

Patient Guide



Patient Guide

Zmachine[®] Insight & Insight+
Model: DT-200

About this Guide

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

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.

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 law of the state in which he or she practices to use or order the use of this device.

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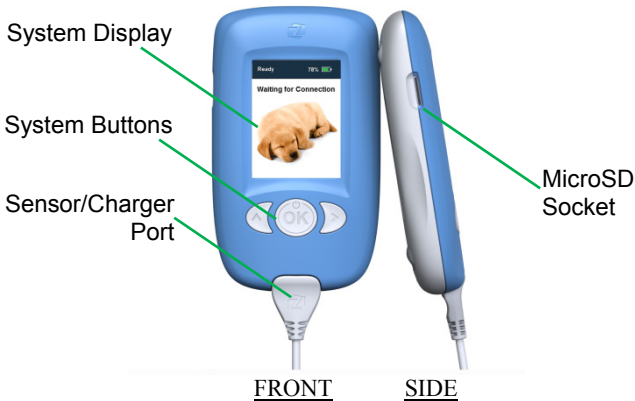
Introduction

The Zmachine[®] Insight and Insight+ are high technology sleep systems that use state-of-the-art brainwave monitoring technology to determine your unique sleep patterns. The Zmachine is typically used in the home to assist your healthcare provider in understanding and improving your sleep.

Indication for Use

The Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.

The Zmachine at a Glance

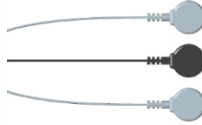


Description of Components

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



Zmachine



Patient Cable



Charger



Sensor Pads



Alcohol Swabs



Patient Guide
(this document)



Hanging Cover



3M Self-Adhesive Hook



Travel Case

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

Contraindications, Warnings and Cautions

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

- *Do not use the Zmachine on newborns, infants, or children. The Zmachine has only been tested on adults.*
- *Do not use the Zmachine if you have a pacemaker, cardiac defibrillator, or other medical electronic device.*
- *Do not use the Zmachine if you have fragile or damaged skin.*
- *Do not use the Zmachine in an oxygen rich or explosive atmosphere.*
- *Do not use the Zmachine if you feel that you may not be capable of freeing yourself in the event that you become tangled with the patient cable.*
- *Take care to arrange the patient cable in such a manner as to avoid entanglement.*
- *Do not open the Zmachine enclosure for any reason.*
- *The Zmachine should be kept away from transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields.*
- *Electric blankets should not be used with the Zmachine as this may interfere with the sensitive amplifiers.*
- *Do not allow the conductive parts of the Zmachine sensor pads and connectors to contact other conductive parts, including earth ground.*

- *Do not immerse the Zmachine in liquid. Care should be exercised to avoid exposing the Zmachine to liquids or small particles.*
- *The Zmachine is designed for indoor use only. If exposed to cold temperatures during transportation, allow the Zmachine system to reach room temperature before using.*
- *If, at any time, function or safety of the Zmachine is thought to be impaired, the Zmachine device should be taken out of operation, secured against unintended use, and returned to your system provider. Do not attempt to service the Zmachine.*
- *Discontinue use of the Zmachine and consult your healthcare provider if you experience skin irritation or hypersensitivity from the sensor pads.*
- *The Zmachine includes an internal Lithium Ion battery and must not be disposed of in a fire.*

Disposal

Dispose of any used sensor pads or alcohol swabs, but do not dispose of the Zmachine system or accessories. These should be returned to your system provider.

Cleaning




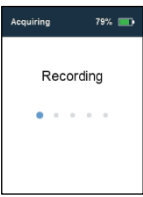



The outer surfaces of the Zmachine may be cleaned as needed. To remove fingerprints and dirt, use a small amount of water or isopropyl alcohol to dampen a soft cloth and wipe the surface clean. Do not immerse the Zmachine or allow any liquid to enter the case.

Interference

The Zmachine acquires and analyzes very low level brainwave signals. As such, equipment that generates strong electromagnetic fields (such as electric blankets) should not be used with the Zmachine.

Usage Overview (Steps 1-7)

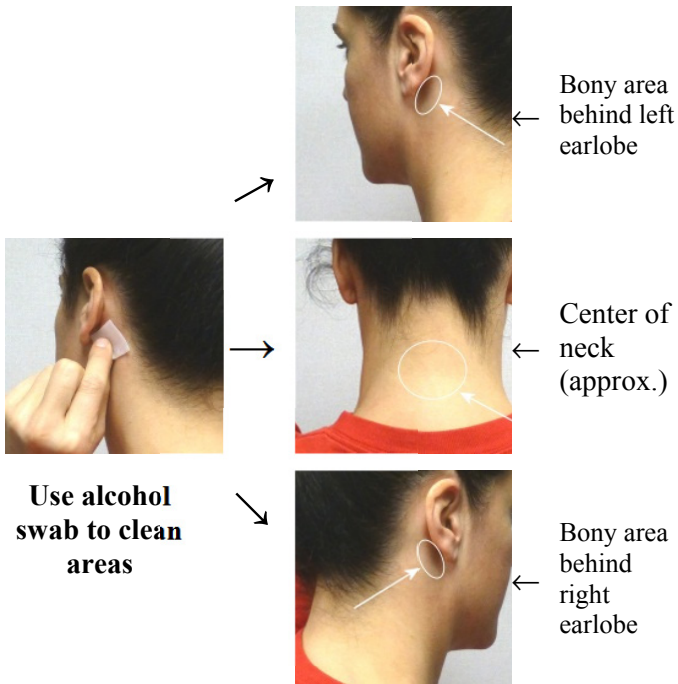
The following is an outline of the steps for using the Zmachine system at home. Review the pages that follow for details and important information:

- Step 1**  At least 30 minutes before bed, clean skin and apply sensor pads.
-
- Step 2**  When ready for bed, snap the patient cable wires onto the sensor pads.
-
- Step 3**  When in bed, insert the patient cable into the Zmachine.
-
- Step 4**  The Zmachine will automatically record your sleep patterns.
-
- Step 5**  When leaving bed, unplug the patient cable from the Zmachine.
-
- Step 6**  When finished, remove sensor pads & clean skin.
-
- Step 7**  Charge system.

Step 1: Applying the Sensor Pads

At least 30 minutes before going to bed, apply the sensor pads as shown:

1. Using an alcohol swab, clean the three circled areas on your skin. One swab is enough for all three areas.

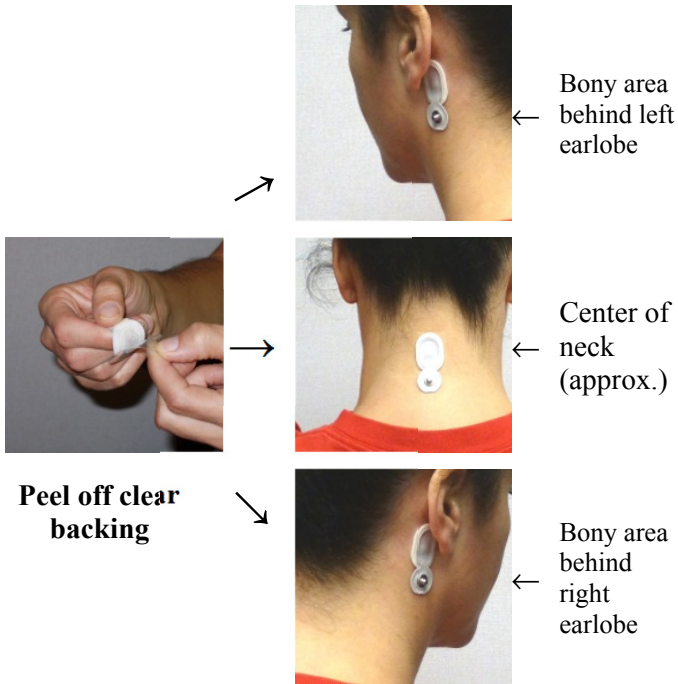


Use alcohol swab to clean areas

Clean each of the circled areas

Note: *Let skin air dry for about 30 seconds, or pat dry with a tissue, before applying the sensor pads.*

2. Apply the sensor pads as shown:



Place sensor pads

Hint: *A mirror can be helpful in positioning the sensor pads behind your ears. The location of the neck sensor pad needs only be approximate.*

Hint: *Do not fold your earlobe out of the way when applying the ear sensor pads as this could place the sensor in the fold of your ear which may be uncomfortable.*

3. Rub the outer edge of each sensor pad with your finger tip to secure the adhesive. Never press the center portion of the sensor pad.



YES



NO!

Note: *If you are not satisfied with the placement of a sensor pad, simply remove, discard, and repeat the steps above using a fresh sensor pad. Never re-use a sensor pad.*

Step 2: Attaching the Patient cable

1. When ready for bed, snap the individual patient cable wires to the sensor pads as shown.

BLACK wire to the NECK sensor pad
WHITE wires to the EAR sensor pads



CORRECT

Note: *The BLACK wire should ONLY be attached to NECK sensor.*

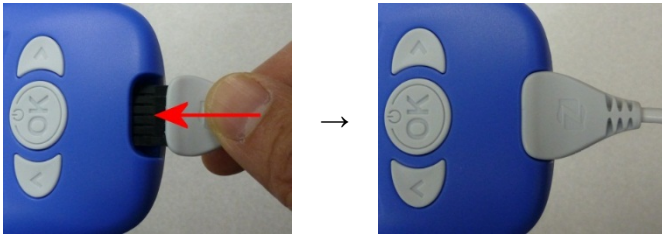
Note: *Either white wire can connect to either ear sensor.*

Hint: *You can arrange the wires to fall in front or behind you, whichever is more comfortable.*

Step 3: Connecting the Patient cable

When you are in bed and ready to attempt sleep (not reading or doing any other activity):

1. Plug the free end of the patient cable into the Zmachine. The Zmachine will turn on automatically.



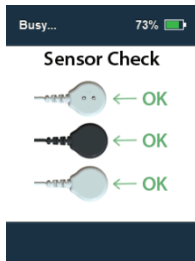
Connecting the Patient cable to the Zmachine

Hint: *The Zmachine display will automatically dim and then turn off while running. Pressing any button will wake the display for a few seconds. The system continues to run while the display is off.*

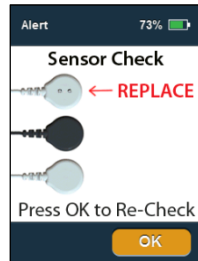
Note: *For best results, only connect the patient cable to the Zmachine when you are in bed and ready to try to sleep.*

- The Zmachine will automatically check the connection between the sensor pads and your skin.

Note: One of the white sensor wires has two raised bumps on the snap connector which can be felt with your finger tip, and the other is smooth. These bumps are used to distinguish the wires during the sensor check.



All Pass

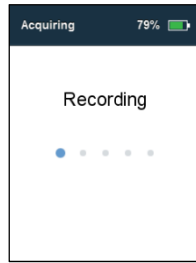


Replace white wire
with 2 raised bumps

- If a sensor needs to be replaced, and at least 30 minutes has passed since sensor pad application (Step 1), simply remove, discard, and repeat the steps above using a fresh sensor pad. Never reuse a sensor pad.

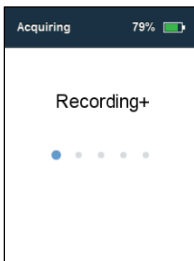
Step 4: Zmachine Sleep Functions

When the Zmachine is collecting your sleep information, it will display the *Recording* screen.

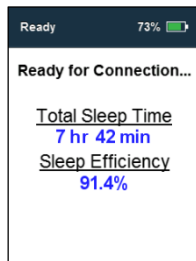


Recording Screen

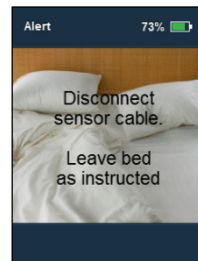
Insight+ Only: After about two nights of use, the Zmachine will automatically switch from *Recording* to *Recording+*. At this time, the Zmachine may display additional information about your sleep (updated and displayed each time you disconnect your patient cable), and/or may produce an alert for you to leave bed (beeping sound with an empty bed displayed).



Recording+



Sleep Statistics



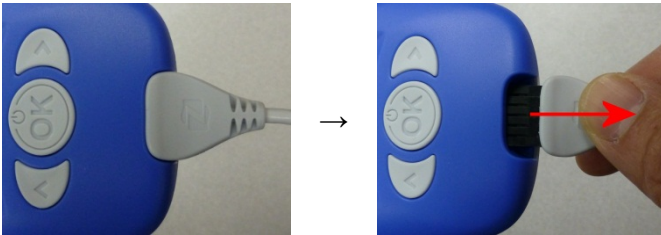
Leave Bed Alert

Note: Your healthcare provider may or may not have enabled the functions described above.

Step 5: Disconnecting the Patient cable

When leaving bed for any reason or when you are no longer trying to sleep:

1. Unplug the patient cable from the Zmachine while lifting slightly on the connector.



Disconnecting the Patient cable from the Zmachine

Note: *The Zmachine will automatically stop monitoring and finish processing (this may take several seconds). The system display will automatically dim and then turn off. The Zmachine will shut down completely within two minutes.*

Hint: *If planning to return to bed, lay the Zmachine on your pillow as a reminder to re-connect when you return to bed. If you are done sleeping, then proceed to the next steps.*

Step 6: Removing the Sensor Pads

When you are finished trying to sleep and the patient cable has been disconnected from the Zmachine:

1. Unsnap the patient cable wires from the sensor pads.
2. Discard all used sensor pads (they will not be re-used).
3. Remove any gel and/or adhesive remaining on your skin from the sensor pads using soap and water or an alcohol swab.



Unsnap patient cable wires



Remove sensor pads & clean skin

Step 7: Charging

The Zmachine has enough battery power to run for one full night and should be charged during the day in preparation for the next night of use.

1. Plug the free end of the charger cable into the Zmachine.
2. Plug the charger into a 120VAC wall outlet. The Zmachine will start and stop charging automatically and can safely remain connected to the charger until ready for use.



Connect charger to
Zmachine



Plug charge to wall
outlet

Note: *Always fully charge the Zmachine before each use. It can take at least three hours to obtain a full charge.*

Frequently Asked Questions

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

Yes, simply unplug your patient cable from the Zmachine and lay the Zmachine on your pillow. The patient cable can stay connected to your sensor pads when you are out of bed. When you return to bed, simply re-connect to the Zmachine to continue.

Can I lie on the patient cable?

Yes, lying on the patient cable and wires is absolutely fine and will not influence the recording.

I feel that my skin is a little irritated when I first remove the sensor pads in the morning. Is this normal?

Yes, the sensor pads you are using can cause minor skin irritation or drying for some people. This is normal with daily use 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 lotion or face lotion over the affected areas in the morning. If you have any concerns, discontinue use and contact your healthcare provider for further instructions.

Do I need to charge the Zmachine every morning?

Yes, the Zmachine needs to be re-charged every morning in preparation for the next night of use. To ensure a full charge, the Zmachine can remain connected to the charger all day until ready for use.

Legal

The Zmachine logo, Zmachine name, and General Sleep are registered trademarks of General Sleep Corporation.

At the time this manual was printed, the Zmachine was protected by the following patents:

United States Patents: 5813993, 7654948, 8089283,
8512221

Canadian Patent: 2201694, 2516093, 2783015

European Patent: 1124611, 2512573

Japanese Patent: 4532739, 4721451, 5684828

Other patents pending