PRIMA-TEMP

PRIYA™

Personal Fertility Sensor

Instructions for Use

Version B

Dear User,

Thank you for choosing the Priya™ Fertility Sensor System (also known as Priya™).
The Priya System personal fertility sensor automatically, continuously, and effortlessly measures your core body temperature via a temperature sensor (referred to as the Priya Sensor). The sensor transmits temperature data wirelessly to the Priya App (software application) on your mobile device.

We wish you the best on your fertility path forward.
Your friends at Prima-Temp, Inc.

This Instructions for Use (IFU) document provides information and instructions which must be followed to ensure safe performance of your Priya System. This IFU also contains warnings and precautions which must be observed at all times.

Please read this IFU carefully and completely before opening and activating your Priya Sensor. In particular, please observe the directions for proper cleaning and hygiene when inserting and removing Priya Sensor. If you have any questions, please contact our expert team at:

priyasupport@kindara.com

www.Prima-Temp.com

1 Indication for Use

The Priya™ System is intended for continuously measuring and recording core body temperature as an aid in ovulation prediction to aid in conception.

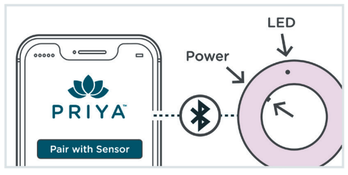
2 Priya Components

The Priya System is delivered fully assembled and has two parts – the Priya Sensor (vaginal ring sensor) and the Priya App.

The Priya Sensor consists of a flexible Printed Circuit Board (PCB) assembly. It is battery powered by four independent 1.55V Silver Oxide batteries. The PCB assembly is embedded in medical grade silicone. The Priya Sensor is intended for vaginal use only, where the maximum inserted outer diameter of the Priya Sensor is 57 mm.

The Priya App will store all your cycle information and temperature data.

The Priya App can be used with iOS 11 or Android™8.0 or higher. Preferably, the most recent version of either operating system should be used to ensure all features and capabilities are compatible.



Priya App Priya Sensor

3 Safety Information

The Priya System is a Class IIb device according to the classification in the Council Directive 93/42/EEC for medical devices. Priya is intended to be used continuously for a short-term duration (less than 30 days). Please see the list below for applicable regulatory guidance.

• Directive 93/42/EEC for medical devices with amendments by 2007/47/EC	• Subsidiary Legislation 427.44, Malta, Medical Device Regulations, Legal Notice 210 of 2008	• ISO 13485:2016
• EN-60601-1, EN 60601-1-1, EN 60601-1-11	• ISO 80601-2-56	• FCC part 15, Subpart C
• FCC Part 2, RF Exposure Assessment	• RSS-247	• RSS-102-RF Exposure Assessment
• EN 300 328 v2.1.1	• EN 62479 SAR/RF Exposure	• EN 301-489-1 with EN 301 489-17
• R&TTE Council Directive 1999/5/EC	• IEC 60086-1, 60086-2, 60086-5	• EU Battery Directive 2006/66/EC Amend 2013/56/EEE

This Instructions for Use document is available in a number of languages. Contact your local distributor should you require a copy of this documentation in another language.

3.1 Environment of Use

The Priya System has been designed for use in the home environment.

3.2 Contraindications

THIS PRODUCT IS NOT TO BE USED FOR CONTRACEPTION

Do not use the Priya System:

- For other than its intended purpose, as described in this IFU.
- If you have known allergies to silicone, epoxy resins, and/or ethylene vinyl acetate (EVA)-copolymers.
- When using other intravaginal products such as diaphragms, tampons, and pessaries.
- During Menstruation. The Priya Sensor may remain in the vagina continually for a maximum of 29 days at a time. The Priya Sensor should be removed when you are menstruating.
- If you have any underlying gynecological infections or during the active phase of any sexually transmitted infections (STIs).
- During the six-week postpartum period after childbirth. This should not be used if you are pregnant.
- For a minimum of six weeks after genitourinary or pelvic surgical procedures.
- If you have any urinary tract infections.
- If you have severe pelvic pain.
- If you use an Intrauterine Device (IUD) or any intrauterine system (IUS).
- The Priya System is a measurement system to aid in the determination of fertile phases, i.e., fertile days. The Priya System is not a substitute for individual measures or methods of pregnancy prevention (e.g., condoms). If you do not wish to become pregnant, you must use the contraceptive method or methods of your choice.
- Do not use the Priya Sensor for protection against pregnancy or sexually transmitted infections (STIs).
- If signs or symptoms of an active vaginal infection are present, such as abnormal discharge, itching, discomfort or pain, the Priya Sensor should not be used until such conditions have been successfully diagnosed and treated. If you suspect you have a vaginal infection, you should stop using the Priya Sensor and consult your healthcare provider immediately.
- Using the Priya Sensor during active symptoms of any pelvic condition, such as a sexually transmitted disease (STD), herpes, yeast infection, or vaginitis may cause increased discomfort or worsen symptoms.
- If you experience discomfort or have a concern about its use, stop use immediately and contact your healthcare provider.

- The Priya Sensor is not intended to be used by children, e.g., anyone under 18 years of age.
- The Priya Sensor should not be used by women with abnormal genital bleeding, prolapsed uterus, or vaginal infection.
- The Priya Sensor is for your personal use. DO NOT share it with other women, as this may present a risk of infection and invalidate your personal results.

3.3 Warnings

- The Priya Sensor is intended to be used for up to 180 days. After the last cycle, the Priya Sensor should be disposed of according to the disposal section of this IFU.
- The Priya Sensor should not be used during your menstrual period.
- Before insertion and after removing the Priya Sensor from the body, the Priya Sensor should be examined for any visible defects and/or changes. Do not use the Priya Sensor if you detect any defects and/or changes. Contact Customer Service for more information and/or a replacement device.
- Do not drop the Priya Sensor; dropping may cause mechanical damage to the device. If the Priya Sensor is dropped, it should be inspected for visible damage. The Priya Sensor should always be cleaned and disinfected prior to use.
- The Priya Sensor should not be used after the Use By date has expired.
- The Priya System is not suitable for direct temperature measurements and should not be used for temperature measurement for fever detection.
- Do not use any other auxiliary means to insert or remove the Priya Sensor.
- Choking hazard: Keep the Priya Sensor out of the reach of children and animals. Mishandling may cause mechanical damage to the device.
- The Priya Sensor should be removed if you are undergoing an MRI, CT, PET, or X-ray examination.
- The Priya Sensor should be removed prior to passing through security areas, such as airport security.
- DO NOT use more than one Priya Sensor at a time. While using the Priya Sensor, you should not have any other products or devices inserted into your vagina.
- DO NOT insert the Priya Sensor anywhere other than your vagina.
- Always wash your hands thoroughly with soap and water and dry well after handling the Priya Sensor.
- During sexual intercourse or a bowel movement, the Priya Sensor may shift out of place. You should routinely check that the Priya Sensor is in the correct position.
- Ensure that your software is up to date. Prima-Temp may issue software updates to improve the performance of the system and to introduce new features.
- Electromagnetic interference from other electrical equipment (such as an antenna) might interfere with the data transfer of the device, and you may not be able to obtain your fertile window prediction.
- Electromagnetic interference while the device is in use might affect other electrical equipment, such as radios, Wi-Fi-connected equipment, etc.

3.4 Possible Side Effects

Talk to your healthcare provider about any potential side effects you might experience with the Priya Sensor. You should also report any adverse events to Customer Service. See Section 14 below for Customer Service contact details. Possible side effects may include:

- Vaginal Irritation – The Priya Sensor is made of durable, medical grade non-absorbent silicone. It should not irritate the inside of your vagina if cleaned and cared for properly. If at any time during your use of the Priya Sensor you experience any discomfort, discontinue use and contact your healthcare provider.
- Vaginal Sensitization – One could have a sensitivity to any substance, but it is extremely rare to have a sensitivity to silicone. Studies indicate that silicone is biocompatible with the body. This is why silicone has been used in healthcare applications for over 50 years. If you do experience skin sensitivity, immediately discontinue use and contact your healthcare provider.
- Vaginal Infection – Vaginal infections should be treated with appropriate antimicrobial therapy before using the Priya System. If a vaginal infection develops during use of the Priya System, then the Priya Sensor should be removed (see **Section 5.9**), and you should contact your healthcare provider.
- Sensor Removal Difficulty – In rare occasions, the Priya Sensor may adhere to the vaginal wall, making the Priya Sensor removal difficult. Vaginal wall ulceration or erosion should be carefully evaluated. If an ulceration or erosion has occurred, consideration should be given to leaving the Priya Sensor out and not replacing it until healing is complete in order to prevent the Priya Sensor from adhering to the healing tissue.

If you are unable to remove your Priya Sensor, don't panic. Refer to the instructions for sensor removal in this IFU (**Section 5.9 "Removing and Turning Off the Sensor" and Frequently Asked Questions** at priyafertility.com). It may also be helpful to bear down (like when you are having a bowel movement) to assist with sensor removal. If you continue to have difficulty, call your healthcare provider and schedule an appointment.

Note: *it may help to use water-based lubrication gel on your finger for sensor removal.*

- **Toxic Shock Syndrome (TSS)** – Although the Priya Sensor is not made of a highly-absorbable material; Toxic Shock Syndrome is a rare condition caused by the bacterium Staphylococcus aureus growing on blood or fluids in the vagina. For this reason, the Priya Sensor should not be worn during your menstrual period. Some of the symptoms are much the same as the flu, but they can become serious. STOP using the Priya Sensor immediately and call your healthcare provider right away if you have the following symptoms:
  - sudden high fever (above 102°F or 39°C)
  - a sunburn-like rash
  - diarrhea
  - muscle aches
  - dizziness
  - vomiting
  - fainting or feeling faint when standing up
- Expulsion – the Priya Sensor can be accidentally expelled, for example during intercourse, or with straining during a bowel movement. If the Priya Sensor is accidentally expelled, wash your hands, and clean the Priya Sensor according to cleaning instructions (see Section 4) before you re-insert.
- Partner Discomfort – if your partner experiences any discomfort from the Priya Sensor (i.e., penis discomfort or irritation), the Priya Sensor can be removed during intercourse. If the Priya Sensor was removed during intercourse, clean according to cleaning instructions (see Section 4) before you re-insert. To achieve the most accurate fertile window prediction, the sensor should be re-inserted as soon as possible (within 1-2 hours).
- Tampon Use – you should not be wearing a Priya Sensor during your menstrual period, and therefore, you should not be using a tampon at the same time that you're wearing the Priya Sensor.
- Other Possible Side Effects – this includes foreign body sensation, tissue irritation inside your vagina or cervix, vaginal discharge, and vaginal discomfort. Should you have any concerns about allergies, please consult your physician or dermatologist.

3.5 Storing and Handling the Priya Sensor

- DO NOT expose the Priya Sensor to temperatures above 55° Celsius or 131° Fahrenheit (such as boiling hot water or microwave).
- To avoid device damage and maintain cleanliness, store the Priya Sensor in the provided package and out of direct sunlight when not in use. Keep the Priya Sensor away from children and pets.
- The Priya Sensor may discolor for various reasons, including exposure to Benzophenone-2, a chemical commonly found in sunscreen and beauty products containing sunscreen. Always be sure to wash your hands before handling the Priya Sensor. If discoloration occurs, contact Customer Service. See Section 14 below for Customer Service contact details.
- Silver Oxide batteries are not listed as dangerous goods under the ADR European Agreement Concerning the International Carriage of Dangerous Goods by Road, the IMDG International Maritime Dangerous Goods Code, UN Dangerous Good Regulations, IATA Dangerous Goods Regulations, ICAO Technical Instructions and the U.S. hazardous materials regulations (49 CFR).
- Ground Transport (US DOT): 49 CFR 172.102 Provision 130
- Air Transport (IATA): Special Provision A123
- Marine/Water Transport (IMDG/ICAO): Provisions 295 and 304

3.6 Device Life Expectancy

The device's life expectancy is dependent on the batteries in the Priya Sensor. It has a life expectancy of 180 days once the device is initially activated (provided the 180 days is complete prior to "Use By" date). It is recommended that the Priya Sensor is turned off between uses to conserve battery life.

3.7 Disposing and Recycling the Priya Sensor

The Priya Sensor should NOT be disposed of with household waste. To ensure the correct waste treatment of the product, please dispose of the sensor in accordance with any applicable local laws or requirements for disposal of electrical equipment. In doing so, you will help to conserve natural resources and improve standards of environmental protection in treatment and disposal of electronic waste.

4 Cleaning and Disinfecting the Priya Sensor

We recommend that you clean and disinfect your Priya Sensor prior to insertion, and after each time it is removed.

Cleaning and disinfecting are not the same thing. Cleaning simply removes macroscopically visible contamination. Disinfecting kills germs and provides an extra level of safety. Some germs can live on surfaces for hours and even for days! You should follow the disinfection process provided as it has been shown to be effective in destroying dangerous bacteria and viruses.

The exterior of the Priya Sensor should only be cleaned and disinfected with a product such as DISPATCH Hospital Cleaner Disinfectant Towels™ or Oxivir Tb Wipes™ which have been tested and shown to be safe and effective. We recommend using DISPATCH towels (or another wipe that contains the active ingredient 0.65% of sodium hypochlorite) or Oxivir Tb Wipes (or another wipe that contains 0.5% accelerated hydrogen peroxide (AHP)). In the following procedure, the first disinfectant towel is used for cleaning and the second towel disinfects the Priya Sensor.

<u>Warnings for cleaning and disinfecting:</u>

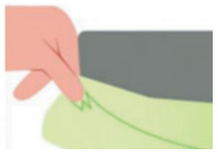
- Do not use any glass or household cleaners on the device.
- Do not put the device in the dishwasher or in the microwave.
- DO NOT BOIL the device.
- Stop using the device and contact customer service immediately if you notice any of the following signs of deterioration:
  - –The device does not turn on or off.
  - –There is a change in color, or the device appears to be damaged.

Clean and disinfect the Priya Sensor with the disinfectant towels according to the following instructions.

Cleaning and disinfecting the Priya System:

1. Wash your hands.

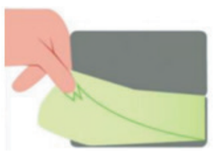
2. Dispense the disinfectant towel from its package or container.



3. Clean the entire surface of the Priya Sensor to remove any blood, dirt or vaginal discharge with one disinfectant towel.

4. Discard used towel according to the instructions provided with the disinfectant towel.

5. Dispense a second disinfectant towel from its package or container.



6. Disinfect the Priya Sensor with the second towel by wiping all outside surfaces thoroughly according to the instructions provided with the disinfectant towel.

7. Discard used towel according to the instructions provided with the disinfectant towel.

8. Wait at least one minute and make sure the Priya Sensor is completely air dried before inserting the Priya Sensor. Make sure that no bubbles from the cleaning and disinfecting agent remain.

9. If you'd like, you may rinse the Priya Sensor under cool running water to clear any residual disinfectant solution.

Note: *You can find both types of cleaning wipes through online retailers such as Amazon.com*

5 How to Use the Sensor and App

The Priya Sensor is a flexible vaginal ring that is self-inserted at home. It is for vaginal use only. The Priya Sensor automatically and continuously measures your core body temperature via a temperature sensor inside of the silicone ring. The sensor transmits temperature data wirelessly to the Priya App (called 'Priya') on your mobile device, where temperature data points are collected. The Priya App must be running (in the foreground or background) in order to collect your temperature data.

Once activated, each Priya Sensor is designed to be used for up to 180 days from initial activation. The Priya Sensor should be inserted on the same day that your period ends or within 24 hours after your period ends (**see Section 5.5**). After the cycle is complete or 29 days have elapsed (whichever comes first), the sensor is removed and cleaned according to cleaning instructions (**see Section 4**).

5.1 Setting Up the Priya App

Before you can use the Priya Sensor, you will have to set up the Priya App on your mobile phone.

STEP 1: Download the Priya App to your iOS or Android mobile phone.

1. Go to the Apple App Store or Google Play store and search for 'Priya Fertility.'
2. Download the Priya App.
3. If you have already downloaded the App, then please make sure you have the latest version by checking Updates on your mobile device.

STEP 2: Open Priya App & Create an Account (**see Figure 2**).

1. Enter your first and last name.
2. Enter your email.
3. Create a password (password must be at least six characters).
4. Tap on "Create Account" at the bottom of the screen.
5. Read and acknowledge the Terms of Use and Privacy Policy.
6. Provide your voluntary consent to the processing of your personal data we will collect from you, if you agree.

Note: *If you do not provide consent or withdraw your consent, we will not be able to provide you with fertility predictions. The withdrawal of your consent will not affect the lawfulness of the prior data processing activities. If you decline the Terms of Use, you will not be able to use the app and your account will be deleted. Also note that you can access the Privacy Policy and Terms of Use at any point in the app by clicking on the Account tab.*

Figure 2: Creating an Account

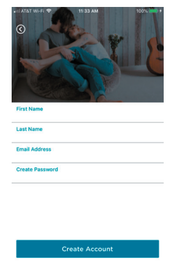
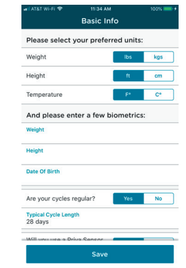


Figure 3: Entering Basic Info



STEP 3: Complete information on the Basic Info page and tap "Save" (**refer to Figure 3**)

You have now completed setting up the Priya App and you will arrive at the Home screen. **You won't need to do anything more until your next period starts!** Note: if you're currently on your period, you can begin using the sensor on the day your period ends, or within 24 hours.

5.2 Your First Menstrual Cycle

STEP 1: From the Home screen, tap "Set Period Start" on the day your period starts and use the selector to select the start date.

Note*: if you're currently on your period, you will enter the historical day that your period began.*

STEP 2: Allow notifications when prompted – this is necessary for you to receive notification of your fertile window. If you accidentally disallow notifications, you may update your notification preferences in the phone app settings.

STEP 3: When your period ends, tap "Set Period End" and use the selector to select the end date.

Note: *If you need to adjust your period start or end dates, tap the corresponding date on the Calendar tab which reveals an edit button to modify the dates.*

STEP 4: On the day your period ends (or within 24 hours), pair your sensor as described in **Section 5.3.**

Note: *Do not insert the Priya Sensor until* ***after*** *you have paired the Priya Sensor with the Priya App and have seen a successful temperature reading in your app.*

5.3 Turning On and Pairing the Priya Sensor with the Priya App

To preserve battery life and to obtain the most accurate results, the Priya Sensor should be activated, paired and inserted within 24 hours after your menstrual period ends (**refer to Section 5.6**). The Priya Sensor will only work for 180 days after it is first activated, so the sensor should not be activated until you are ready for insertion. The chart below details how to use the sensor and the LED light modes associated with each action.

I want to...	Action to take	LED light mode	Notes
Turn the sensor on and pair	Squeeze the power button until the LED lights green (about 1 second)	Green, followed by breathing blue	Breathing blue means the sensor is in pairing mode. When the sensor is paired with the phone, LED turns off. If you do not pair, then after 30 seconds LED turns off and the sensor turns itself off.
Turn the sensor mode to off	Squeeze the power button until the LED lights purple (about 3 seconds)	Turns purple then fades off	Sensor will be off
Check if my sensor is on and paired.	Squeeze and release the power button	LED flashes blue	The blue flash confirms that the sensor is on, and that it is paired. Your phone should receive temperatures within a few seconds, which confirms that the sensor is paired with the app on your mobile device.
Know when the sensor life is over	None	LED holds orange for 3 seconds	If you press the button to turn the sensor on and the battery is too low for use, the LED will hold orange for 3 seconds before the sensor turns itself off.

Note: The Priya App will not let you pair the device if your period end date was more than 2 days ago.

1. Wash hands with warm water and soap before handling the Priya Sensor.
2. Have the Priya App opened on your mobile device.
3. Have your pairing code ready (displayed on the Priya Package).
4. Do not throw away the Priya Package. You will need it to reference the pairing code and to store the Priya Sensor between cycles.

a) Tap "Pair with Sensor" in the Priya App. This will make the app scan for a sensor for 60 seconds.

b) TURN ON the Priya Sensor by squeezing the power button until the LED lights green.

c) The LED will be green and then turn blue to indicate it is attempting to pair.

d) Enter the Pairing Code in the app if prompted. You will have 30 seconds to enter the code before the Priya Sensor turns off.

e) Within a few seconds, the app will alert you that pairing was successful.

f) At this point, you may insert the Priya Sensor as described in **Section 5.5.**

Troubleshooting Note: if at any time during your cycle you become concerned about whether or not the sensor and the app are still paired, you can remove the sensor and perform an instant data transfer as described in the Troubleshooting section.

Figure 4: Pairing the Priya Sensor and the Priya App

5.4 Priya Data Transfer

- Your temperature data will be visible on the ""Home" screen once the Priya App receives the first temperature reading.
- The app will not display temperatures immediately. The sensor reads a temperature every 6 minutes and sends them over Bluetooth® in groups of 10 readings, thus temperatures sync with the app hourly.
- The "Sensor" tab displays the time of your next expected temperature sync.

<u>Remember:</u>

- Once the Priya Sensor has paired with your mobile device, the Priya App **MUST** be running in the foreground or background. If the app is completely closed, your data will not be transmitted, and you may miss your fertile window prediction.
- Keep Bluetooth on your mobile device on at all times – the Priya App cannot receive temperature information if Bluetooth is turned off.
- The Priya App must have access to Wi-Fi or mobile data to upload your temperature and cycle information to the cloud.
- To ensure the most accurate communication and data transfer from the Priya Sensor, it is best to <u>keep your mobile device in close proximity to your body</u> during the expected sync times (e.g., in your front or back pocket or while you're sleeping, on the nightstand next to your bed).

5.5 Inserting the Priya Sensor

To ensure an accurate fertile window prediction, you should insert the Priya Sensor on the day your period ends.

STEP 1: Disinfect Priya Sensor for first use – Refer to **Section 4** for full cleaning and disinfection instructions.

STEP 2: Prepare Priya Sensor for insertion

1. Place your thumb next to the LED window and index finger across to compress the sensor
2. Gently press on the Priya Sensor to make it lightly folded into an oval shape (**see Figure 5**). DO NOT TWIST.

STEP 3: Choose a position for inserting Priya Sensor. You can choose a position that is most comfortable for you. For example, standing with one leg up on a chair, lying down, or squatting (**see Figure 6**).

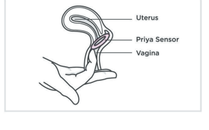
STEP 4: Inserting Priya Sensor into your Vagina

1. Insert the compressed Priya Sensor into your vagina and gently push it further into your vagina using your index or middle finger (**see Figure 7**).
2. The Priya Sensor may move around slightly in your vagina. This is normal.
3. If you feel discomfort, the Priya Sensor is likely not fully inserted. Use your finger to push the Priya Sensor further into your vagina gently.
4. If you find that the Priya Sensor is "dry" and you are having difficulty inserting it into your vagina, apply a very small amount of standard water-based lubricant for vaginal use or fertility-friendly lubricant. DO NOT use gels with warming or cooling additives; the lubricant should not contain a spermicide.
5. After insertion, clean and dry your hands.

Figure 5: Prepare the Priya Sensor for Insertion

Figure 6: Choose a Position

Figure 7: Inserting the Priya Sensor



5.6 Priya Notifications

The Priya App may generate the following notifications during your active cycle.

- **Fertile window** – When the Priya App detects temperature variations that indicate imminent ovulation, you will receive a notification, and your fertile window will be highlighted on the temperature graph on the "Home" screen.
- **Reminder to clean sensor** – If you are using the sensor for more than 28 days, you should temporarily remove it and clean it. You will receive a reminder to do so.
- **Sensor expiration** – Based on your subscription, you will receive a notification when your Priya Sensor will soon expire and when it has expired. Once expired, the sensor will no longer collect temperature data.

5.7 Priya Error Messages

- **Sensor Failed to Pair** – You will receive a pop-up alert if the sensor failed to pair. The pop-up alert will have instructions to re-attempt pairing your Priya Sensor.
- **App Failed to Find sensor** – You will receive a pop-up alert if the app doesn't discover the sensor during pairing. The pop-up alert will have instructions to re-attempt pairing your Priya Sensor.
- **Too long since Bluetooth sync** – You will receive a notification that it has been too long since the app synced with the Priya Sensor.
- **Temperature update without cloud sync** – You will receive a notification that the Priya App received temperature data that was not successfully saved to the cloud.

Note: *Troubleshooting steps are in* ***Section 11****.*

5.8 End of Cycle

Your cycle ends and a new one begins on the day your next period starts. At that time, you will need to remove and clean the Priya Sensor and enter your next period start date in the Priya App by tapping the "Set Period Start" button. Add personal notes in the "Calendar" tab as often as you like, such as for luteinizing hormone (LH) or pregnancy test results. This section is optional and for your personal use.

5.9 Removing and Turning Off the Priya Sensor

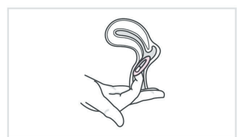
You will remove the Priya Sensor when your period starts, for periodic cleaning (at least every 29 days), and for sexual intercourse if desired. You do not need to turn off the sensor when you remove it for periodic cleaning and intercourse.

NOTE: *If the Priya Sensor has been out of your vagina more than two hours during your cycle (when not on your menstrual period), it may affect the accuracy of your fertile window prediction. Therefore, except for when you remove the Priya Sensor during your menstrual period, you should re-insert the Priya Sensor as soon as possible after it has been removed.*

STEP 1: Preparing to Remove the Priya Sensor

1. Before removing the Priya Sensor, wash and dry your hands.
2. Choose the position that is most comfortable for you, for example, standing with one leg up on a chair, or lying down, or squatting (**see Figure 6**).

Figure 8: Removing the Priya Sensor



STEP 2: Removing the Priya Sensor

1. Put your index or middle finger into your vagina and hook it through the Priya Sensor as shown (**see Figure 8**).
2. Gently pull downward to remove Priya Sensor. See Frequently Asked Questions at www.priyafertility.com if you have difficulty removing the sensor..

STEP 3: Cleaning the Priya Sensor

1. Dispense the disinfectant towel from its package or container.
2. Clean the entire surface of the Priya Sensor to remove any blood or dirt with one disinfectant towel.
3. Discard used towel according to the instructions provided with the disinfectant towel.
4. Rinse the sensor under running water then dry the sensor completely.

STEP 4: Turning off the Priya Sensor

To TURN OFF the Priya Sensor, squeeze the power button until the LED lights purple (about 3 seconds).

STEP 5: Storing the Priya Sensor

Place the sensor in the storage case until it is ready to be used again for the next menstrual cycle. Be sure that the sensor is completely dry before putting it in the case.

6 Additional Menstrual Cycles

For additional menstrual cycles, follow the instructions described in **Section 5.3**. The full cleaning and disinfection instructions in **Section 4** should be completely followed for all additional menstrual cycles.

7 Pairing Additional Sensors or Changing Sensors

The Priya App can only communicate with one Priya Sensor at a time.

If you are changing your sensor at a new cycle, simply follow the instructions to pair.

If you are changing your sensor mid-cycle, proceed to the "Sensor" tab, tap "Technical Data" to proceed to the "Technical Data" screen. Tap the "Unpair Sensor" button then return to the "Home" tab and pair as instructed.

8 Show "Technical Data"

When contacting Customer Service, you may need to see Technical Data about your sensor and your app. This is displayed in the "Technical Data" page. To access this data, tap the "Advanced" button on the "Sensor" tab, then click "Technical Data."

9 Technical Specifications

WARNING: The Priya Sensor is not a serviceable part. In other words, modification, repair or change of the Priya Sensor is not possible and is forbidden by the manufacturer.

Operating Ranges
Temperature: 5.0° to 40.5°C (41.0° to 104.9°F)
Temperature Measurement Range: 34.5° to 40.5°C ± 0.1°C (94.1° to 104.9°F ± 0.18°F)
Transient Response Time: 20 minutes (time for the device to raise/lower by 2°C)
Humidity: 10% to 100% relative humidity
Atmospheric pressure: 700 hPa to 1060 hPa
Ingress Protection: IP67 (Device is designed to protect against dust ingress and liquids up to 1m deep)

Electrical & Power Ratings
Electrical Specifications:
3.10V Silver Oxide Battery (Mercury free); 43mAh

Environmental
Use By: 30 months from the date of manufacture
Storage temperature range: -25°C to 55°C (-13°F to 131°F)
The relative humidity range: 10% to 90% non-condensing
Atmospheric pressure: 70 kPa to 106 kPa

Other Technical Specifications
Communication: Bluetooth
Bandwidth: 2.402 to 2.480 GHz
Data Modes: BLE (Bluetooth Low Energy)
ERP (Effective Radiated Power): 8.85 dBm
Output: Core body temperature readings, Priya App report
Priya Sensor Weight: 9.9 ± 2 g (0.35 ± 0.07oz)
Priya Sensor Dimensions: 57 mm OD, 38mm ID (2.24 in OD, 1.50 in ID)

Other Requirements
A mobile device with a stable connection to the Internet for downloading/installing software, registering Priya account, and uploading data to the secure cloud server is required. The Priya Sensor will store approximately 30 days of temperature data; a stable Bluetooth connection is required to transfer data from your Priya Sensor to the Priya App.

Prima-Temp recommends a mobile device with the following specifications:

- Operating System: iOS 11 or Android™ 8.0 or higher, preferably the most recent available version
- WiFi: Yes
- Bluetooth: Yes, 4.2 Bluetooth
- GPS: Yes
- Battery Size: 2500mAh minimum
- Number of Cells: 1

Note: *An Internet connection is used to register the device, and to download/upload data to the cloud system. The Priya Sensor will store your temperature data for approximately 30 days. Once the Priya App receives temperature data, your mobile device will store all of your temperature information within the Priya App.*

10 Electro Magnetic Compatibility

The Priya Sensor requires special precautions regarding the EMC (Electro Magnetic Compatibility) and should be used according to the EMC information provided in this IFU.

For EM compliance, it is important only to use accessories that meet the specifications recommended by Prima-Temp (**Refer to Section 9**).

Recommendations for actions to assure that the Priya System remains safe with regard to EM disturbances:

- If the Priya System is used in a location near (e.g., less than 1.5 km from) AM, FM, or TV broadcast antennas, it may be necessary to take preventative actions for reducing the electromagnetic (EM) interfering level (for instance, by physically moving to a different location).

The Priya System contains Bluetooth wireless modules which intentionally receive and transmit RF electromagnetic energy in the 2.4 GHz ISM frequency band.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Priya System is intended for use in the electromagnetic environment specified below. The customer or user of the Priya System should assure that it is used in such an environment. When the Priya System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Priya System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Priya System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Priya System is intended for use in the electromagnetic environment specified below. The customer or user of the Priya System should assure that it is used in such an environment. When the Priya System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Not applicable – The device is intended to be used internally.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Priya System is intended for use in the electromagnetic environment specified below. The customer or user of the Priya System should assure that it is used in such an environment. When the Priya System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF Immunity IEC 61000-4-3	3 V/m 80 MHz to 6 GHz 27V/m 385 MHz 28 V/m 450 MHz 9V/m 710/745/780 MHz 28 V/m 810/870/930 MHz 28 V/m 1720/1845/1970 MHz 28 V/m 2450 MHz 9 V/m 5240/5500/5785 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Priya System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d=1.17√P d=1.17√P 80 MHz to 800 MHz d=2.33√P 800 MHz to 6 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). The Priya System is fairly sensitive to radiated RF. Disturbances in data transfer are possible at and below the specified test level. It may be necessary to move away from interfering equipment. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Priya System is used exceeds the applicable RF compliance level above, the Priya System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary.			

Recommended separation distances between portable and mobile RF communications equipment and the Priya Sensor			
The Priya System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Priya System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Priya System as recommended below, according to the maximum output power of the communications equipment. ⚠ **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to a part of the Priya System. Otherwise, degradation of the performance of this equipment could result.			
Rated maximum output power of the transmitter W	**Separation distance according to the frequency of the transmitter m**		
	150 kHz to 80 Hz d=1.17√P	**80 MHz to 800 mHz** d=1.17√P	**800 MHz to 6 GHz** d=2.33√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

11 Troubleshooting

11.1 If you cannot pair the Priya Sensor with the App:

1. Verify that Bluetooth is enabled on your mobile device.
2. Make sure you have the correct pairing code (displayed on the Priya Sensor packaging).
3. Verify that after depressing the power button the LED lights green then breathes blue. (If the LED lights green and then fades out, or does not light at all, the battery life of your device has been depleted and your sensor will need to be replaced.)
4. Retry pairing the sensor and the app using the instructions in Section 5.3.
5. If you are still unable to successfully pair the devices, press the Priya Sensor power button for at least 10 seconds (this resets the sensor's Bluetooth), and in your phone Bluetooth settings' list of known Bluetooth devices, remove any devices named "Priya-Ayola" (in iOS, removing the device is the "forget device" action). Now, retry pairing using the instructions in Section 5.3.

If you still cannot get your devices to pair, contact Customer Service for further instructions at priyasupport@kindara.com.

11.2 If your Priya Sensor has not synced with the app for more than 12 hours, try the following options:

Note*: The Priya Sensor stores at least 30 days of temperature readings until they are sent to the app, so there is no risk that you will lose temperatures. The only risk is that a fertile window prediction may be delayed if temperatures are not received by the app.*

1. Ensure that Bluetooth is enabled on your phone, and that the app is on (either in the foreground or background).
2. In the app's sensor tab, ensure that "Sensor Status" is "Paired". If not, you will need to pair your sensor as described in Section 5.3.
3. In the app's sensor tab, select "Advanced" then "Technical Data" to view the Sensor's Battery Level. This displays the battery level at the time of last successful temperature transmission. If the battery level is below 10% your sensor battery may be too low to transmit.
4. In the app's sensor tab, view the "Next Sensor Sync" time. Starting one minute before this time and continuing until a transmission is received, keep your phone very near your abdomen. Some women find that the front or back pants pocket works well. (Once a sync occurs, you should see new temperature readings in your temperature graph.)
5. Assisted Syncing: If you are still unable to sync with the sensor, try an "Assisted Sync." To do this, first remove your sensor. Then depress the power button for just one second to trigger a sync. (The LED should briefly light blue to indicate the sync.) Now look at your temperature graph to ensure new temperatures were received, and clean and re-insert your sensor as you did when starting your cycle.

If you still cannot get the sensor to sync with the app, contact Prima-Temp, Inc. Customer Service for further instructions at priyasupport@kindara.com

12 Device Specifications and Symbols

Warning Labels/Safety Labels

Symbol	Symbol Title	Explanatory Text	Standard Reference
NON STERILE	Non Sterile	Indicates a medical device that has not been subjected to a sterilization process.	EN 980, ISO 15223-1, ISO 7000-2609
	Use by	Indicates the date after which the medical device is not to be used.	EN 980, ISO 15223-1, ISO 7000-2607
LOT	Batch (Lot) Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN 980, ISO 15223-1, ISO 7000-2492
	Attention: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use and/ or user manual for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	EN 980, ISO 15223-1, IEC 60601-1, ISO 7000-0434
	Do not use if the package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1, ISO 7000-2606
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use and/ or user manual.	EN 980, ISO 15223-1, IEC 60601-1, ISO 7000-1641
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN 980, ISO 15223-1, ISO 7000-2497
	Manufacturer	Indicates the medical device manufacturer.	EN 980, ISO 15223-1, ISO 7000-3082
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.	IEC 60601-1, IEC 60417-5333
SN	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	EN 980 Clause 5.5, ISO 15223-1 Clause 5.1.7, ISO 7000-2498
REF	Catalog or model number	Indicates the manufacturer's catalog number so that the medical device can be identified.	EN 980, ISO 15223-1, ISO 7000-2493
CE	CE Marking	Signifies European technical conformity.	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II
EC REP	Authorized European Representative	Indicates the Authorized Representative in the European Community.	EN 980, Clause 5.1.3, ISO 15223-1, Clause 5.1.2
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	EN 980, ISO 15223-1, ISO 7000-0632
	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.	EN 980, ISO 15223-1, ISO 7000-0632
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	EN 980, ISO 15223-1, ISO 7000-0632
	Recycle Electronic Equipment	DO NOT THROW IN TRASH.	EN 50419
	Bluetooth® wireless or enabled technology	Bluetooth® wireless or enabled technology.	(Trademarks of Bluetooth Special Interest Group (SIG)
FCC ID: XXXXXXX	Radio Frequency Devices (U.S.)	Federal Communication Commission Number (FCC ID #) Complies with the United States Radio communication requirements.	47 CFR Part 15
	Radio frequency transmitter	The symbol for non-ionizing radiation. All equipment and systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment must be labeled with this symbol.	Radio Equipment Directive (2014/53/ EU)
IC: 0000X-000	Radio Standards Specifications (CA).	Industry Canada Radio Communications License (IC:#) Complies with Industry Canada Radio communication requirements.	(RSS-102)
	Australian Radio Communications Requirements.	Australian Radio Communications License Complies with Australian Radio communications requirements.	(AS/NZS 4417.1:2012)
	Japan Radio Law	Japan Radio Communications License Complies with Japan Radio Law Notice 88.	(MIC Article 38-33)
FC	Radio Frequency Devices (U.S.)	This device complies with Part 15 of the FCC Rules. The operation is subject to the following two conditions: (1)This device may not cause harmful interference and (2)This device must accept any interference received, including interference that may cause undesired operation.	47 CFR Part 15

13 Warranty and Compliance

Your Priya System is guaranteed to be free from material defects for a period (herein after referred to as Warranty Period) of one (1) year from the date of delivery if you reside in the United States of America or Canada. If you reside in the European Union, Iceland, Norway, Liechtenstein or Switzerland and you purchased your Product in the European Union, Iceland, Norway, Liechtenstein or Switzerland, the Warranty Period shall be two (2) years from the date of delivery.

If you reside in the United States of America, Canada, European Union, Iceland, Norway, Liechtenstein or Switzerland, and if at any time during the Warranty Period, your Priya System does not work for any reason (other than as described in the Limitations below), it will be replaced with a new or a substantially equivalent device or repaired, free of charge.

If you reside in the European Union, Iceland, Norway, Liechtenstein or Switzerland, you may ask for a price reduction or a refund in the following instances:

- if you are entitled to neither repair nor replacement; or
- if Prima-Temp has not completed the remedy within a reasonable time; or
- if Prima-Temp has not completed the remedy without significant inconvenience to you.

Damaged or defective units should be returned within TWO YEARS of delivery to the manufacturer at the address identified in the Warranty Policy, which can be found at: www.priyafertility.com.

NOTE*: Your Priya Sensor will only work for a maximum of 180 days from the date of first activation.*

Limitations On Warranty

This warranty is subject to the following exceptions and limitations:

This warranty is applicable only to the original purchaser.

This warranty does not apply to units that malfunction or are damaged due to obvious abuse, misuse, alteration, neglect, unauthorized maintenance or failure to operate the Priya System in accordance with instructions.

There is no other express warranty for this product. The option of replacement, repair, price reduction and refund described above, are the warrantor's obligation under this warranty.

Please see the complete list of Limitations in Warranty Policy at: www.priyafertility.com

For Warranty Service

The original purchaser must contact Customer Service at priyasupport@kindara.com

FCC Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. The FCC ID is 2AE3ZPTPL1007. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

Using this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by doing one of the following:

Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet that is on a different circuit from the receiver.
- Consult Prima-Temp or an experienced radio/TV technician for help.

FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

FCC Radiation Exposure Statement

This equipment complies with FCC Radiation Exposure Limits for an uncontrolled environment.

This transmitter must not be co-located with or operating in conjunction with any other antenna or transmitter.

14 Customer Service

If you should have any questions not covered either here or in the question and answer section of our website, please contact us at www.priyafertility.com or at priyasupport@kindara.com.

For more information about the Priya System, or if your Priya Sensor is broken, quits working, or you need further assistance, please contact us via email at priyasupport@kindara.com.

Disclaimer

This product is not intended to diagnose, cure or prevent disease. Prima-Temp, Inc. makes no claims, representations or warranties regarding the ability of this product to cure any physical or mental conditions. A qualified health professional should be consulted with regard to any condition requiring medical attention.

Part Numbers

PT PFS 1001 Priya Sensor

16300001 Instructions for Use

18300001 Priya App

For faulty or defective units, please email priyasupport@kindara.com for return authorization number and address.

Manufacturer

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