



Patient Guide

Zmachine[®] Synergy

*20 minutes before bedtime,
begin the instructions on page 6*

About this Guide

You are advised to read and understand this entire guide before using the Zmachine Synergy.

The information in this guide has been carefully checked and is believed to be accurate. However, in the interest of continued product development, General Sleep Corporation reserves the right to make changes and improvements to this guide and to the product(s) that it describes, at any time, and without notice or obligation. If you do not understand the instructions contained in this guide, or require assistance in setting up, using, or maintaining this equipment, please contact your healthcare provider or General Sleep Corporation.

IMPORTANT: Please note that your use of the Zmachine Synergy is exclusively governed by General Sleep's Terms and Conditions located at <https://www.generalsleep.com/terms.html>, and by using the Zmachine Synergy, you hereby agree that you have read, understand and agree to be bound by General Sleep's Terms and Conditions.

Caution:

Federal Law (USA) restricts this device to sale by, or on the order of, a physician or other qualified healthcare practitioner licensed by the laws of the state in which he or she practices to use or order the use of this device.

Mailing and Shipping Address

General Sleep Corporation
26250 Euclid Avenue, Suite 709
Cleveland, OH 44132, USA

Telephone

(888) 330-4424

Website

www.generalsleep.com

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Introduction

The Zmachine® Synergy is a high technology sleep monitor developed by General Sleep Corporation. The system records signals related to your brainwave patterns, breathing, and body position during sleep. The system was designed for easy in-home use.

Indications for Use

The Zmachine® Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.

Symbol Descriptions

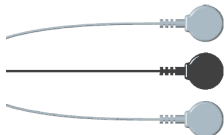
Symbol	Definition of Symbol
	Read and understand the instructions before using this system.
	This system is not rated for use in wet conditions. Keep dry.
	Federal Law (USA) restricts this device to sale by, or on the order of, a physician or other qualified healthcare practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.
	IEC 60601-1 Type BF applied parts.
	Built according to RoHS (Restriction of Use of Hazardous Substances) regulations that limit or ban specific substances in new electronic and electric equipment.
	Product tested and certified by SGS North America, Inc. to meet worldwide safety standards.

Description of Components

The Zmachine Synergy system may include some or all of the following items:



Zmachine Synergy



EEG Cable



Nasal Cannula



Effort Belt



Effort Belt Cables



Finger Probe



Sensor Pads



Alcohol Swabs



Paper Tape

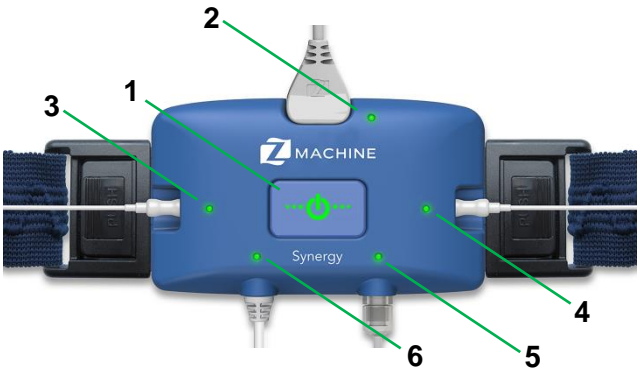


Belt Clip

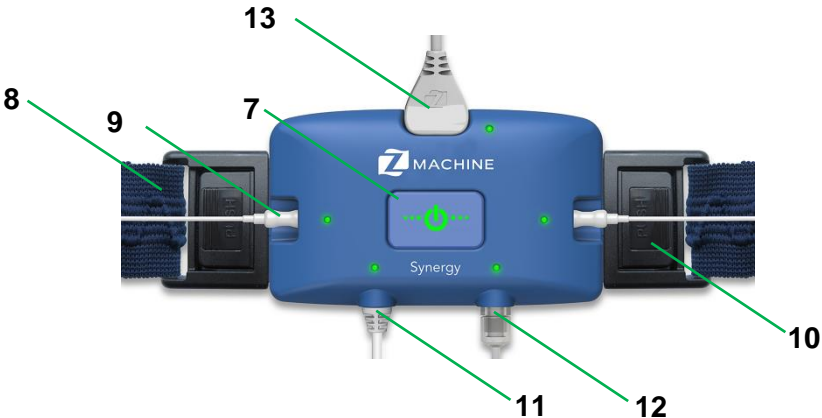
Note: The nasal cannula will not be included for CPAP studies. A CPAP Interface will be provided instead.

Note: Due to differences in brand and model numbers, part appearances may vary. Only use General Sleep approved parts and accessories.

The Zmachine Synergy Indicators & Elements



Ref.	Description	Ref.	Description
1	Main system status	4	Effort belt status
2	Sensor pads status	5	Cannula status
3	Effort belt status	6	Finger probe status



Ref.	Description
7	Power Button: Turns the system on & off
8	Effort Belt: Senses chest movements while breathing
9	Effort Belt Cable: Connects effort belt to system
10	Effort Belt Buckle: Holds effort belt
11	Pulse Oximeter: Senses heart rate and oxygen levels
12	Nasal Cannula: Senses airflow and snoring
13	EEG Cable: Senses sleep patterns

Warnings and Cautions

If you have any questions or concerns, you should contact your Healthcare Provider before using the Zmachine Synergy.

Contraindications, Warnings and Cautions

Do not use the Zmachine on newborns, infants, or children. The Zmachine has only been tested on adults.

Keep all parts and accessories out of reach of children and pets. The small parts, plastic bags, and accessories (such as EEG sensors and their clear backings) could present a choking hazard to children and pets.

Do not use the Zmachine in an oxygen rich or explosive atmosphere. The Zmachine could ignite flammable gases.

Take care in arranging the system cables to avoid becoming tangled during the night.

Do not use the Zmachine if you cannot free yourself if tangled with the system cables. This could present a strangulation hazard.

Do not use the Zmachine if you have fragile or damaged skin. The self-adhesive EEG sensors or paper tape could damage fragile skin.

Some patients may experience skin irritation, hypersensitivity, or allergic reaction to the self-stick sensors or adhesive tape. If this occurs, stop using and contact your healthcare provider for further instructions.

The cannula and other sensor wires can leave temporary welts, marks and/or indentations on your face and skin.

Laying on the wires or tubes can cause injury or breakdown to fragile skin.

Do not open the Zmachine enclosure or attempt to service for any reason. Otherwise, the safety and/or performance of the system could be compromised.

Only use General Sleep approved parts and accessories described in this guide. Other parts may not function correctly with the Zmachine and could pose a safety hazard or lead to poor performance.

Do not expose the Zmachine to excessive heat, as the internal Lithium Ion battery may leak or explode.

To avoid interference with the recorded signals, do not use transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields near the Zmachine.

Do not immerse the Zmachine in liquid for any reason as this could damage the system.

Avoid exposing the Zmachine to any liquids or small particulates as this could damage the system.

The Zmachine is designed for indoor use only. Allow the Zmachine system to reach room temperature before using.

Contraindications, Warnings and Cautions

Do not connect the Zmachine to any equipment except as described in this guide.

Do not modify the Zmachine and/or open Zmachine enclosure for any reason. The Zmachine contains no user serviceable parts.

The Zmachine could become damaged if it has been subjected to unfavorable conditions or mishandling. If, at any time, the Zmachine or accessories are thought to be damaged or malfunctioning, stop using the Zmachine and contact your healthcare provider for further instructions.

Disposal

Dispose of any used sensor pads, alcohol swabs and cannulas. Return all other parts and accessories to your Healthcare Provider.

Cleaning

The outer surfaces of the Zmachine Synergy will be cleaned by your healthcare provider. If you need to remove fingerprints or dirt, use a small amount of water or isopropyl alcohol to dampen a soft cloth and wipe the surface clean. Do not immerse the Zmachine or allow any liquid to enter the case.

Interference

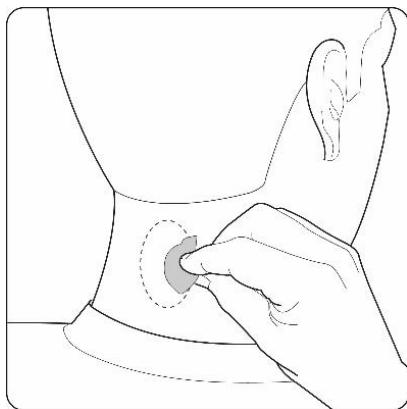
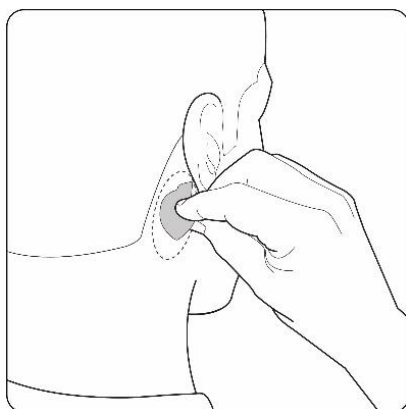
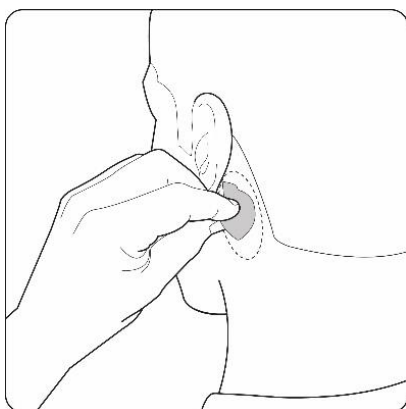
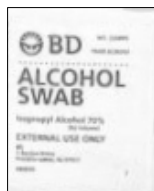
The Zmachine acquires and analyzes very small electrical signals from your body and brain. To avoid interference with the recorded signals, equipment that generates strong electrical fields (such as electric blankets) should not be used with the Zmachine.

Using the System

Closely perform the steps beginning on the next page to help ensure a comfortable night and a great recording.

Step 1: Clean/Prepare Skin

Use an alcohol swab to clean the bony areas behind the left and right earlobes, and also the back of the neck as shown.

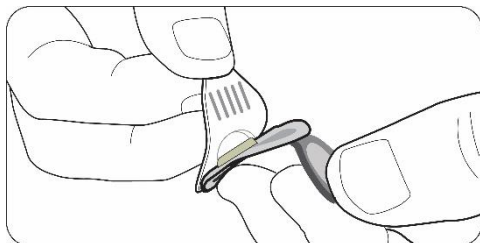


Hint: A mirror can be helpful for this and the next step.

Note: Let skin air dry for about 20 or 30 seconds after cleaning before proceeding onto Step 2.

Step 2: Apply the Sensor Pads

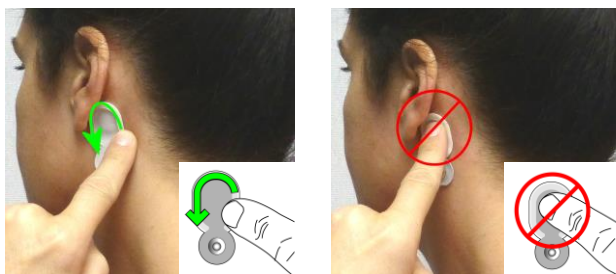
Remove clear backing from sensor pad.



Apply a sensor pad to each of the three cleaned areas as shown.



Secure each sensor pad with finger by rubbing the outer edge only.
Avoid pressing the center as gel will spread onto the adhesive.

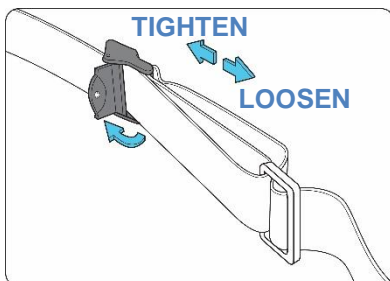
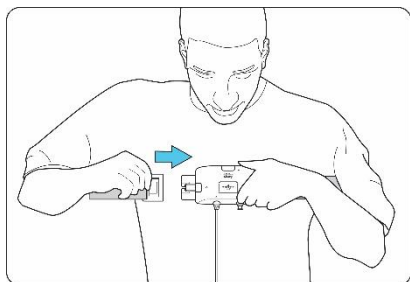


Hint: If you positioned a sensor pad incorrectly, simply repeat the steps above using a new sensor pad (never reuse a sensor pad).

Wait 20 minutes before continuing onto Step 3.
This will let the sensor pads adhere properly to your skin.

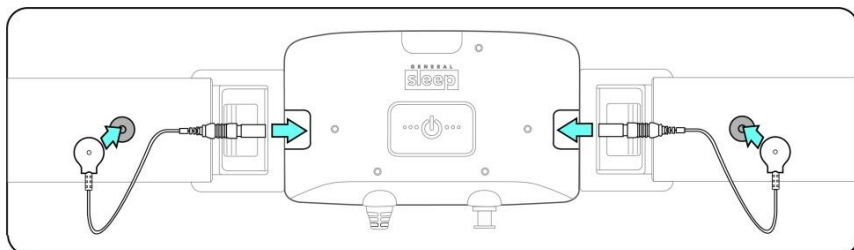
Step 3: Set Up the Effort Belt

Attach effort belt to Synergy and adjust length to fit your body. Always wear the Synergy over a shirt.

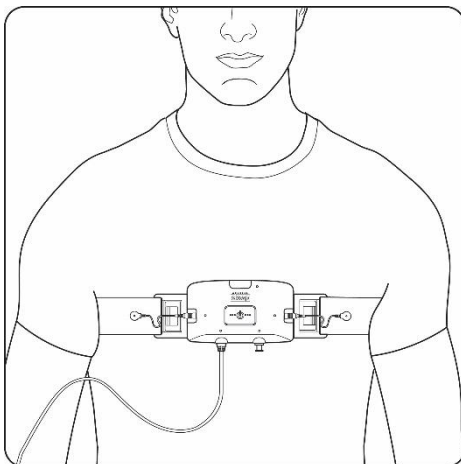


Click belt onto tabs and position high under the armpits with the system above the pectoral muscles/breasts. Adjust belt length for a snug but comfortable fit that hugs your chest and moves with your breathing.

Insert belt cables into Synergy and snap free ends onto belt.

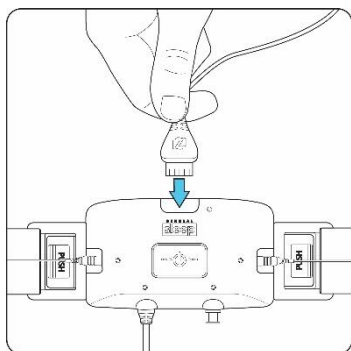


It should look like this when finished (high and centered).

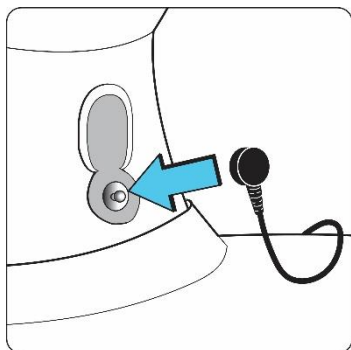


Step 4: Connect the Cable and Sensors

Insert free end of EEG Cable into Synergy.

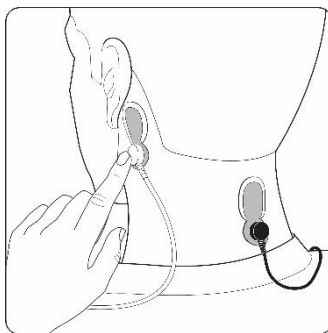
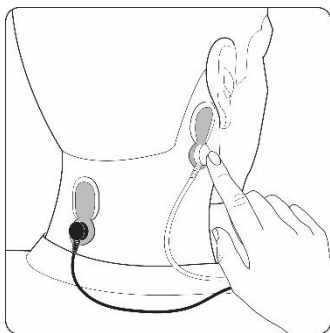


Snap BLACK wire to NECK sensor.



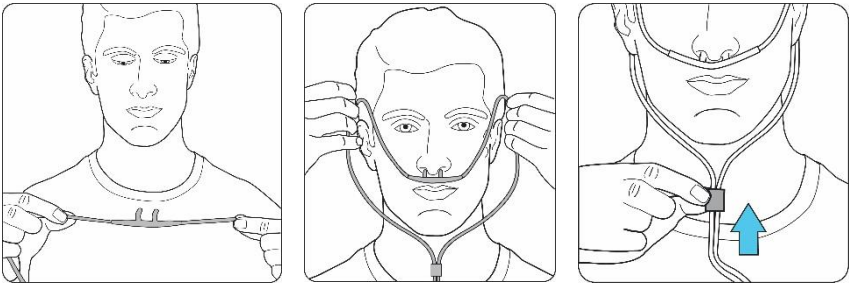
Connect the black wire to the neck sensor (not the ears).

Snap the two WHITE wires to the two EAR sensors. Either white wire can be connected to either ear sensor.



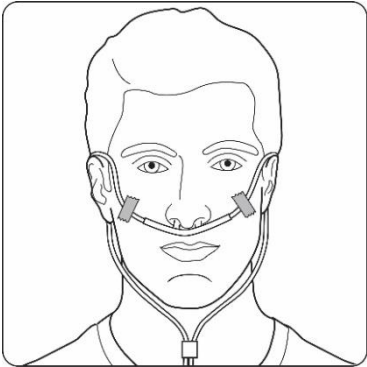
Step 5: Connect the Cannula

Place cannula in nostrils, drape over ears, & remove some slack.



Adjust slider to remove some slack – there’s no need to tighten. If the prongs are too long for your nasal passages, they can be trimmed or shortened with a scissors for comfort, but do not remove them entirely.

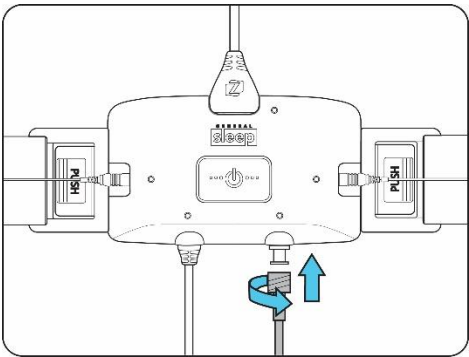
Apply small two pieces of tape as shown.



The slider should not be tight; a tight cannula can be uncomfortable. The tape will keep the cannula in the correct position all night. Loosen the slider now if needed.

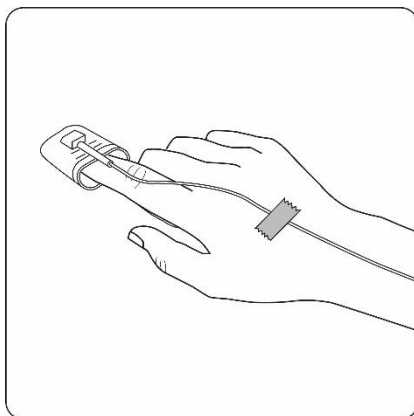
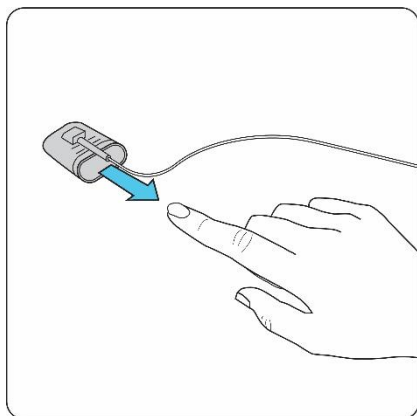
Note: *If you have sensitive skin, the tape can leave temporary marks on your face.*

Twist cannula onto the fitting until it is snug.



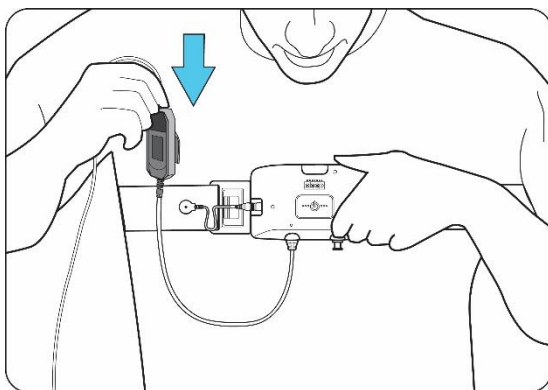
Step 6: Connect the Finger Probe

Position the finger probe with the cord exiting over the top of your hand as shown. Apply a small piece of tape to secure the cord (be sure to leave a little slack in the cord for comfort).



Nail polish and false nails will interfere with the test and should be removed prior to use.

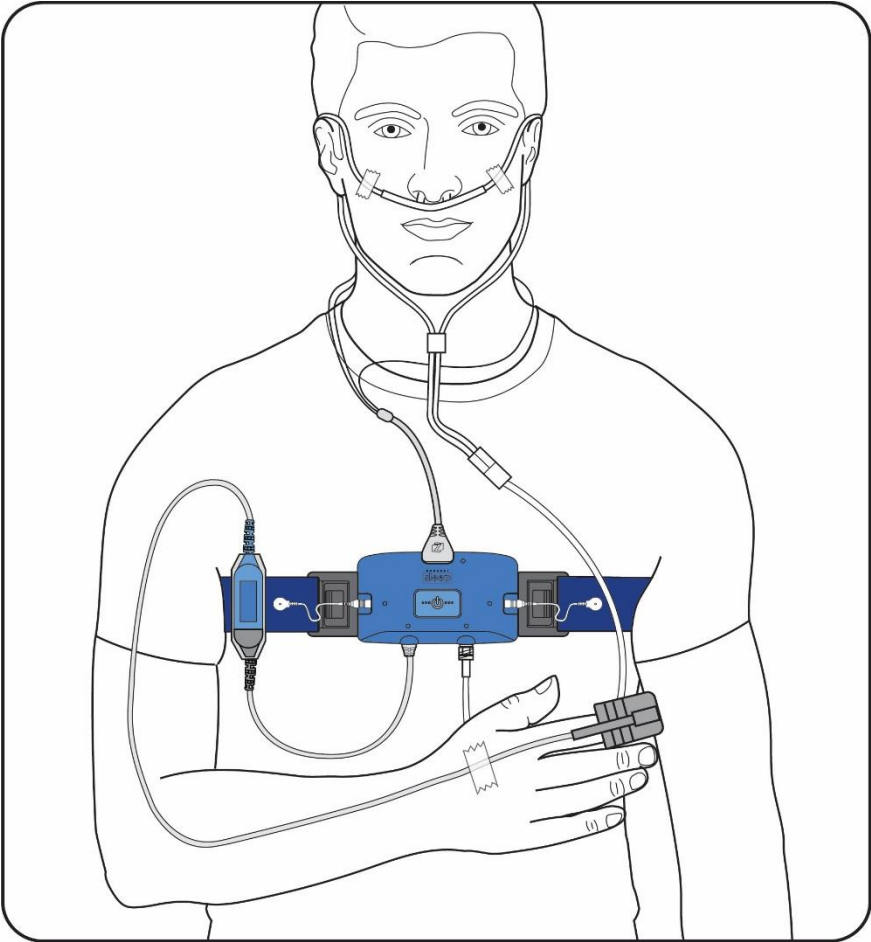
Clip the cord onto either side of the effort belt.



Hint: If you notice the finger probe becoming uncomfortable during the test, you may move it to another finger at any time.

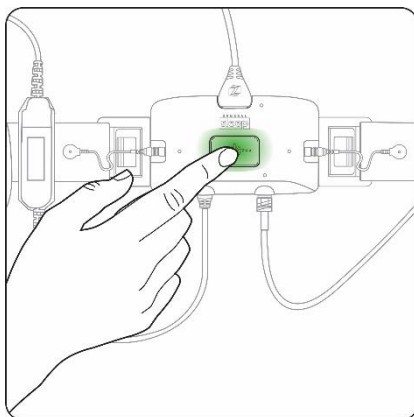
Step 7: Review (not really a step)

The complete setup should look similar to this...



Starting the Test

Press the button for about 1-2 seconds until the lights turn on, then release. Do not hold for too long or the system will shut off again.



Note: The Synergy will automatically check your sensors. A yellow light indicates that the corresponding sensor is not yet connected or needs further attention (green means good). Refer to the previous instructions and correct any problems. If you are unsuccessful in correcting a yellow indicator, simply continue with the test.

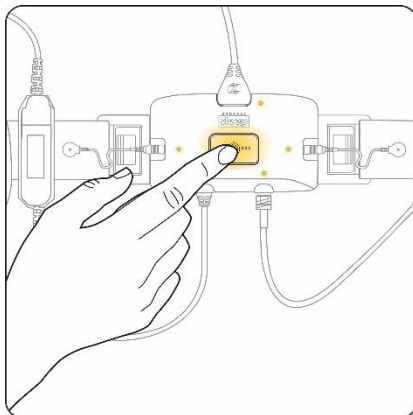
Go to bed when ready. Sleep in any position that is comfortable. It is perfectly acceptable to lie on the wires or any other part of the system.



Hint: The lights will auto-dim to minimize interference with your sleep. The system is still running while dim. A momentary button press will briefly show the current status of all sensors and then auto-dim again.

Stopping the Test

Press the button for about 3-4 seconds until the system beeps, then release. All lights will glow orange, then turn off.



Unhook yourself from the system.

- Remove finger probe and tape
- Remove nasal cannula and tape
- Remove sensor pads
- Unsnap effort belt cable
- Unbuckle effort belt
- Remove any gel and/or adhesive remaining on your skin from the tape and sensor pads using soap & water or an alcohol swab
- Place all parts and accessories into the travel case (except Cannula and Sensors Pads)

Return all equipment as instructed.

Frequently Asked Questions

Can I get out of bed for a drink, to use the bathroom, etc. when connected to the Zmachine Synergy?

Yes. However, use caution around water to prevent water from entering the system.

Can I lie directly on the Zmachine Synergy system and cords?

Yes, lying on the system and cords is absolutely fine and will not influence the recording. Sleep in any position that is comfortable and representative of your normal sleep.

My skin was a little irritated when I removed the Sensor Pads in the morning. Is this normal?

Yes, the Sensor Pads can cause minor skin irritation or drying for some people. This is normal and should disappear within about a half hour following removal of the sensor pads. If your skin is dry, you may use a dab of hand or face lotion over the affected area(s) in the morning. If you have any concerns, discontinue use and contact your healthcare provider for further instructions.

What should I do if I find that a sensor has become dislodged or disconnected during the night?

Simply re-position / re-attach the affected sensors as soon as this has been discovered and continue using the system as before.

Why did the Zmachine Synergy turned itself off before I started using it?

The Zmachine may shut itself off after 20 minutes if it never detected a good signal at any point in time following power on. So, don't power on the Synergy too far in advance of applying the sensors.