



Patient Guide

Zmachine[®] Insight & Insight+

***30 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.

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.

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.

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Table of Contents

About this Guide	i
Table of Contents	ii
Introduction	1
Indications for Use	1
Symbol Descriptions	1
Description of Components	2
The Zmachine Indicators & Elements	3
Warnings and Cautions	3
Disposal	4
Cleaning	4
Interference	4
Positioning the Zmachine	5
Step 1: Clean/Prepare Skin	6
Step 2: Apply Sensor Pads	7
Step 3: Secure the Sensor Pads	8
Step 4: Attach the Patient Cable	9
Step 5: Connect the Patient Cable	10
Step 6: Zmachine Sleep Functions	11
Step 7: Disconnect the Patient Cable	12
Step 8: Remove the Sensor Pads	13
Step 9: Charge	14
Frequently Asked Questions	15
Legal	16

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.

Indications 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.

Symbol Descriptions

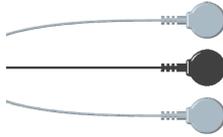
Symbol	Definition of Symbol
	Read and understand the instructions before using this system.
	This system is not rated for use in wet conditions. Keep dry.
	Federal Law (USA) restricts this device to sale by, or on the order of, a physician or other qualified healthcare practitioner licensed by the law 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 system may include some or all of the following items:



Zmachine



Patient Cable



Charger



Sensor Pads



Alcohol Swabs



Patient Guide
(this document)



Hanging Cover



Travel Case

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

The Zmachine Indicators & Elements



Warnings and Cautions

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

Warnings and Cautions

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 in an oxygen rich or explosive atmosphere.

Do not use the Zmachine if you have fragile or damaged skin.

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.

Keep all parts and accessories out of reach of children and pets. The small parts and accessories (such as sensor pads and their clear backings) could present a choking hazard to small children and pets.

Some patients may experience skin irritation, hypersensitivity, or allergic reaction to the self-stick sensors. If this occurs, discontinue use of the Zmachine and contact your healthcare provider for further instructions.

Take care to arrange the patient cable in such a manner as to avoid entanglement.

Do not open the Zmachine enclosure for any reason.

Electric blankets should not be used with the Zmachine as this may interfere with the sensitive amplifiers.

Warnings and Cautions

The Zmachine should be kept away from transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields.

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.

The Zmachine includes an internal Lithium Ion battery and must not be disposed of in a fire.

Disposal

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

Cleaning

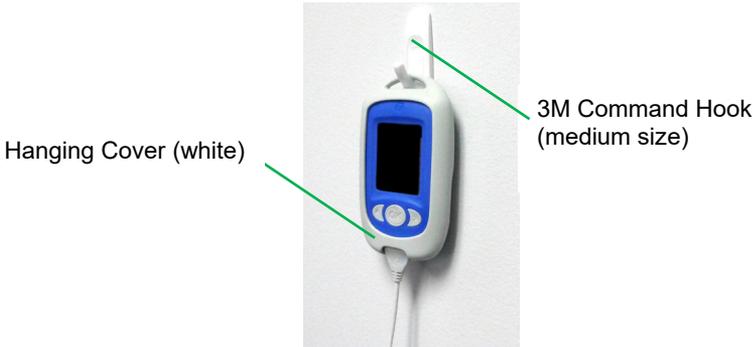
The outer surfaces of the Zmachine may be cleaned as needed. To remove fingerprints and dirt, use a small amount of water or isopropyl alcohol to dampen a soft cloth and wipe the surface clean. Do not immerse the Zmachine or allow any liquid to enter the enclosure.

Interference

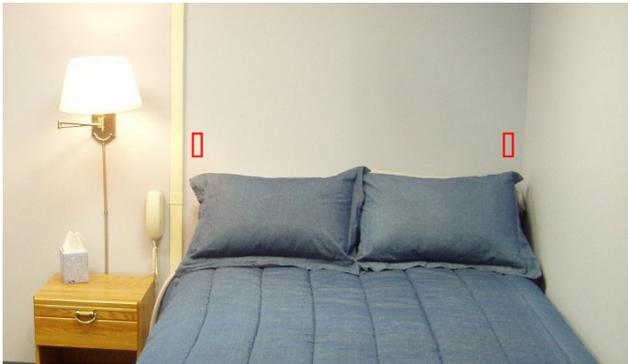
The Zmachine acquires and analyzes very low level brainwave signals. As such, equipment that generates strong electromagnetic fields (such as electric blankets) should not be used with the Zmachine.

Positioning the Zmachine

If you received your Zmachine with a hanging cover and a 3M Command[®] Medium Utility Hook (pictured), your system can be positioned to hang behind your head during sleep. This allows you to orient the patient cable toward the top of your head, thereby allowing the maximum freedom of movement during sleep.



Apply the 3M Command Hook in accordance with manufacturer instructions. Locate the hook at the head of your bed, either on the wall or headboard, just to the side of where you normally sleep, and approximately two (2) feet above your bed (see red boxes for sample locations).



Locate the hook such that the Zmachine will not hit your head if it were to fall.

Step 1: Clean/Prepare Skin

At least 30 minutes before going to bed, prepare skin for the sensor pads as shown:

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

↗			Bony area behind left earlobe
→			Center of neck (approx.)
↘			Bony area behind right earlobe



Use alcohol swab to clean these areas

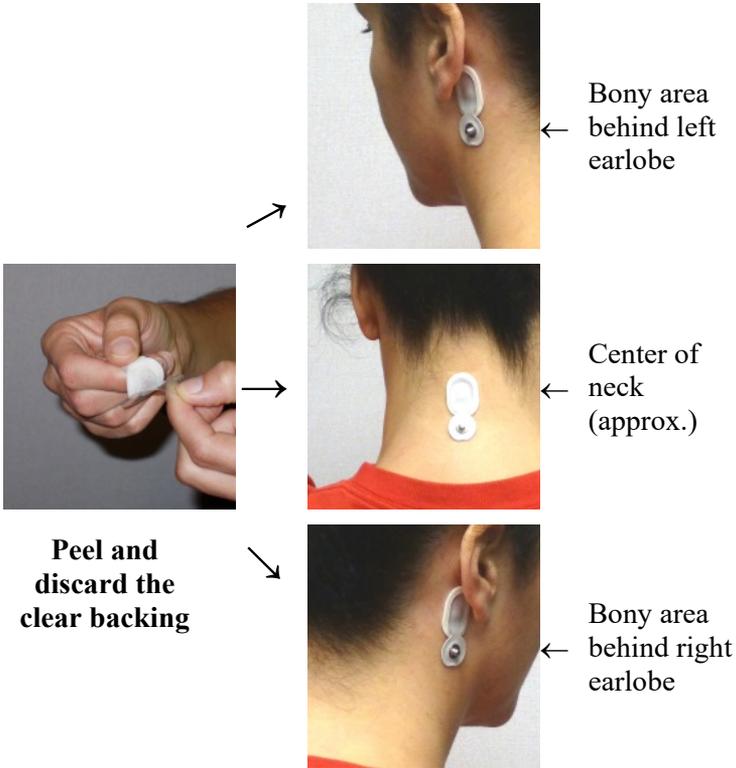
Clean these areas

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

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

Step 2: Apply Sensor Pads

Apply the sensor pads as shown:



Peel and discard the clear backing

Place sensor pads

Warning! The clear backings are a choking hazard and should be kept away from children and pets.

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.

Step 3: Secure the Sensor Pads

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



NO!



YES

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.*

Now, wait 30 minutes before continuing onto Step 4.
This will allow time for the sensor pads to adhere properly to your skin.

Step 4: Attach the Patient Cable

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

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



CORRECT

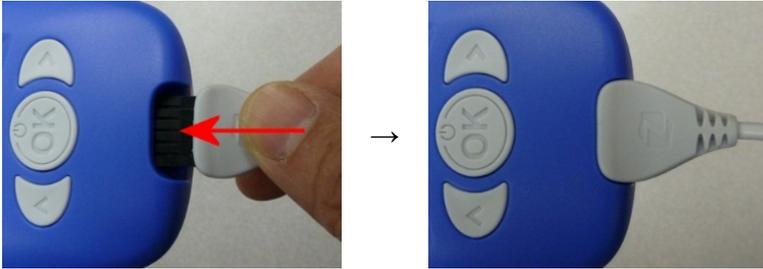
Note: *The BLACK wire should ONLY be attached to NECK sensor.*

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

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

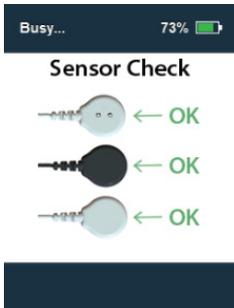
Step 5: Connect the Patient Cable

When you are in bed and ready to attempt sleep (not reading or doing any other activity), plug the free end of the patient cable into the Zmachine. The Zmachine will turn on automatically.

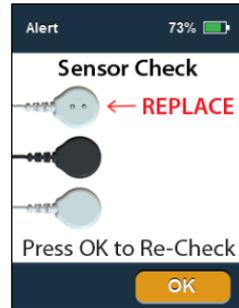


Connecting the Patient cable to the Zmachine

After starting, the Zmachine will automatically check the connection between the sensor pads and your skin. If a sensor needs to be replaced, and at least 30 minutes has passed since the sensor pads were applied, simply remove, discard, and repeat the steps above using a fresh sensor pad. Never re-use a sensor pad.



All Pass



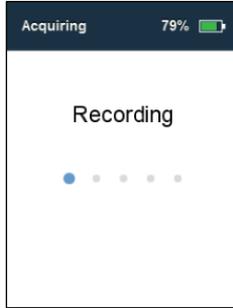
Replace white wire with
2 raised bumps

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.

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.

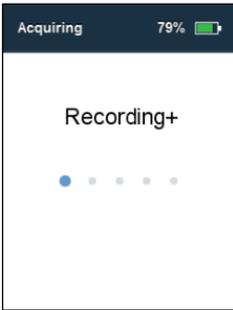
Step 6: Zmachine Sleep Functions

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

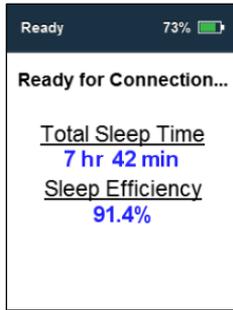


Recording Screen

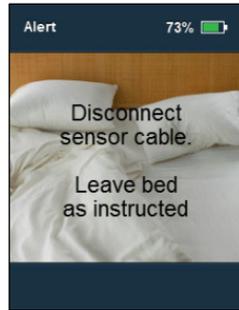
Insight+ Only: After about two nights of use, the Zmachine will automatically switch from *Recording* to *Recording+*. At this time, the Zmachine may display additional information about your sleep (updated and displayed each time you unplug the patient cable), and/or may produce an alert for you to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



Recording+



Sleep Statistics

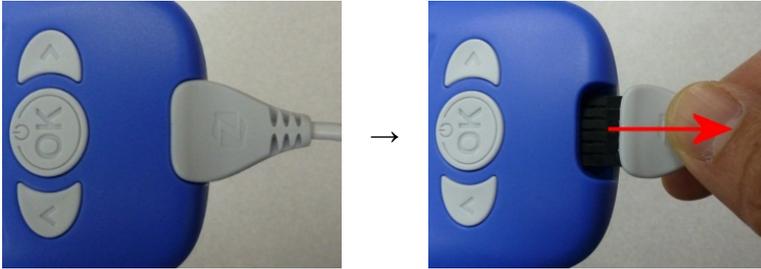


Leave Bed Alert

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

Step 7: Disconnect the Patient Cable

When leaving bed for any reason or when you are no longer trying to sleep, unplug the patient cable from the Zmachine while lifting slightly on the connector to disengage the locking tab.



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, place 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 8: Remove 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. Carefully peel the sensor pads from you skin and discard.
3. Remove any remaining gel and/or adhesive from your skin using soap and water or an alcohol swab.



Unsnap patient cable
wires



Remove sensor pads &
clean skin

Warning! The used sensor pads are a choking hazard and should be kept away from children and pets.

Step 9: Charge

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 wall outlet. The Zmachine will start and stop charging automatically and can safely remain connected to the charger until ready for the next use.



Connect charger to
Zmachine



Plug charge into 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 the patient cable from your Zmachine and place 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 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 and cleaning of any residual gel and/or adhesive. 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 until ready for the next use.

Trademark and Intellectual Property Rights

The Z logo, Zmachine, and General Sleep are registered trademarks of General Sleep Corporation. The Zmachine has been designed and developed by General Sleep Corporation, Cleveland, Ohio, USA. At the time this manual was printed, the Zmachine was protected by the following patents:

United States Patents: 5813993, 7654948, 8089283, 8512221

Canadian Patents: 2201694, 2516093, 2783015

European Patents: 1124611, 2512573

Japanese Patents: 4532739, 4721451, 5684828

User Agreement

This User Agreement (“Agreement”) sets forth the terms of use by and between Consolidated Research, Inc. d/b/a General Sleep Corporation (“GSC”), an Ohio corporation, whose address is 26250 Euclid Avenue, Suite 709, Cleveland, OH 44132, and the user of the subject equipment known as the Zmachine (“User”). User agrees that the Zmachine will at all times be used and operated solely in the conduct of User’s business for the purpose for which it was designed and intended and under and in compliance with applicable laws and all lawful acts, rules, regulations and orders of any governmental bodies or officers having power to regulate or supervise the use of such property. User further agrees to ensure that third parties to which it gives access to the Zmachine will at all times be used and operated solely in the conduct of User’s business for the purpose for which it was designed and intended and under and in compliance with applicable laws and all lawful acts, rules, regulations and orders of any governmental bodies or officers having power to regulate or supervise the use of such property. The Zmachine contains certain pre-loaded computer software which is licensed but not sold or otherwise transferred to User and is subject to the Software License Agreement terms contained in this Manual. GSC warrants that the Zmachine will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of two (2) years (“Warranty Period”) from the date of its shipment to User. Excluded from this warranty are expendable components and supply items such as, but not limited to, sensors and sensor cables. GSC’s obligations under this warranty are to repair or replace any warranted product (or part thereof) that GSC reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the User has given notice of such warranty claim within the Warranty Period and the warranted product is returned to the GSC with freight prepaid. Repair or replacement of products under this warranty does not extend the Warranty Period. To request repair or replacement under this warranty, User should contact GSC directly. GSC will provide User with a Return Material Authorization (RMA) number to return the Zmachine (or part thereof) (“Warranted Product”) to GSC. GSC shall determine whether to repair or replace the Warranted Product; all products or parts replaced shall become GSC’s property. In the course of warranty service, GSC may, but shall not be required to, make engineering improvements to the Warranted Product. If GSC reasonably determines that a repair or replacement is covered by the warranty, GSC shall bear the costs of shipping the repaired or replaced product to User. All other shipping costs shall be paid by User. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the product. Products shipped by User under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the product. If User ships a product to GSC in unsuitable packaging, any physical damage present in the Product on receipt by GSC (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of User. This warranty does not extend to any Warranted Product that has been subject to misuse, neglect, or accident; that has been damaged by external causes such as failure of or faulty electrical power; use in violation of GSC’s instructions; nonstandard accessory attachment; on which the serial number has been removed or made illegible; modification by anyone other than GSC; disassembly, service, or reassembly by anyone other than GSC, unless authorized by GSC. GSC shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. GSC makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than GSC or a GSC-authorized distributor or (c) with respect to any product sold under a brand name other than GSC. This warranty is void if the User resells the Zmachine to a third party. **THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR GSC’S PRODUCTS, EXTENDS ONLY TO THE USER THAT HAS PURCHASED THE ZMACHINE FROM GSC OR AN AUTHORIZED DEALER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY**

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Privacy Policy

For purposes of this Agreement (“Agreement”), the following terms have the following meanings: “User” means anyone using the Zmachine (described in this manual), or any associated systems or software. “De-identified Information” shall mean Information that has been de-identified in accordance with the requirements for de-identification of protected health information under 45 CFR §164.514(b). “Information” shall mean written or electronic health information or data received by GSC from a User and includes Information or data provided in any form, including De-identified Information and Limited Data Sets. “Limited Data Set” shall have the same meaning as the term “limited data set” in 45 CFR §164.514(e), and shall include Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers (including finger and voice prints), full face photographic images, and any comparable images. “Protected Health Information” or “PHI” shall have the same meaning as the term “protected health information” in 45 CFR § 164.501. GSC has created and established a data repository to receive and store Information received from a User. The Information submitted by a User, may be stored by GSC in one or more data repositories. De-identified Information from the data repositories may be moved to a separate data repository for use as set forth herein. User agrees that GSC may use such De-identified Information for any purpose. User agrees that GSC is the exclusive owner of the De-identified Information. User licenses to GSC data identified as PHI for the purposes of carrying out the operations as requested by User. Unless otherwise permitted in this Agreement, no User shall have direct access to Information in the data repository. Requests, if any, from User to access or amend PHI shall be referred to GSC in writing.