

Instructions for Participating in the Ventos-LOAM Validation Study

Study Procedures Overview

- As a participant, you will wear Ventos for approximately 22 hours during each wear session, beginning Tuesday morning and ending Wednesday morning, and again beginning Saturday morning and ending Sunday morning, for five consecutive weeks (ten wear sessions total). On each Tuesday and Saturday morning, shortly after waking up, fully charge Ventos, start a challenge in the app, and then snap the device to your underwear and wear it continuously throughout the day and overnight while you sleep. The next morning, remove Ventos, plug in the Ventos and upload data.
- You may go about your normal routine on each wear day. However, do not wear the device in situations where it may be unsafe or could be damaged, such as during airport security screening, swimming, showering, or strenuous exercise.

Contents of Ventos Kit

To participate in this study, you will be mailed a package with all the required items.

Your package will include:

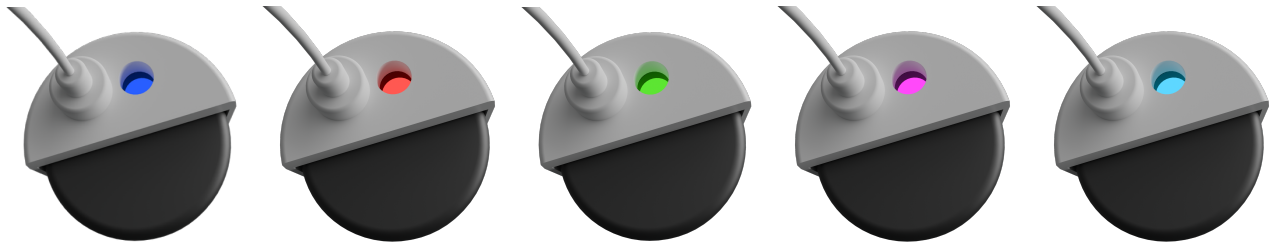
1. Getting Started Card
2. One Ventos
3. Four snaps for attachment of Ventos
4. One magnetic charger cradle with a USB-A end
5. One USB-A charging block
6. Alcohol hand wipes to clean Ventos

Ventos

What is Ventos?

Ventos is a small, discreet device that easily attaches to regular underwear to help understand gut health by analyzing intestinal gas patterns. Similar to how a fitness tracker monitors heart rate and movement, this device monitors natural gas release patterns throughout the day to provide insights into digestive health and the activity of gut microbes. Ventos is designed to be comfortable during routine activities, using sensors that measure different aspects of intestinal gas, along with temperature and movement, to ensure accurate readings. Made with skin-safe materials, Ventos attaches to regular underwear and aims to help identify digestive conditions like lactose intolerance by monitoring changes in gas patterns after consuming certain foods.

Status LED Code Colors



Blinking Blue: Occurs once when Ventos is plugged in.

Blinking Red: Occurs every second when Ventos is charging.

Solid Green: Charging complete. Ventos is ready to wear.

Blinking Purple: Occurs every five seconds when Ventos is measuring.

Blinking Sky-Blue: Occurs every second when Ventos is transferring data via Bluetooth.

Charging Ventos

1. Insert Ventos into the charging cradle

Ventos uses a magnetic charging cradle.

- Place Ventos into the semicircular charging cradle, aligning its status LED with the cradle's LED opening. Once aligned, the magnetic contacts will snap into place, and charging will start automatically.
- For an animated rendering of this process, visit flatus.info/charging.

2. Plug the cable into a power source

The charging cable ends in a USB-A connector, which fits into the USB-A charging block provided to you. Plug this into any outlet.

3. Check the status LED

- Once connected to power, the status LED will flash **blue**, indicating that the device is powered on.
- While charging, the status LED will blink **red**. A full charge usually takes about **15 minutes** if the battery is fully drained.
- When the status LED turns solid **green**, the device is fully charged and ready to wear.

4. Wait until the status LED turns solid green before starting a challenge and attaching Ventos to your underwear

If your Ventos is not charging as expected, follow the steps outlined in the **Charging Troubleshooting** section on page 13 of this document.

If You Need a New Ventos

If you need to request a new Ventos for any reason (it is damaged, hot to the touch, lost, etc), please contact Alethios.

The Ventos App

You will do most of your study activities through the Ventos app. This is where you will transfer data from your Ventos. The app has built-in instructions to walk you through each step.

Getting Started With the Ventos app

1. Download the Ventos app

- The Ventos app is available for iOS and Android devices. Scan the QR code on the Getting Started Card included in your Ventos box to be taken to the App Store or Google Play store. Alternatively, you can search for the app manually by searching for “Ventos” in the iOS App Store or Google Play store.

2. Accept the required permissions

- When you open the app for the first time, you may be asked to accept notification, Bluetooth, camera, and file permissions. Please accept them all.

3. Enter your Participant ID

- The quickest way is to scan the same QR code on the Getting Started Card from your Ventos box again from inside the app.
- Alternatively, the Participant ID is written under the QR code on the Getting Started Card and you can enter it manually.

4. When you are ready to start the study protocol

- Charge your Ventos until the LED indicator is solid green.
- Keep it plugged in during connection.
- In the app, select **Start Challenge**.
- Ventos will connect automatically. If the connection fails, tap **Cancel**, ensure the LED is green, and retry.

Note: There is a function in the Ventos app to upload food photos. Food logging isn't required during this study. Please do not photograph your food.

Wear Day Activities for the Ventos- LOAM Validation Study Protocol

Start a Wear Session

1. Ensure that your Ventos is charged – the status LED should be solid green.
2. In the Ventos app, press Start Challenge (while Ventos is still plugged in).
3. After you press Start Challenge, a countdown will appear. You will be able to transfer your data after this countdown has completed.
4. To confirm that Ventos has entered measuring mode, check that the status LED flashes purple once every 5 seconds.
5. Attach Ventos by following the instructions below.

Snap Ventos to Your Underwear

Participants typically attach Ventos in the morning when getting dressed.

Please follow these step-by-step instructions to attach Ventos securely to your underwear.

1. Start with the default snap

- Your kit includes two snaps in different sizes for different underwear thicknesses: a default snap for thin underwear and an alternative snap for thick underwear.
 - Start with the default snap.
 - You will only need to use the alternative snap if you have thick underwear fabric.

2. Snap Ventos to the outside of your underwear

- You can attach Ventos before putting on your underwear.
- Place Ventos in the middle of the crotch area, between your legs towards your bottom.
- The snap goes inside the underwear, and Ventos goes on the outside of the underwear.
- Sandwich your underwear between the snap and Ventos case.
- Secure the snap into the hole in Ventos case. You will not hear a "snap" sound.
- Gently shake your underwear to make sure Ventos is secure.
- If you can not get the default snap into the snap hole at all, it is too tight. Try the alternative snap.

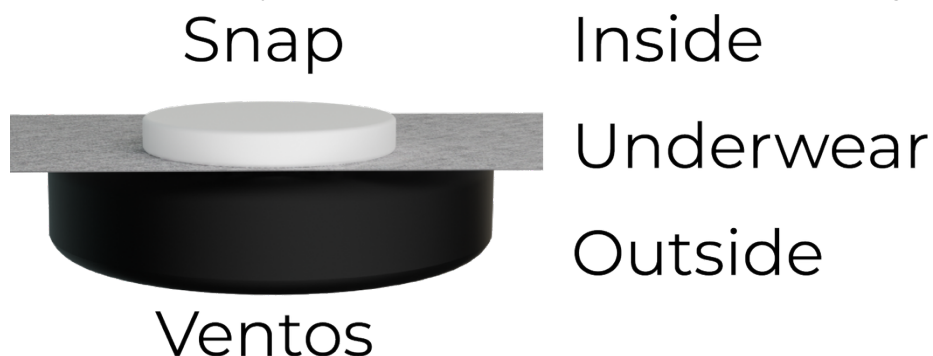
3. Check Ventos position

- Carefully sit down in a chair and see if Ventos is uncomfortable.
- If you feel like you are sitting directly on Ventos, we recommend repositioning the device “lower” in the crotch area between your legs.
- Most people have found a position that is comfortable enough that they forget they are wearing Ventos. Please try repositioning the device until you find a comfortable spot.
- Refer to the pictures above for correct positioning.



Transfer the Data (After Wearing For the Day)

1. After wearing Ventos overnight, remove it the following morning and open the Ventos app on your phone **with Bluetooth on and with access to the internet**.
2. Connect Ventos to the charger.
3. Click on “Transfer Data” on the Ventos app. Under “Choose a device”, select your Ventos. If you do not see your Ventos, this may be due to it not being connected to the charger.
4. Wait for the data to be completely transferred to the server. There will be a loading screen for pairing



Ventos, followed by another loading screen for transferring the data. You should see a blinking **sky-blue light** on your Ventos indicating the data is being transferred to the phone and the server. After this is finished, press “Okay”.

5. Disconnect the Ventos from the charger.

View Your Report

To view the report of your microbiome activity, navigate to your report page by pressing the “Results” button in the bottom right corner of the Home page. This page will include all data and graphs collected from Ventos. You will see information about your microbiome activity.

Begin a new wear session each Tuesday morning and each Saturday morning for five weeks. Each session lasts approximately 22 hours and ends the following morning (Wednesday or Sunday).

Key Things to Keep in Mind

- Each wear session lasts approximately 22 hours. Ventos should remain attached as much as possible, including overnight while you sleep, from the morning you start the session until the following morning when you remove it to charge and transfer data.
 - It is fine to remove Ventos to use the bathroom, shower, or do activities like running or strenuous exercise. Just try to wear it whenever you can.
- Ventos needs to be recharged before each wearing day until you see the status LED illuminate green.
- Do not wear the Ventos until after you have started a challenge in the app and you see the status LED flash purple every five seconds.
- When changing underwear, remember to remove the Ventos and reattach it to your clean underwear.
- Your Ventos can be cleaned with alcohol hand wipes. You could also wipe it off with a damp paper towel. Please do not use hand sanitizer on the device. Do **not** wash Ventos with water (in a sink).

Charging Troubleshooting

If your Ventos is not charging as expected, reference the following troubleshooting steps.

No Status LED Upon Insertion into the Charging Cradle

- 1. Remove and reinsert Ventos into the charging cradle**
 - Remove Ventos from the charging cradle and then reinsert it, making sure the device's LED properly aligns with the status LED hole in the charging cradle.
- 2. Check the USB connection**
 - Ensure the USB end of the cable is fully inserted into the power adapter included in your Ventos kit.
- 3. Confirm the power source**
 - Make sure the power adapter is plugged into a working outlet.

Still Blinking Red After 60 Minutes

- 1. Restart the charging process**
 - If the status LED continues blinking red after an hour, unplug the charger from both Ventos and the power source. Wait a few seconds, then reconnect everything. This can help reinitialize the charging cycle.
 - If Ventos status LED never turns green, assume that it has broken. Request a replacement from the research team following the instructions below.

If You Need a New Ventos

If you need to request a new Ventos for any reason (it is damaged, hot to the touch, lost, etc), please contact Alethios.

Additional Information About Ventos

When NOT to Wear Ventos

- Do not wear the Ventos when going through security checkpoints (Airports, Courthouses, Ports of Entry, Sporting events).
- Do not wear the Ventos in situations where it can become wet (showering, swimming, water park rides).
- Do not wear the Ventos in situations where it causes discomfort (for example, strenuous exercise).
- Do not wear Ventos if it is damaged in any way or is hot to the touch.
- Do not wear Ventos if it has been washed (for example, in a washing machine)

Safety Considerations for This Study

- Ventos is in a sealed case. Do not open the case or tamper with the device.
- Ventos could cause discomfort while walking, sitting, or sleeping. Forceful sitting or falling directly onto Ventos could cause scrapes and bruises. If Ventos causes discomfort, including during sleep, you are free to stop wearing it at any time.
- Prolonged wear may cause skin irritation, redness, chafing, or rash, especially where the snap contacts the skin. Check your skin regularly and discontinue use if symptoms occur.
- Ventos is intended to be worn overnight as part of the study protocol. Most participants find it comfortable enough to forget they are wearing it. If Ventos causes pain or significantly disrupts your sleep, you may remove it.
- Keep the Ventos away from children. The small size of the pieces presents a choking hazard. Magnets are a choking hazard. Do not swallow them, and keep the charger away from children.
- Keep Ventos away from pets.
- Extended contact with the battery during sleep is unlikely to cause harm, but discontinue use immediately if the device feels unusually warm, uncomfortable, or is damaged.
- Leakage may occur if the Ventos is crushed or abused. If Ventos is crushed or in any way visibly damaged, stop wearing it immediately and dispose of it accordingly.
- Ventos contains a rechargeable **lithium-ion battery**, which may be a hazard if it becomes damaged or ingested. Call Poison Control (1-800-222-1222) if ingested.
- The charging cradle contains magnets. Do not insert metal or other objects into the cradle and do not allow it to contact anything except Ventos, as this may cause a short circuit.
- Do not place metal inside the charger.
- Only charge Ventos with the provided charging cradle and charging block. Never charge the device with a USB hub.
- Please be sure to charge the device on a non-flammable surface and to discontinue charging if repeated sparking or unusual heat is observed.

Disposal of Ventos

Ventos contains a **lithium-ion battery** and should **not** be thrown away in regular household trash.

Please follow these steps for safe disposal:

1. Do not disassemble

- Do not attempt to open, dismantle, or remove the battery from Ventos.

2. Do not dispose of in household waste

- Because of the lithium-ion battery, Ventos must be treated as electronic waste.

3. Approved disposal only

- Dispose of Ventos at an approved e-waste or battery recycling facility, or return it to the research team if instructed.
 - Many communities offer drop-off points for batteries and electronics at local recycling centers or retail stores.

Thank you for participating in the Ventos-LOAM Validation Study!