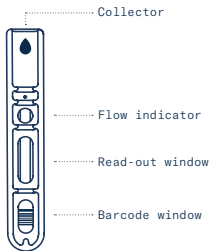
Review

# How to collect a saliva sample for accurate results

## 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.

**CAUTION** Ensure that saliva is only deposited into the collector to prevent invalidating the test.



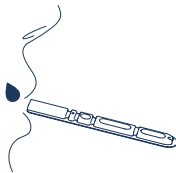
1

## COLLECT SALIVA

Collect a pea-sized amount of saliva in your mouth and deposit it gently into the collector side marked with a droplet symbol.

**CAUTION** Keep the strip horizontal after collection until the strip has been inserted into the reader.

**CAUTION** Do not use if inne Progesterone STRIP is damaged. Please take another one.



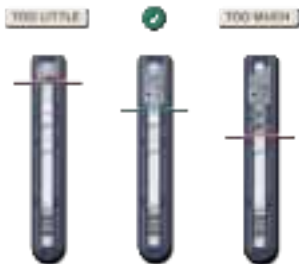
2

### WHAT IS THE RIGHT AMOUNT?

When collecting a saliva sample, make sure to only fill the collector cavity of the strip up to the green line as shown below.

**CAUTION** Do not fill more saliva than the amount indicated below as it can lead to inaccurate results. If you collected too much saliva repeat the test with a new inne Progesterone STRIP.

**CAUTION** Do not use the inne Progesterone STRIP with blood in saliva.



3

### OBSERVE THE FLOW INDICATOR

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

Insert the strip into the reader immediately after successful collection as described on p.32.

**CAUTION** If saliva is not starting to flow through the inne Progesterone STRIP within 30 seconds please refer to the help section in the inne APP.



4

## Insert the inne Progesterone STRIP into the inne READER to start the measurement

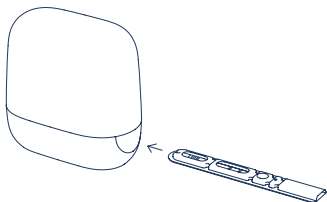
---

### START READING

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

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

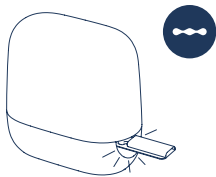
**CAUTION** The inne READER shall remain still and upright on a flat surface until the measurement has ended.



### 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 ended, the inne Progesterone STRIP can be removed from the inne READER and should be discarded as residual waste.



## Review your progesterone results in the inne App.

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### 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.



## UNDERSTAND YOUR CYCLE

If you are using the inne MINILAB for understanding your cycle, then you can use the results provided by the inne APP as information about your cycle and your fertile status.

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

A high chance of pregnancy result indicates that you are on your fertile window and, as such, would have higher chances of getting pregnant on that day.

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

A low chance of pregnancy indicates that you are either at the beginning of your cycle or past ovulation, therefore, you would have lower chances of getting pregnant on that day.

**NOTE** The inne MINILAB does not protect you from sexually transmitted infections.

## GETTING PREGNANT

If you are using the inne MINILAB for trying to conceive, you should interpret the results provided by the inne APP as follows:



You have a **small chance** of getting pregnant

A small chance of pregnancy indicates that you are within a time span where sperm is able to survive until the onset of a predicted ovulation happening.



You have a **high chance** of getting pregnant


A high chance of pregnancy result indicates that you are on your fertile window and should try to have unprotected sexual intercourse on that day to increase the likelihood of conceiving in that cycle.



You have a **very high chance** of getting pregnant

A very high chance of pregnancy result indicates that you are in your fertile window and close to your predicted ovulation. You should try to have unprotected sexual intercourse on that day to increase the likelihood of conceiving in that cycle.

The inne APP will display progressively darker orange background bars on the days leading to your predicted ovulation to indicate the days with higher chances of getting pregnant



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

A low chance of pregnancy indicates that the likelihood of pregnancy on that day is low.

**NOTE** The inne MINILAB does not protect you from sexually transmitted infections.

If you suspect you might be pregnant, you should take a pregnancy test and consult with your doctor to get the most appropriate information about the next steps. The sooner you consult with your doctor, the better it is for your health.

**NOTE** The inne MINILAB can help you achieve your pregnancy goal by providing you with personalized information about your most fertile days based on your progesterone levels and aided by our algorithm. However, there are many factors that can impact fertility, we cannot guarantee a positive pregnancy outcome.

**NOTE** It can take healthy couples several months to achieve a pregnancy. You should consult with your doctor if you are younger than 35 years and have been trying to get pregnant for more than 12 months, if you are older than 35 years and have been trying to get pregnant for more than 6 months, or if you are more than 40 years old.

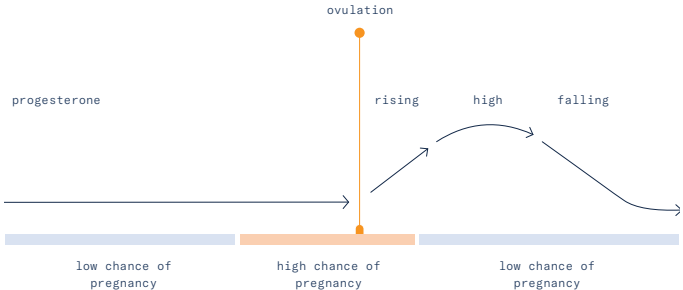
## THE BEHAVIOR OF PROGESTERONE

→ 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

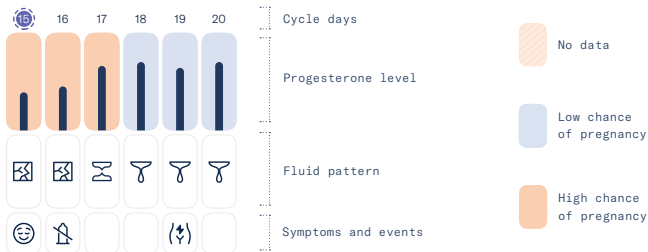
→ High: Progesterone level is high during the luteal phase. Ovulation has taken place

→ Falling: Progesterone level decreases as the cycle ends



# Fertility Monitoring

## The graph in detail



Cycle days

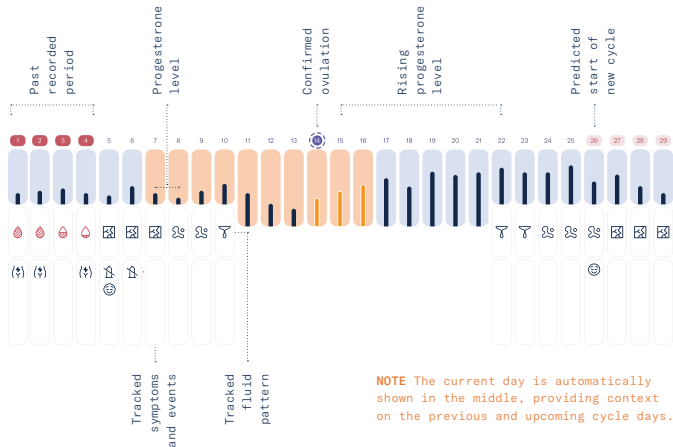
The timeline of the graph is structured in cycle days.  
20 the current day 19 past days 21 future days  
1 predicted start of a new cycle

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.

# Fertility Monitoring

## Your cycles

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### 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.

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

# Maintenance

## Cybersecurity & Data Protection

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The inne MINILAB is designed with security in mind to protect user data and ensure safe operation. To maintain a secure system and prevent unauthorized access or potential cybersecurity risks, users must follow these guidelines:

### SECURE NETWORK USAGE

- The inne READER should always be connected to a secure, password-protected Wi-Fi network.
- Public or unsecured networks are not supported.

### SOFTWARE & FIRMWARE UPDATES & SECURITY PATCHES

- Regular software & firmware updates are required to maintain security and device functionality.
- Updates will be made available through the inne APP and should be installed promptly when notified. If Wifi is connected, firmware updates will be conducted Over the Air (OTA) during the night.

### AUTHORIZATION & DATA PRIVACY

- User authorization is required before accessing personal fertility data in the inne APP.
- Personal data is encrypted and stored securely according to GDPR and IVDR requirements.

### INCIDENT RESPONSE & SECURITY MONITORING

- If unauthorized access or a potential cybersecurity threat is detected, please contact support immediately at [support@inne.io](mailto:support@inne.io).
- Any security updates or vulnerabilities will be communicated via the inne APP and official website.

**CAUTION** Failure to follow these cybersecurity recommendations may lead to data loss, unauthorized access, or improper device functionality.





# Maintenance

## Troubleshooting

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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.46) and ship the inne READER to the manufacturer for servicing.

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

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](mailto: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.

**CAUTION** 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

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### READER REPAIR & CLEANING

Your inne READER contains no user-serviceable parts. There is danger of explosion if the battery is mishandled or incorrectly replaced. 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.

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.

### 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](mailto: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.

The inne Progesterone STRIP pouches can be disposed in the recycling waste bin after removing the desiccant bags.

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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:

IVD Directive 98/79/EC (IVDD)  
EN ISO 13485:2016 + AC:2018 + A11:2021  
EN 13532:2002  
EN 13612:2002  
EN 13641:2002  
EN ISO 14971:2019 + A11:2021  
EN ISO 15223-1:2021  
ISO 18113-1:2022-10  
ISO 18113-4:2022-10  
ISO 18113-5:2022-10  
EN ISO 23640:2015  
IEC 61010-1:2010 + COR:2011 + A1:2016, modified + A1:2016/COR1:2019  
EN IEC 61010-2-101:2022 + A11:2022  
EN IEC 61326-1:2021  
EN IEC 61326-2-6:2021  
IEC 62304:2006 + A1:2015  
EN IEC 62311:2020  
IEC 62366-1:2015 + COR1:2016 + A1:2020  
ETSI EN 300 328 V2.2.2  
ETSI EN 301 489-1 V2.2.3  
ETSI EN 301 489-17 V3.2.4

## 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

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



Keep dry



In vitro diagnostic  
Medical device (only for use outside of the body)



Serial Number



Batch code



Manufacturer



Do not reuse



Date of manufacture



Do not use if  
package is damaged



Use-by date



Temperature limit for  
storage and usage of inne  
Progesterone STRIPS and inne  
READER



Indicates opening where to  
deposit a saliva sample in  
the inne Progesterone STRIP



Temperature limit  
for transport of inne  
Progesterone STRIPS and inne  
READER