

TempuRing

Personal Fertility Sensor

User Manual



TEMPURING

User Manual

Thank you for choosing **TEMPURING**.

TEMPURING personal fertility sensor *automatically, continuously and effortlessly* measures your core body temperature via a temperature sensor. The sensor transmits temperature data wirelessly to the TEMPURING App on your smart phone or iPod.

We wish you the best in your personal fertility path forward.

Your friends at Prima-Temp, Inc

www.prima-temp.com

This device complies with Part 15 of the FCC Rules. 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.

§2.925(a)(1)

FCC ID: 2AE3ZPT-DS-5000

FCC Information on software application can be found by opening Priya app, clicking on menu in upper left corner, and clicking on 'About'.

Caution: changes or modifications not expressly approved by Prima-Temp, Inc could void the user's authority to operate the equipment.

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Manufacturer

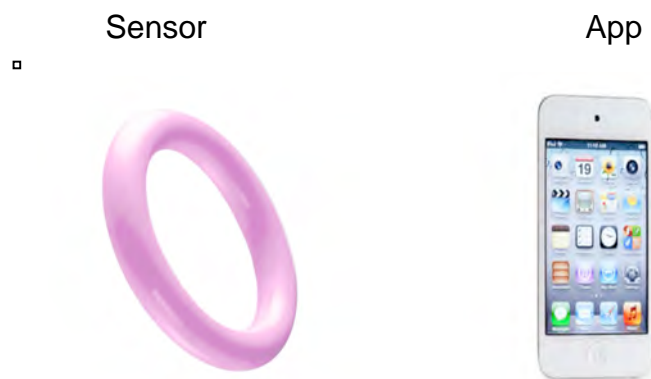
Prima-Temp, Inc.
2820 Wilderness Place, Suite C
Boulder, Colorado 80301
United States
1-866-398-1032
www.Prima-Temp.com

1 TEMPURING DESCRIPTION

TEMPURING personal fertility sensor consists of a **flexible vaginal ring** that is self-inserted at home. TEMPURING automatically and continuously measures your core body temperature via a temperature sensor inside of the ring. The sensor transmits temperature data wirelessly to the TEMPURING App (called 'Priya') on your smart phone or iPod, where the temperature data are collected. The TEMPURING App (Priya) can be used with an iPhone (4s and higher, with iOS 7 and higher) and iPod Touch (3rd generation or higher).

Components of TEMPURING

The TEMPURING system has two parts – the TEMPURING vaginal ring sensor, and the TEMPURING mobile App (Priya).



The TEMPURING vaginal ring sensor is made of medical-grade silicone. It is for vaginal use only.

When you first unpack TEMPURING, it must be activated and paired with your iPhone/iPod (see '*TEMPURING Activation and Pairing with iPhone/iPod*' below).

It is best to keep your iPhone/iPod with you at all times to ensure the most accurate communication and data transfer from TEMPURING.

Indication for Use

TEMPURING is intended for continuously measuring and recording core body temperature as an aid in ovulation prediction to aid in conception.

THIS PRODUCT IS NOT TO BE USED FOR CONTRACEPTION

2 INSTRUCTIONS FOR MEASURING AND RECORDING ORAL TEMPERATURE, FACTORS THAT MAY AFFECT TEMPERATURE, AND URINARY LH

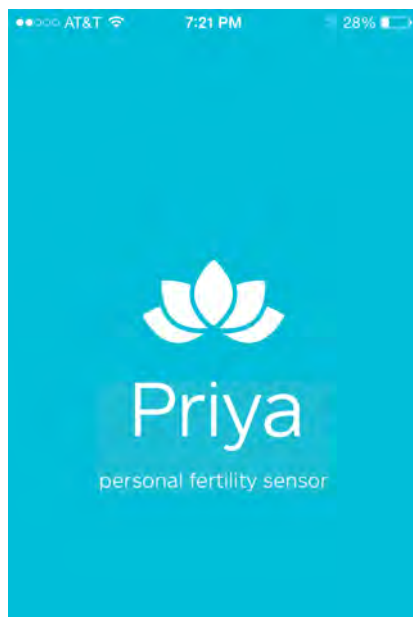
The TEMPURING App's 'My Diary' Entry

You must start using your TEMPURING App (Priya) on the first day of your menstrual cycle / your period (the first day of bleeding or spotting is the first day of your cycle - Cycle Day 1).

The TEMPURING App will store all of your cycle information, your oral Temperature data, your Factors (that may affect your core body temperature), Luteinizing Hormone (LH) data, and TempuRing Temperature.

Please bring your provided iPod/iPhone to every study visit. The study coordinator or study nurse will review all the data stored in the TEMPURING App (Priya) and will export and email all your collected data to the study sponsor. You will also be emailing your data to the study sponsor – please refer to Reports to Sponsor section below.

To begin using your TEMPURING App (Priya), please go to TEMPURING App (Priya) on provided iPod/iPhone.



About You Screen

In the 'About You' screen.

- Enter your name, email, and date of birth.
- The study coordinator or nurse will enter your study ID. **DO NOT CHANGE YOUR STUDY ID.**
- After filling in your name, email and date of birth, tap 'Save'.

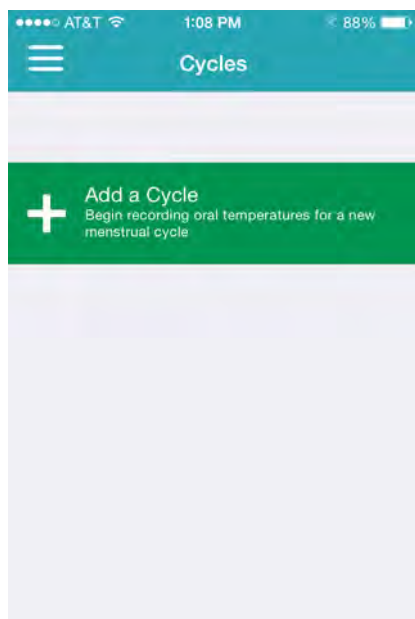
- It will ask you to confirm your entry. Please confirm by clicking 'sure'.

- Enter Name
- Enter Email address
- Study Coordinator enters subject ID
- Enter Date of Birth
- Tap on 'Save'

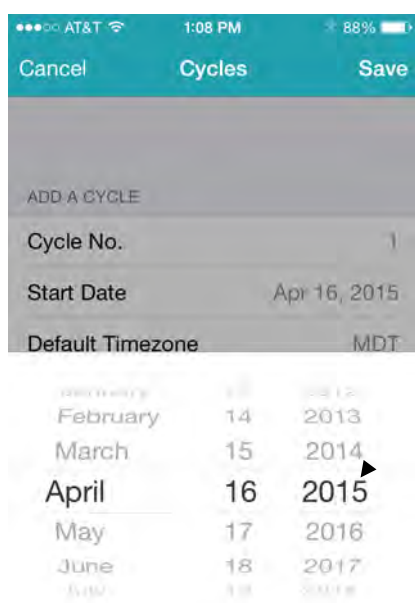
- Click on 'Sure' to Confirm

To Add New Cycle

- Tap on 'Add a Cycle'
- Select 'Start Date,' which is the first day of your cycle (the first day of bleeding or spotting is the first day of your cycle - Cycle Day 1).
- Tap on 'Save'.



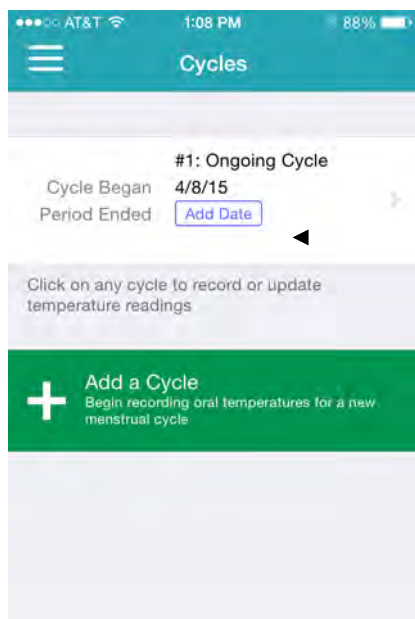
- Tap on add a Cycle



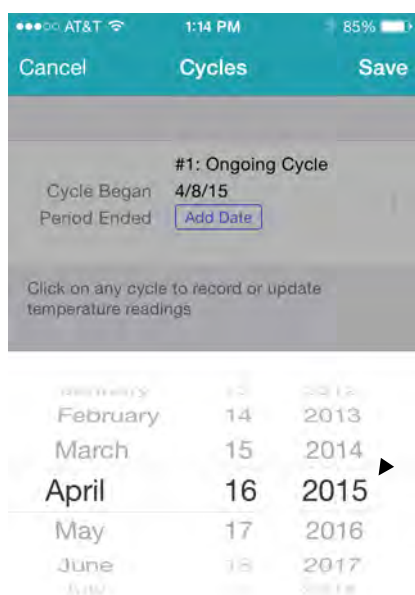
- Select a Start Date of your cycle and Tap 'Save'

Add 'Period End' Date

- This is the last day of your period, or the last day of bleeding or spotting.
- Once your period ends, next to 'Period Ended', Tap on 'Add Date'.
- Select the date when you period ended.



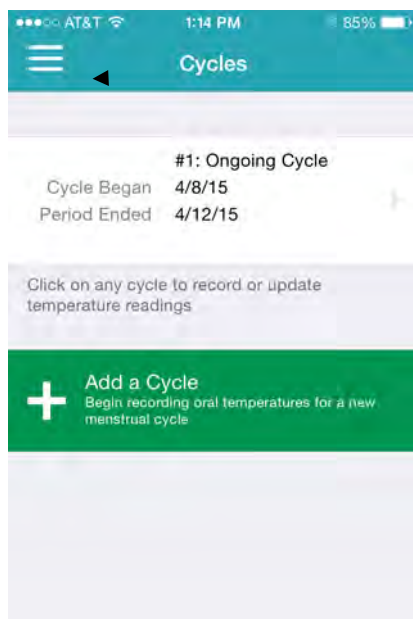
- On the day your period ends, next to 'Period Ended', Tap on 'Add Date' to enter the day.



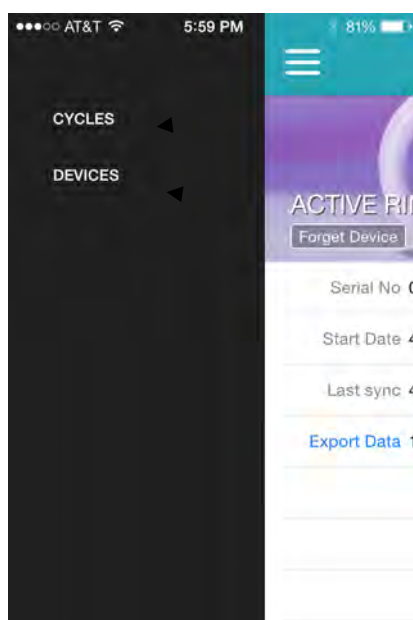
- Select a date and Tap on 'Save'

Main Menu

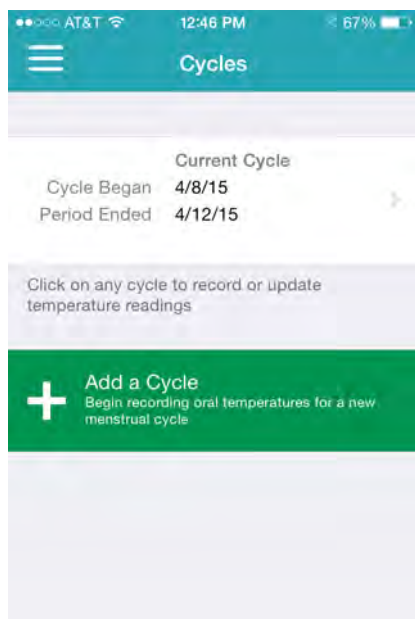
- Tap on Main Menu – the 3 small lines in the upper left of the app screen.
- Click on 'Cycles' to monitor your current and previous cycles.



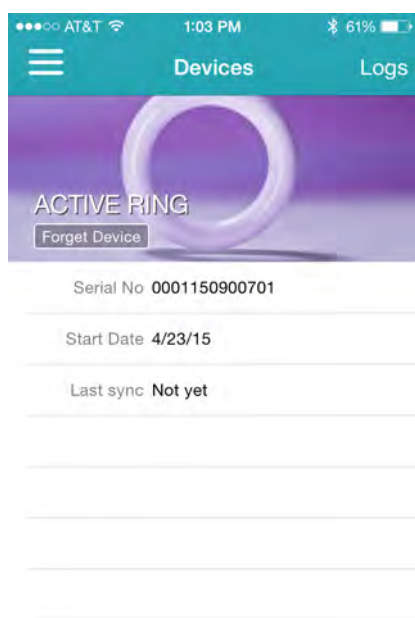
- Tap on Main Menu



- Tap on 'Cycles' to go to Cycles Screen
- Tap on 'Devices' to go to Device Screen



Cycles Screen



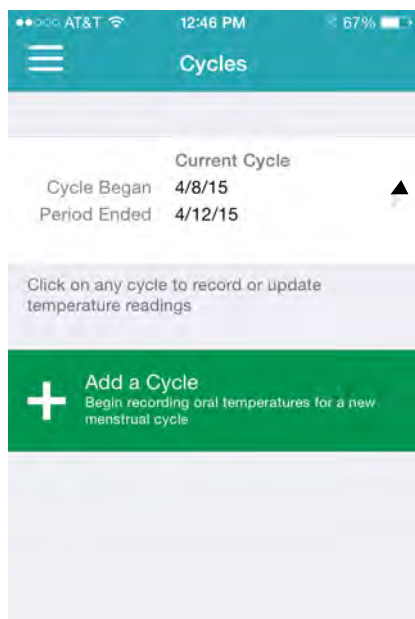
Device Screen

My Diary Screen

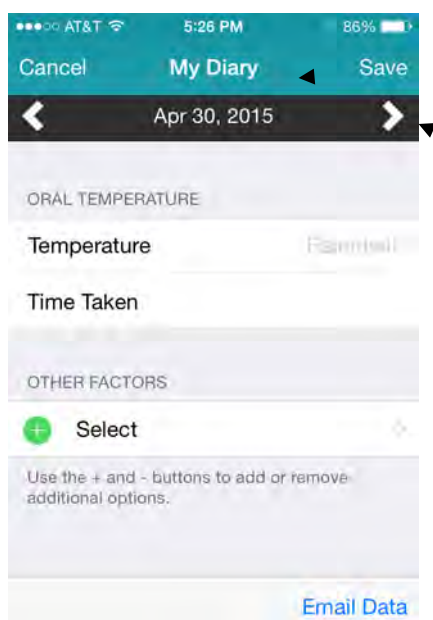
Tap on 'Current Cycle'.

Program will take you to 'My Diary' screen.

To navigate from day to day, Tap on the date bar under 'My Diary'.



- Tap on 'Current Cycle' to see the 'My Diary' screen.



- My Diary Screen
- Tap on Date to navigate from day to day.

ORAL TEMPERATURE MEASUREMENT AND RECORDING INSTRUCTIONS

Some important guidelines to follow:

- Start measuring your oral temperature on day one of your period (the first day of bleeding or spotting is the first day of your cycle (Cycle Day 1)) and stop the first day of your next period. This is the length of your cycle.
- Place the thermometer and iPod/iPhone with TEMPURING App next to your bedside before you go to sleep.

- Set an alarm to wake you at the same time every morning. The time you took your temperature is important for the analysis – be sure to record this in the App (under My Diary).
- *It is important to take your temperature ***every morning at the same time.**** Record your temperature as soon as you take it.
- Take your temperature as soon as you wake up, before doing anything: **DO NOT** stand up, walk around or go to the bathroom, eat anything, drink anything, or engage in any kind of activity until after you have taken your oral temperature.
- Use the oral digital thermometer provided for this study. If it stops working, or you lose it, or you use a new one, make a note of it in the **Factors** section in your APP.

Recording Your Oral Temperature and the Time You Took Your Temperature

Tap on 'Current Cycle'.

Program will take you to 'My Diary' screen.

- Tap on 'Fahrenheit' Next to Temperature and record the oral temperature. Record the temperature to the tenths decimal place (record 97.0 rather than 97).
- Tap next to 'Time Taken' and select the time you took your temperature; e.g. if you take your temperature at 6:30 am, select 6:30 am.

You will also record Factors that may influence your core body temperature for that day – see next section below.

The screenshot shows a mobile app interface titled 'My Diary' with a teal header. Below the header is a date selector showing 'Apr 30, 2015'. The main content area is divided into two sections. The first section, 'ORAL TEMPERATURE', has a light blue background and contains two input fields: 'Temperature' with a 'Fahrenheit' unit selector and a 'Time Taken' field. The second section, 'OTHER FACTORS', also has a light blue background and features a green '+' button labeled 'Select' and a note: 'Use the + and - buttons to add or remove additional options.' At the bottom right of the screen is a blue button labeled 'Email Data'.

- Tap on 'Temperature' to record the oral temperature.
- Tap on 'Time Taken' to select the time you took your oral temperature.

- Select the time you took your oral temperature. Select 'AM.'
- ✓ Tap on 'Time Taken' again.

▪ Tap on 'Save'

FACTOR INSTRUCTIONS

There are certain factors that can influence your temperature. These Factors should be noted in the App.

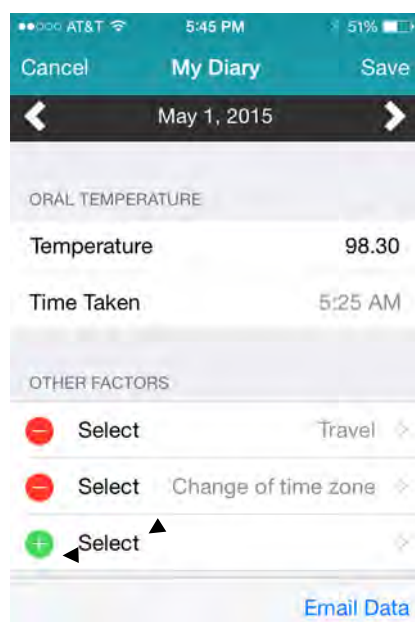
Tap on 'Current Cycle'.

Program will take you to 'My Diary' screen:

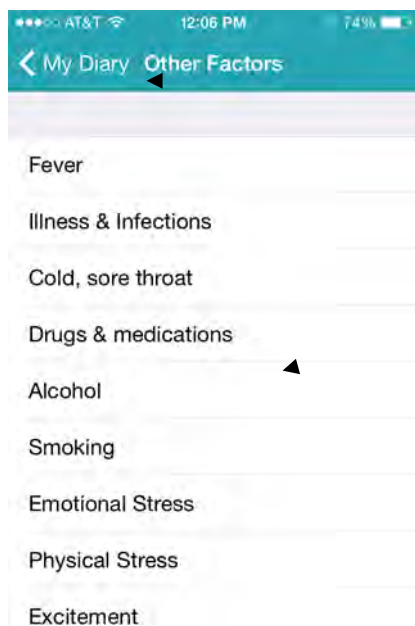
- If you were exposed to any factors during the day and/or night of your oral temperature recording, tap on 'Factors' to select a factor that you were exposed to.
- If you were exposed to more than one factor, Tap on the '+' to add additional factors that you were exposed.

Factor Table	
Number	Factors May Influence Your Oral Temperature
1	Fever
2	Illness and infections (even those that do not produce a fever)
3	Cold, sore throat
4	Drugs and medications
5	Alcohol (especially in large quantities, though all alcohol consumption should be recorded)
6	Smoking
7	Emotional stress
8	Physical stress
9	Excitement

Factor Table	
Number	Factors May Influence Your Oral Temperature
10	Change in waking time
11	Jet lag
12	Travel
13	Change time zone
14	Change of climate
15	Sleep disturbances (insomnia, night-waking, upsetting dreams, poor sleep)
16	Use of electric blanket
17	Change of room temperature
18	New thermometer
19	Hot tubs
20	Suana
21	Bikram yoga
22	Other



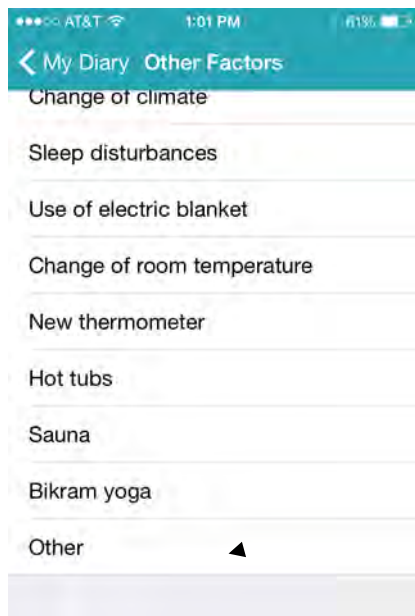
- Tap on 'Select' to select the factor.
- You can add more than one factor.
- Tap on the '+' to add additional factors that you were exposed to.



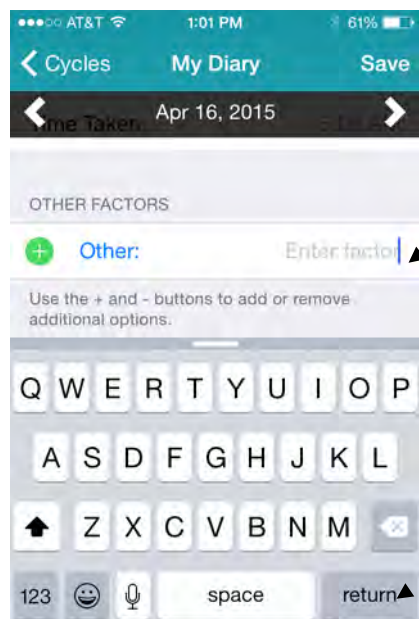
- Screen with the list of all factors will appear.
- Tap on the Factor that you were exposed to.
- Tap on 'My Diary' to return to My Diary Screen. The App will save your selection.

If a factor that you were exposed to is not listed in the list of Factors, you can enter a new factor.

- In the list of Factors, Tap on 'other'.
- Enter Factor you were exposed to.



- Tap on 'Other'



- Enter the factor that you were exposed to.

- Click on 'return', the App will save the factor.

- Tap 'Save' to save your Factors.

URINARY LUTEINIZING HORMONE (LH) MEASUREMENTS AND RECORDING INSTRUCTIONS

- Use the LH detection kit provided to you for this study.
- Follow all other instructions as provided in the LH kit.
- Start on **DAY 8** of your cycle; Using the first day of bleeding or spotting as Day 1 of your period, count forward 8 days to begin LH testing. Do not wait until next cycle.
- On day 8 of your cycle, start self-testing with the LH kit twice a day, in the morning and in the evening.

Day 1 Period Starts	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8 Start LH Testing 2 Times per Day
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Record Your LH Result

Starting Day 8 of your cycle, in the App please record the following:

- 'Is LH surge detected?'

If **NO**, LH surge is not detected:

- Record the time you tested your urine.
- Continue testing at the same time twice per day.

If **YES**, the LH surge is detected:

- Turn 'LH Surge Detected' on.
- Record the time you tested your urine.
- Once your LH surge has been detected, **call your study coordinator** to schedule a visit for blood draw and ultrasound.
- There is no need for further testing during this cycle.

If you have not detected an LH surge by Day 16 of your cycle, **call your study coordinator** to schedule a follow up visit.

[Add the Study Coordinator name and phone number to call!]

Cancel My Diary Save

May 6, 2015 95.5%

Time Taken 5:18 AM

LH SURGE

LH Surge Detected ☐ LH Surge Detected - "NO"

Time of 1st test 7:00 AM Time LH tested 1st time

LH Surge Detected ☒ LH Surge Detected - "YES"

Time of 2nd test 5:09 PM Time LH tested 2nd time

OTHER FACTORS

Email Data

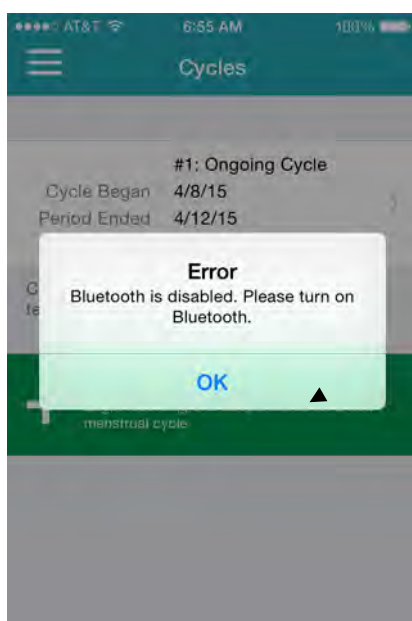
3 INSTRUCTIONS FOR TEMPURING USE

Read these '*Instructions for Use*' before you start using TEMPURING.

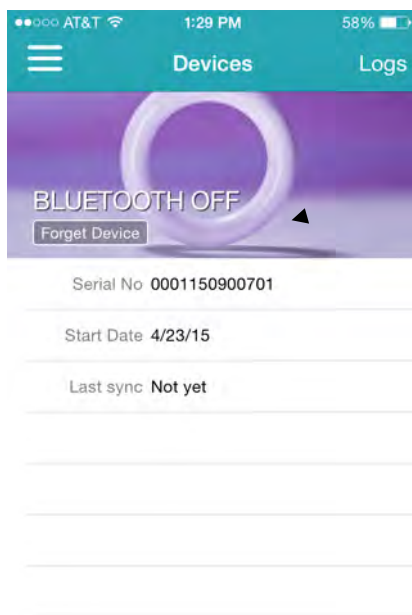
TEMPURING should be inserted on the last day of your menstrual period (i.e. the day after you stop menstrual bleeding).

Turn on Bluetooth on your iPhone/iPod

- Go to “Settings” on your iPhone/iPod.
- Turn Bluetooth ‘ON’ and **Keep it On!**
- If you disable Bluetooth, the ring will be unable to transfer the temperature data to the App.
- If you disable Bluetooth, the App will show you an ‘Error’ message and will show you ‘Bluetooth Off’ on the device screen.
- If you received ‘Bluetooth Off’ message, turn the Bluetooth ON.



Tap on 'Ok'

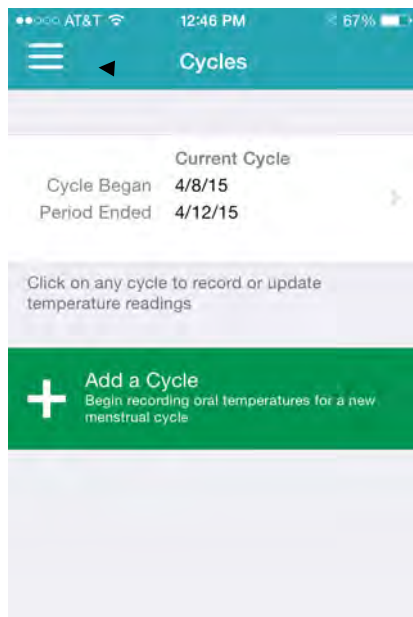


Bluetooth Off

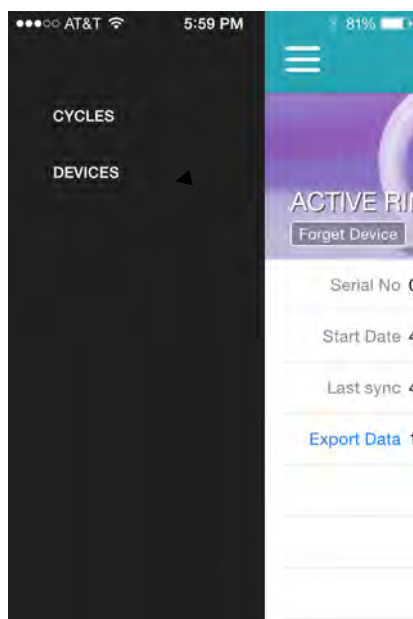
TEMPURING Pairing with iPhone/iPod

Immediately before inserting TEMPURING, you must pair (connect) it with your iPhone/iPod and activate it (turn TEMPURING on).

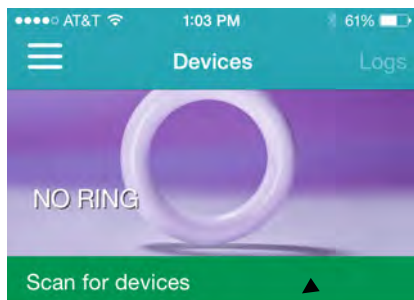
- Go to TEMPURING App on your provided iPhone/iPod (*See Device Pairing With App Screenshots below.*)
- Tap on Main Menu (three small lines in the upper left of your screen)
- Tap on 'Devices'.
- Tap on 'Scan for device'.
- The App will start scanning for device.



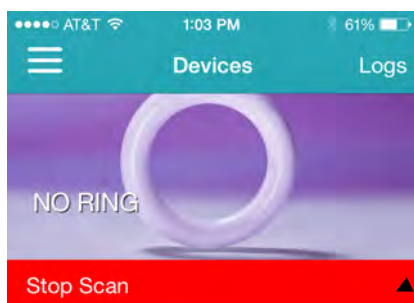
- Tap on Main Menu



- Tap on Devices



- Tap on 'Scan for devices'



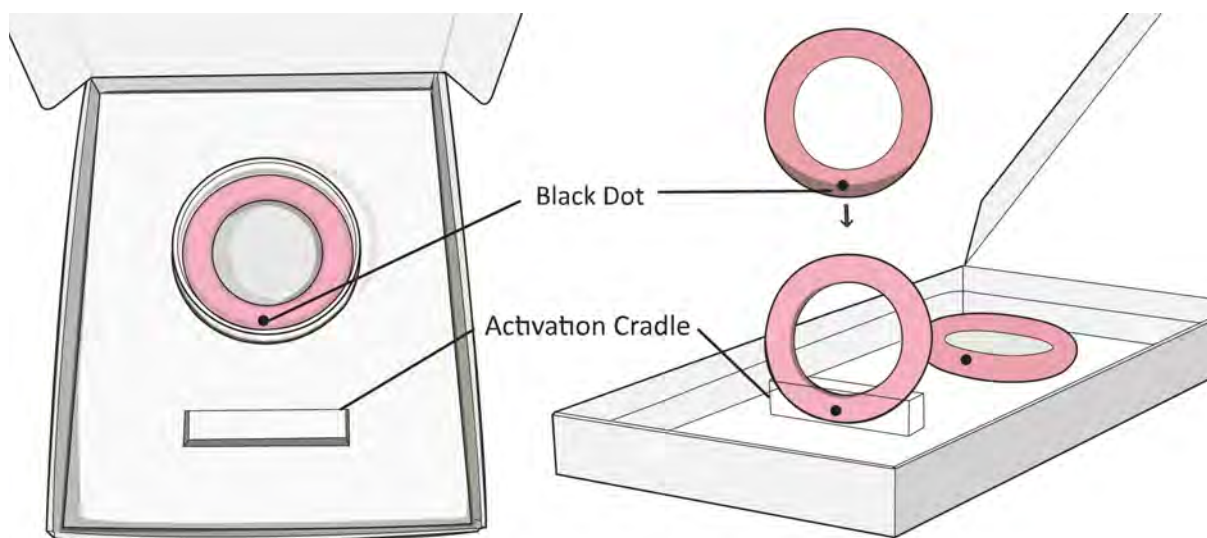
- App will start scanning for Device

TEMPURING Activation

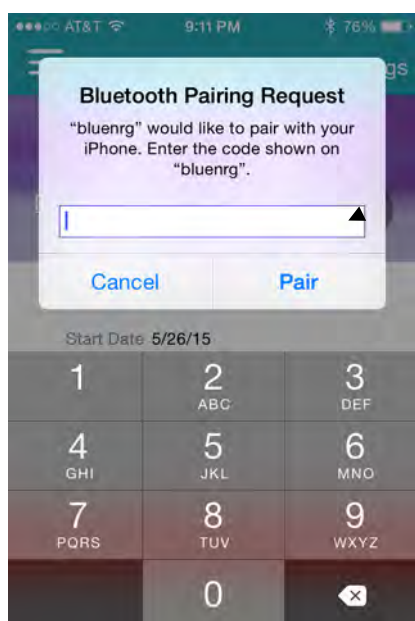
- After the App starts scanning for device, immediately open the TEMPURING box.
- **NOTE:** Save the TEMPURING box as you will be returning TEMPURING to your study coordinator in the same box when you are finished using it.
- Carefully remove TEMPURING from the package.
- Locate the BLACK DOT on TEMPURING – this marks the on/off switch.

- Place TEMPURING into the cradle with the BLACK DOT facing down (see *Turn TEMPURING ON* image below.)

Turn TEMPURING ON

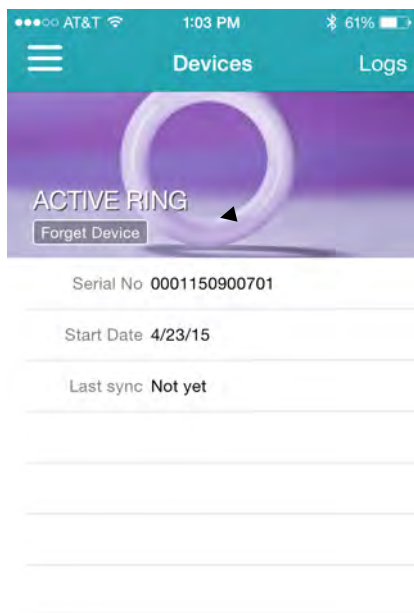


- The App will automatically enter 'Pairing Mode'.
- The App will ask you to enter the code. **Enter 1.**
- Tap on Pair.



Enter 1

- Once TEMPURING and iPhone/iPod are paired, the message 'Active Ring' will appear.
- The App will ask you for permission to send you notifications.
- Click 'Ok'.
- Take TEMPURING out off the cradle.



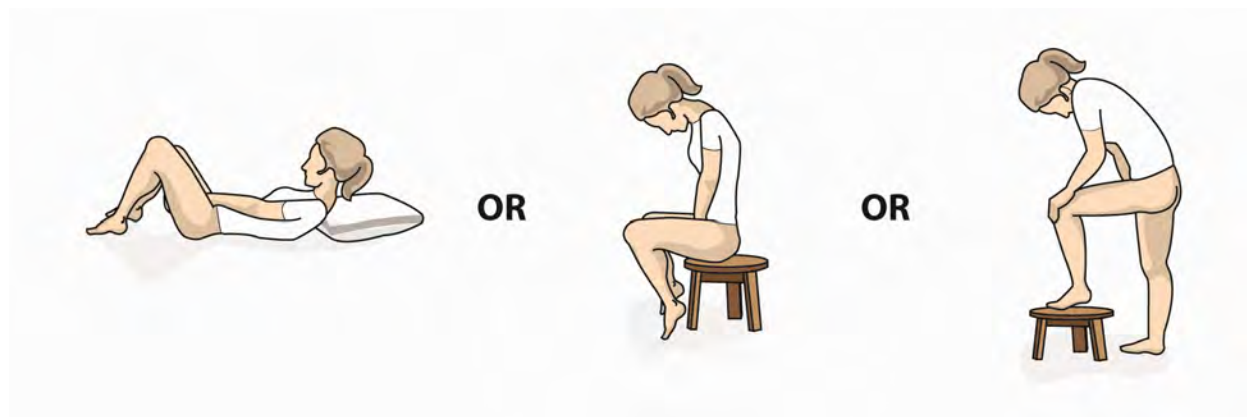
- Once the Ring is activated, the message 'Active Ring' will appear.

Inserting TEMPURING

- TEMPURING should be inserted into the vagina on **the day after menstruation ends** (when your menstrual bleeding has ended).

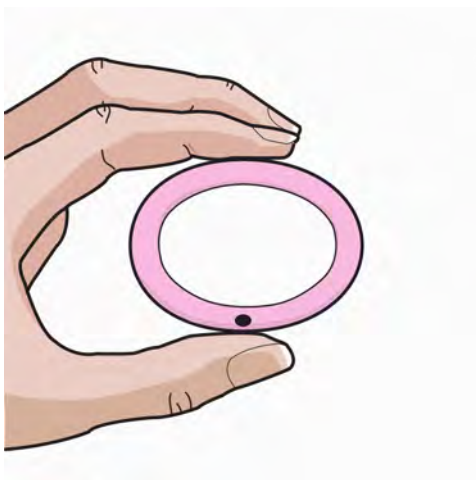
Step 1. Choose a position for insertion of TEMPURING

- You can choose whichever position is most comfortable for you. For example, standing with one leg up on a chair, or lying down, or squatting (see *Figure below*).



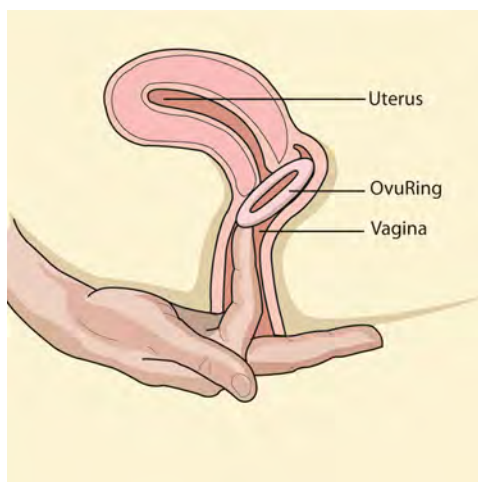
Step 2. Prepare TEMPURING for insertion

- Prior inserting TEMPURING, wash and dry your hands.
- Place one finger near the black dot (the on/off switch) and the other finger on the other side of the ring.
- Gently press on the ring to make it lightly folded (an oval shape).



Step 3. Insert TEMPURING into your vagina

- Insert the folded TEMPURING into your vagina and gently push it further up into your vagina using your index or middle finger.
- If you find that TEMPURING is “dry” to insert, apply a very small amount of standard water-based lubricant for vaginal use or fertility-friendly lubricant such as Pre-seed®. DO NOT use gels with warming or cooling additives.
- TEMPURING may move around slightly in your vagina. This is normal.

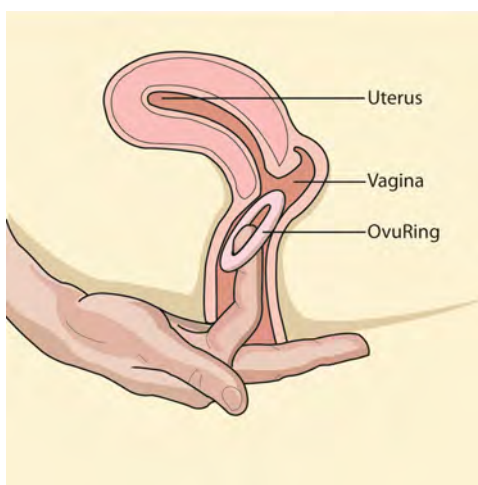


- If you feel discomfort, TEMPURING is probably not fully inserted. Just use your finger to gently push TEMPURING further into your vagina.

Step 4. Removing TEMPURING

TEMPURING should remain inserted from the last day of the menstrual cycle until the start of your next menstrual cycle (first day of your menstrual bleeding). Before removing TEMPURING, wash and dry your hands.

- 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 above images, step 1*).
- Put your index or middle finger into your vagina and hook it through TEMPURING.
- Gently pull downward to remove TEMPURING.



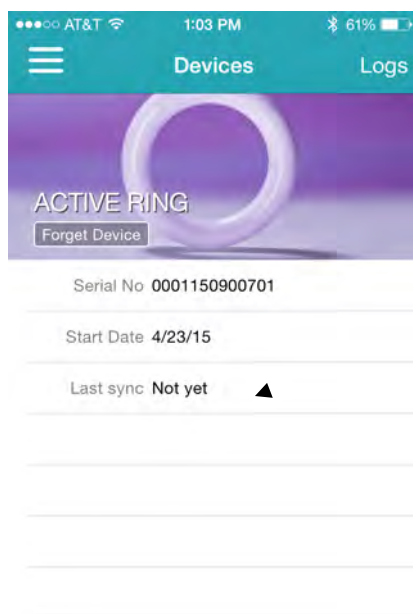
Step 5. Used TEMPURING

- Wash your used TEMPURING with soap and cool to warm water and dry it.
- Place TEMPURING in the box that it was provided in.
- Bring your used TEMPURING to your study doctor.
- DO NOT throw TEMPURING in the trash or toilet.

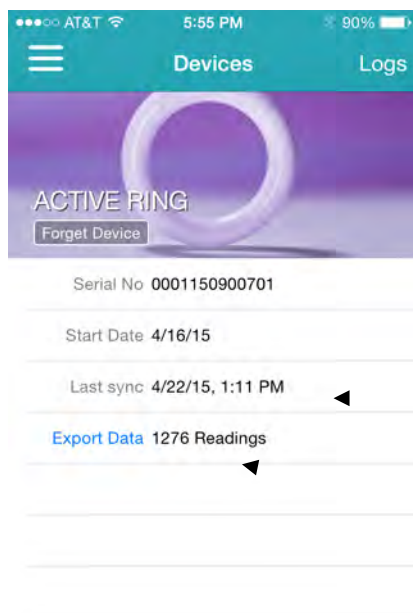
4 TEMPERATURE DATA TRANSFER

- It will take about 3-4 hours for the first temperature transfer to take place as TEMPURING warms to your body temperature.
- Do NOT 'kill' (turn off) your App.
- As soon as the data transfer is complete, you will see near Last Sync "Date and Time" when the data were transferred and the 'Export Data' text will appear (see *Data Transfer Screenshots below*).

Data Transfer Screenshots



- Last sync 'Not yet'



- After the initial 3 - 4 hours after activation and insertion, 'Last sync' will show 'Date and Time'.
- Once the Data are transferred, the 'Export Data' text will appear

5 TEMPERATURE DATA SENT TO YOUR IPOD/IPHONE

- It is best to keep your iPod/iPhone within 8 feet of you as often as possible so the temperature data from the TEMPURING can be easily transmitted to your App.
- If you are separated from your iPod/iPhone by a range of 8 feet or more, the temperature data may not be transferred to your iPod/iPhone.
- However, the data **will be transmitted the next time** you are within range of your iPod/iPhone if it is within 2-3 days.
- If you have not received a successful data transmission in 24 hours, you will receive an alert on your App. *Please refer to notification section below.*

6 REPORTS TO SPONSOR

You will be asked to export / email three (3) sets of data from your app to the Study Sponsor on a weekly basis: the 'My Diary' report, the 'TEMPURING temperature data' report, and the TEMPURING Logs.

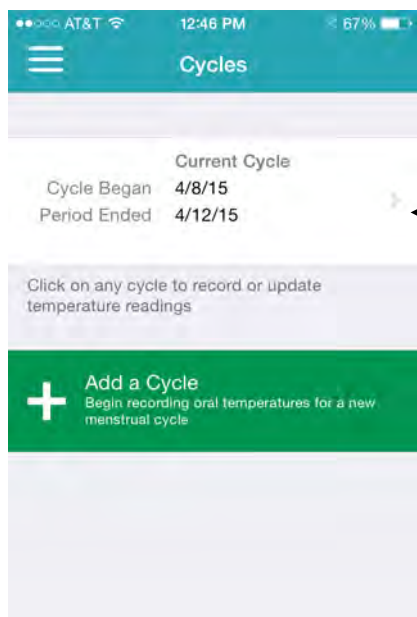
'My Diary' Data Reports (1)

You will be expected to export and email **My Diary** weekly to your study sponsor.

The study coordinator or study nurse will review and export all your cycle data in **My Diary** and will email this Report to the study sponsor at the end of each cycle visit.

To export My Diary Report:

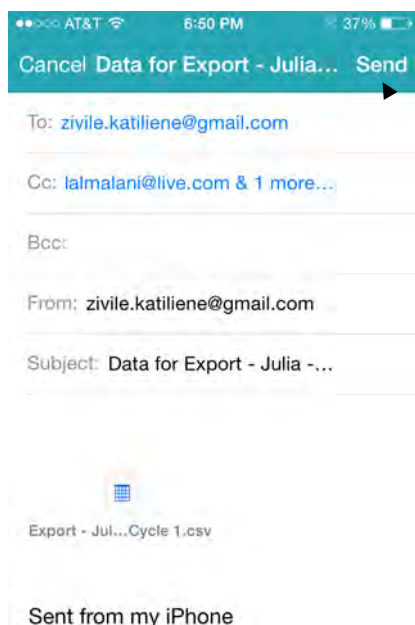
- Tap on Main Menu
- Tap on 'Cycles'
- Tap on 'Current Cycle'
- Tap on 'Email Data' at the bottom of the screen
- The App will open up an email screen
- Tap on 'Send'
- The App will send the email to the study sponsor



- Tap on 'Current Cycle'



- Tap on 'Email Data'



- An email screen will appear.
- Tap on 'Send.' The App will email your Diary Data to Sponsor.

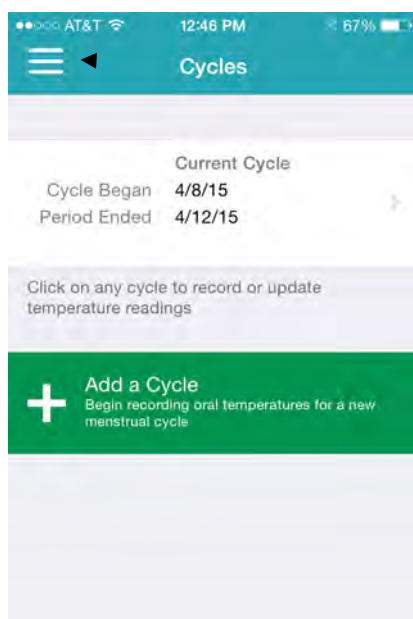
TempuRing Temperature Data Reports (2)

You will be expected to export and email **TEMPURING temperature data** weekly to your study sponsor.

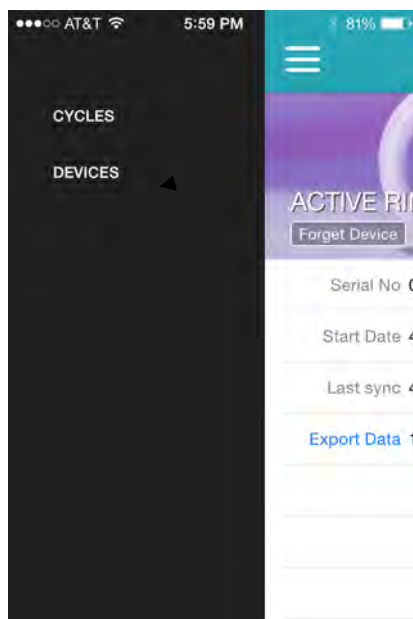
The study coordinator or study nurse will email all your **TempuRing Temperature Data** to the study sponsor at the end of each cycle visit.

To email TempuRing Temperature Data to Sponsor:

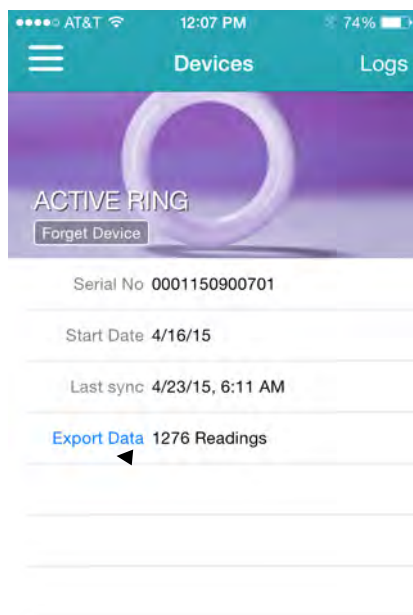
- Tap on Main Menu
- Tap on 'Device'
- Tap on 'Export Data'
- The App will open up an email screen
- Tap on 'Send'
- The App will send the email to the study sponsor



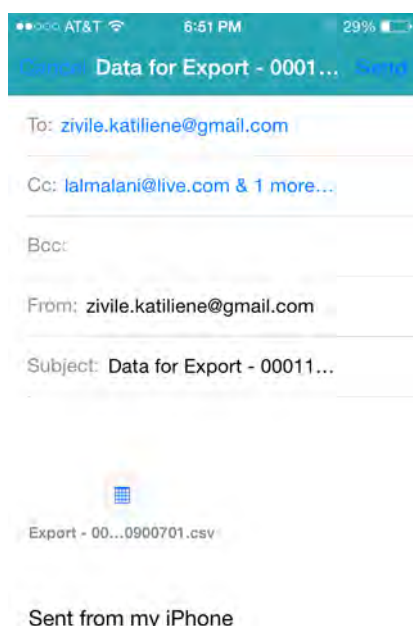
- Tap on Main Menu



- Tap on Devices



- Tab on 'Export Data'



- An email screen will appear.
- Tap on 'Send.' The App will email your Temperature data to Sponsor.

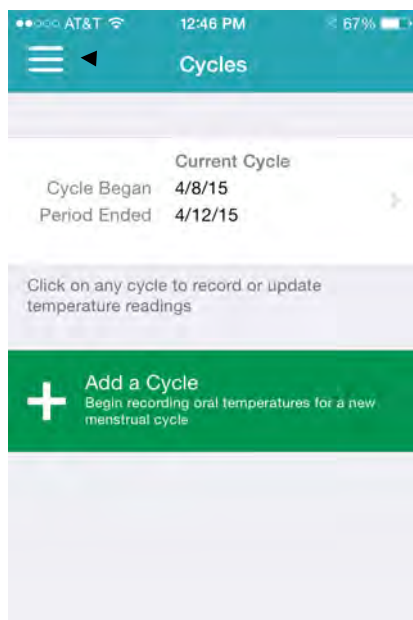
TempuRing App Logs Reports (3)

You will be expected to export and email **TEMPURING App Data Logs** weekly to your study sponsor.

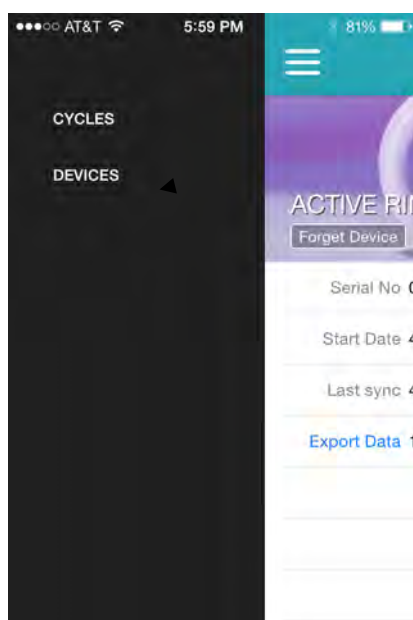
The study coordinator or study nurse will review, export, and email all your **TempuRing App Data Logs** to the study sponsor at the end of each cycle visit.

To email TempuRing Data Logs to Sponsor:

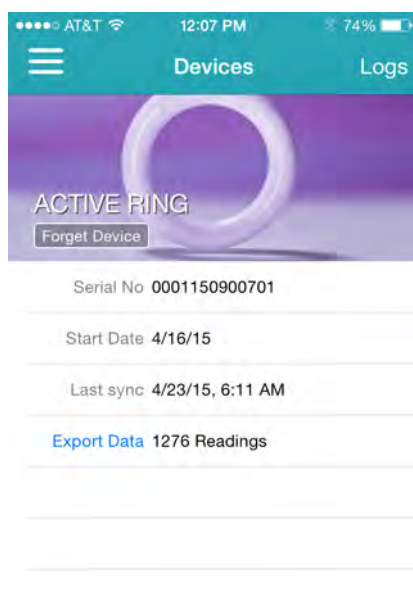
- Tap on Main Menu
- Tap on 'Device'
- Tap on 'Logs'
- The App will open up an email screen
- Tap on 'Send'
- The App will send the email to the study sponsor



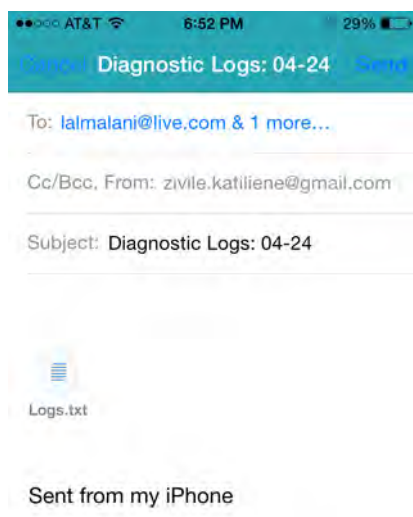
Tap on Main Menu



Tap on Devices



- To email Logs, Tap on 'Logs'



- An email Screen will appear.
- Tap on 'Send.' The App will email Logs to Sponsor.

Multiple Devices

The TEMPURING App can only communicate with one ring at a time.

To add a new ring to the App, you must first 'forget' the currently active ring.

This can be done by:

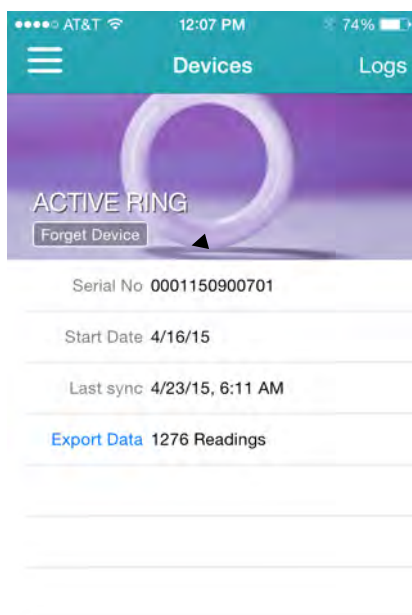
- Tap on Main Menu
- Tap on 'Device'
- Tap on 'Forget Device'

- To activate the new device, please refer to TEMPURING Pairing and Activation with iPhone/iPod section above.

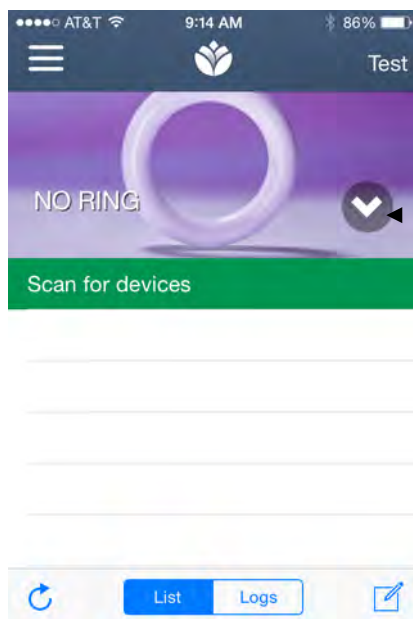
Only after you have used multiple rings, you will be able to see data from the previous TEMPURINGS.

If you need to export the collected data from previously-used rings:

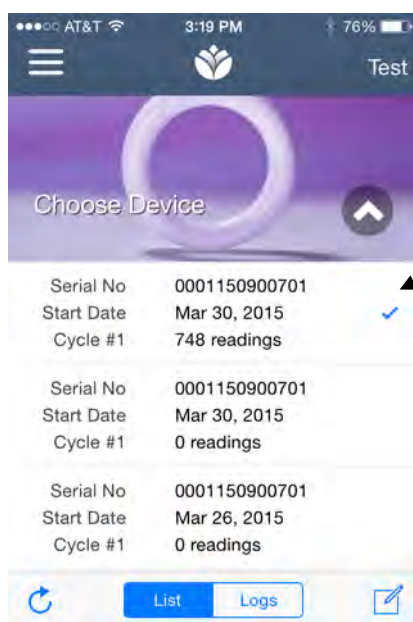
- Tap the 'Down Arrow' and switch between devices.
- The ring that you are currently looking at will have a checkmark next to it.
- Tap on the ring that you want to export the data.



- Tap on 'Forget Device'



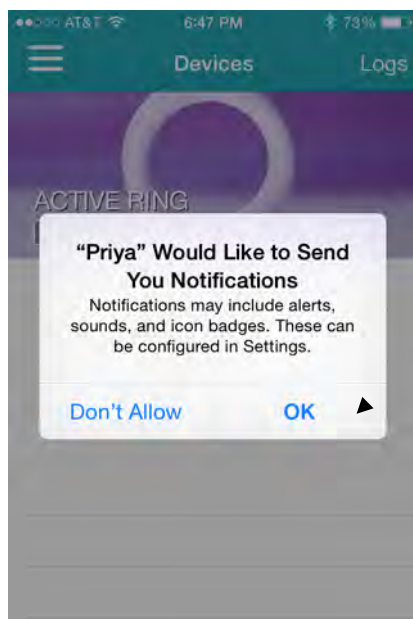
- Tap on 'Down Arrow'



- The ring that you are currently looking at will have a checkmark next to it.
- Tap on the ring that you want to export the data.

Notifications

- Once you successfully connect a ring to the App for the first time, the App will ask you for permission to send you notifications.
- Select 'OK'.
- The App alerts you when you have **NOT** had a successful temperature transmission in 24 hours. The alert will display the alert, "Your device has not synced in 24 hours."



Tap on OK

7 FAQs:

How should I Use TEMPURING?

- Read the ***Instructions for TEMPURING Use*** for detailed instructions about the right way to use TEMPURING.

How do I wear TEMPURING?

- TEMPURING is for vaginal use only.

What if I don't use TEMPURING for the whole time period?

- You may stop using TEMPURING whenever you wish. Please contact your study coordinator if you do stop using TEMPURING.

How long should I wear TEMPURING?

- TEMPURING is used in 4 week cycles (approximately 28 Days).
- Once you have inserted TEMPURING, it should not be removed, stored, and then used again for later cycles.
- After activation, TEMPURING will only remain active for one cycle – approximately 28 Days. It cannot be turned off then turned on again.

- If TEMPURING has been left inside your vagina for more than 4 weeks (approximately 28 days), TEMPURING will be deactivated and will no longer collect or transmit temperature recordings. The TEMPURING App will alert you that it is time to remove TEMPURING.
- If TEMPURING has been out of your vagina more than one day, you may not receive accurate temperature readings.
- Do not use more than one (1) TEMPURING ring at a time.

How Should I clean TEMPURING

- The TEMPURING ring is provided clean.
- DO NOT clean TEMPURING in disinfectants or alcohol, or with antibacterial or disinfectant wipes.
- If you need to wash the TEMPURING, wash it with a mild, unscented, hand soap (Ivory hand soap) for 30 seconds and then rinse in warm water for 30 seconds (*please refer to section Expulsion and Partner Discomfort below.*)

Can I sterilize TEMPURING using sterilizing solutions?

- No. TEMPURING material is designed from specific biocompatible materials that prevent the growth of bacteria, and simple washing with soap and water is sufficient to maintain this material properly. Use of sterilizing solutions, alcohol wipes or sanitizing gels may damage the ring material.

What are the restrictions on using birth control, yeast infection treatments, and tampons while using TEMPURING?

- While using TEMPURING, you should not use a vaginal diaphragm as a method for birth control because TEMPURING may interfere with the correct placement and position of a diaphragm.
- Use of spermicides will not stop TEMPURING from working.
- You should not be wearing TEMPURING during your menstrual bleeding, so tampons will not be used at the same time that you are wearing TEMPURING.
- If you are undergoing treatment for a yeast infection or an STI, you should not use TEMPURING. If you suspect you have an infection or condition, you should stop using the TEMPURING and consult your study coordinator immediately. Wait until all symptoms have cleared and treatment finished before starting to use TEMPURING again.

What are the possible side effects of TEMPURING?

TEMPURING is made of the highest medical grade materials already used in a number of other approved medical devices. In addition, TEMPURING has undergone extensive biocompatibility and toxicity testing and passed all of these tests. It therefore should cause no irritation, and nor should it increase the chances of infection. If you notice any signs of irritation or infection, you should stop using TEMPURING and contact your study coordinator immediately.

TEMPURING 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.

Talk to your healthcare provider about any side effects. The possible side effects of TEMPURING may include:

Vaginal Infection

Vaginal infections should be treated with appropriate antimicrobial therapy before initiation of TEMPURING. If a vaginal infection develops during use of TEMPURING, then TEMPURING should be removed and reinserted only after the infection has been appropriately treated.

Ring Removal Difficulty

In rare occasions, the ring may adhere to the vaginal wall, making ring 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 ring out and not replacing it until healing is complete in order to prevent the ring from adhering to the healing tissue.

Toxic Shock Syndrome (TSS)

Although TEMPURING is not made of highly-absorbable material, Toxic Shock Syndrome is a rare condition caused by the bacterium *Staphylococcus aureus* growing on blood or fluids in the vagina. Some of the symptoms are much the same as the flu, but they can become serious. STOP using TEMPURING immediately and call your healthcare provider right away if you have the following symptoms:

- sudden high fever (above 102°F or 39°C)
- muscle aches
- vomiting
- a sunburn-like rash
- diarrhea
- dizziness
- fainting or feeling faint when standing up

Expulsion

- TEMPURING can be accidentally expelled, for example during intercourse, or with straining during a bowel movement. TEMPURING should be left in the vagina for a continuous period of 28 Days. If the ring is accidentally expelled,

wash the TEMPURING with mild, unscented, hand soap (Ivory hand soap) for 30 seconds and then rinse in warm water for 30 seconds (*See Steps 1 through 3 above*).

Partner Discomfort

If your partner experiences any discomfort from TEMPURING (e.g. penis discomfort or irritation), TEMPURING can be removed during intercourse and reinserted after intercourse. If the ring was removed during intercourse wash the TEMPURING with mild, unscented, hand soap (Ivory hand soap) for 30 seconds and then rinse in warm water for 30 seconds, and insert it again right away after intercourse (*See Steps 1 through 3 above*).

Tampon Use

You should not be wearing TEMPURING during your menstrual period, so tampon use should not take place at the same time that you're wearing TEMPURING ring.

Other Possible Side Effects

- Foreign body sensation,
- Tissue irritation inside your vagina or cervix,
- Vaginal discharge,
- Vaginal discomfort,

These are not all the possible side effects of TEMPURING. Tell your study coordinator about any side effects.

How should I store TEMPURING?

- Store TEMPURING at room temperature between 68-122° Fahrenheit (20 – 50° Celsius).
- Store TEMPURING for up to 2 years after you receive it.
- The TEMPURING App contains information about TEMPURING battery life, and informs you if the battery has expired.
- TEMPURING will record your temperatures between 94.1-104.9° Fahrenheit (34.5C - 40.5° Celsius).
- DO NOT expose TEMPURING to temperatures above 122° Fahrenheit (such as boiling hot water).
- Keep TEMPURING out of the reach of children.

How is TEMPURING Supplied?

- Each TEMPURING Ring is individually packaged in a TEMPURING box, with a User Manual included.

What if I miss my regularly scheduled period when using TEMPURING?

- Consider the possibility that you may be pregnant. Consider a visit with your healthcare provider for a pregnancy checkup.

Can I have sexual intercourse while wearing TEMPURING?

- The use of TEMPURING should not prevent you from having sex as frequently as you wish.
- Having sex will not affect the temperature recordings or recordings.
- You DO NOT need to remove TEMPURING before sex.
- **Note:** if either you or your partner finds that intercourse with TEMPURING is uncomfortable, you may remove TEMPURING during intercourse and reinsert it after intercourse. Wash the TEMPURING with mild, unscented, hand soap (Ivory hand soap) for 30 seconds and then rinse in warm water for 30 seconds and insert it again right away (*See Steps 1 through 3*).

Can I started using TEMPURING later and not on the first day after my period stopped?

- No. Wait for next cycle.
- To prevent loss of continues temperature monitoring efficacy, you should not deviate from the recommended regimen.
- Ideally, TEMPURING should be left in the vagina for a continuous period of 28 days.

What should I do if TEMPURING is damaged or lost?

- If your TEMPURING is not working or is damaged, you should contact your study coordinator to receive a new TEMPURING.
- Bring your used TEMPURING to your doctor's visit.

Can I give TEMPURING to a friend?

- No. The ring is for your personal use. Sharing it with other women may present a hygiene risk, and will invalidate your personal data.