



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

Clinician Instruction and Service Manual
Rev. 1.3

About this Manual

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

This manual contains all of the information that is needed to set up and operate the Zmachine, and does not assume prior knowledge or experience with operator-programmable medical electronics devices. Retain this manual for future reference.

The information in this manual has been carefully checked and is believed to be accurate. However, in the interest of continued product development, General Sleep Corporation ("GSC") reserves the right to make changes and improvements to this manual 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.*

Mailing and Shipping Address

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

Telephone

(888) 330-4424

Web Site

www.GeneralSleep.com

Note: This manual is applicable to the Zmachine Insight & Insight+ with firmware version 4.5.0 and later.

Table of Contents

Introduction	1
Description	1
Indications for Use.....	1
The Zmachine at a Glance	2
Description of Reusable Components.....	3
Description of Disposable Components	4
Description of Documentation and Software Components.....	5
Glossary of Symbols.....	6
Contraindications, Warnings and Cautions.....	7
Contraindications.....	7
Warnings.....	7
Cautions.....	8
Care and Maintenance.....	10
Inspection	10
Cleaning.....	10
Interference.....	10
Environmental Parameters for Shipping and Storage.....	11
Environmental Parameters for Operation	11
Disposal of Equipment	11
Usage Overview	12
Understanding the Zmachine.....	12
Zmachine New Patient Setup.....	14
Pack Supplies for Patient to Take Home	14
Familiarize Patient with the Zmachine	14
Generate a sleep report and review.....	14
Adjust System Setup & Discuss	15
Re-Fill Zmachine Travel Case and Provide to Patient.....	15
General System Setup and Operation	16
Charging the Zmachine	16
Booting the Zmachine	17
Accessing the Zmachine System Menu	18
Setting the Time and Date	19
Prepare the Zmachine for a New Patient	20
Setting the Alerts to Get-Out-Of-Bed (Insight+ only).....	21
Setting the Statistics to Display (Insight+ only).....	22
Setting the Day Break Time	23
Sleep Report and Statistics Files	24
Generate Sleep Report and Statistics	24
MicroSD Card Operations (Eject, Copy Data, Insert)	25
About the Sleep Report & Statistics Files	26
File: score.csv	26
File: Stats.csv.....	27
System Utilities	30
Display System Information	30
Update Firmware	31
Setting the Failed Sensor Alert	32

Troubleshooting and Specifications	33
Troubleshooting.....	33
Zmachine Insight & Insight+ Specifications	34
Clinical Performance	35
Clinical Performance Summary.....	35
Legal Notices	36
Trademark and Intellectual Property Rights	36
User Agreement.....	36
Software License Agreement.....	38

Introduction

Description

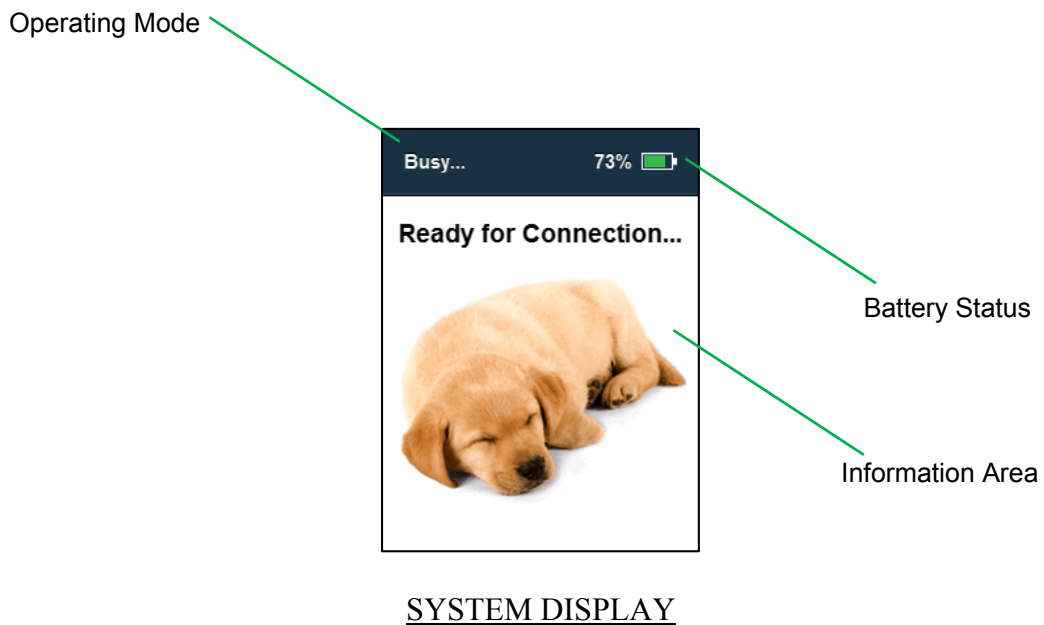
The Zmachine is a high technology sleep monitor, developed by General Sleep Corporation, which uses state-of-the-art electroencephalography (EEG) hardware in combination with advanced signal processing algorithms to detect sleep stages, including Wake, Light Sleep, Deep Sleep and REM. The Zmachine was designed for use in the clinical or home environment. The Zmachine gathers high quality, objective, epoch-by-epoch, sleep state information and summary sleep statistics, all of which can be reviewed by a clinician either independently, or in the presence of their patient.

The Zmachine acquires the EEG signal necessary for sleep monitoring using three high quality, self-stick, single-use, disposable EEG sensors. The three sensors are designed for easy, self-application by the patient with minimal skin preparation (alcohol wipe and dry). The sensors are located completely outside of the hairline on the mastoids (signal) and the back of the neck (ground). Integrated impedance measurement technology verifies the quality of the sensor connections immediately prior to the start of monitoring and at periodic intervals during use.

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.

The Zmachine at a Glance



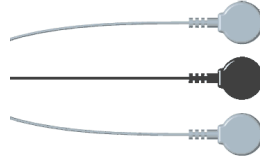
Description of Reusable Components

The Zmachine system may include some or all of the reusable items described below.



Zmachine

Rating: 5VDC ~ 600mA
GSC P/N 200-160B (Blue)
GSC P/N 200-160G (Green)



Zmachine Sensor Cable

Silicone jacket / 1.2m length
GSC P/N 200-017



Zmachine System Charger

IN: 90-264VAC ~ 0.1A,
47-63Hz || OUT: 5VDC ~ 1.2A
GSC P/N 200-028



MicroSD Card

GSC P/N 200-051-16G



USB-MicroSD Card Reader

GSC P/N 200-070



Zmachine Clinician Key

GSC P/N 200-034



Zmachine Travel Case

GSC P/N 200-120



Zmachine Hanging Cover

GSC P/N 200-154

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

Description of Disposable Components

The Zmachine system may include some or all of the disposable items described below.



Zmachine Patient Sensors
GSC P/N 200140-1



Alcohol Swabs
GSC P/N 200-060

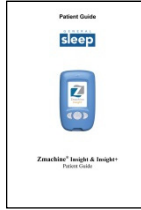


Self-Adhesive Hook
GSC P/N 200-155

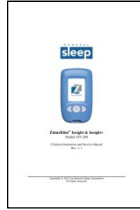
Note: *Due to differences in brand and model numbers, part appearances may vary. Only use General Sleep approved parts and accessories.*

Description of Documentation and Software Components

The Zmachine system may include some or all of the documentation and software items described below. Documentation and software are also available for download from the General Sleep website.



Patient Guide (printed)
GSC P/N 200-170








Clinician Instruction and Service Manual (pdf)
GSC P/N 200-171



Zmachine Data Viewer (Windows Software)
GSC P/N 200-103

Glossary of Symbols

SYMBOL	DEFINITION OF SYMBOL
	IEC 60601-1 Type BF applied parts.
	Attention. Check the accompanying documentation.
	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.
	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 both United States and Canadian safety standards.

Contraindications, Warnings and Cautions

Contraindications

- *Do not use the Zmachine on newborns, infants, or children. The Zmachine has only been tested on adults.*
- *Do not use the Zmachine on patients with a pacemaker, cardiac defibrillator, or other medical electronic device.*
- *Do not use the Zmachine on patients with fragile or damaged skin. The self-adhesive sensors could damage fragile skin.*

Warnings

- *Do not use the Zmachine in an oxygen rich or explosive atmosphere.*
- *Do not use the Zmachine in conjunction with high frequency surgical equipment.*
- *Do not connect the Zmachine to a patient undergoing cardiac defibrillation.*
- *Do not use the Zmachine in an MRI environment.*
- *Do not use the Zmachine on a patient that may not be capable of freeing themselves in the event of entanglement with the sensor cable.*
- *Advise patient to take care in arranging the sensor cable to avoid entanglement.*
- *Do not dispose of the Zmachine improperly as the internal Lithium Ion battery may leak or explode.*
- *Do not open the Zmachine enclosure for any reason. The Zmachine contains no user serviceable parts and service or repairs must be performed only by General Sleep Corporation.*

- *The Zmachine has been designed so that it cannot be connected to the wall charger and connected to a patient simultaneously. Please do not attempt to defeat this intentional safety feature.*

Cautions

- *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.*
- *Read and understand this entire manual before using the Zmachine.*
- *Clinicians are advised to instruct patients on the proper use of the Zmachine system.*
- *The Zmachine includes an internal Lithium Ion battery and must not be disposed of in a fire.*
- *The Zmachine contains an internal Lithium Ion battery; this battery is not user replaceable. Following a full charge, if the Zmachine fails to operate for at least 12 hours, then the battery has reached end-of-life. Please contact General Sleep for battery replacement.*
- *Only use General Sleep approved parts and accessories, including but not limited to, sensors, sensor cables, chargers and microSD cards.*
- *The Zmachine employs high sensitivity amplifiers to acquire and analyze very low amplitude EEG signals. As such, it is possible that there may be some unavoidable interference from radio frequency magnetic fields, electrostatic discharges and low frequency magnetic fields. This interference may alter the results from the Zmachine system. Transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields should not be used in close proximity to the Zmachine.*
- *Electric blankets should not be used with the Zmachine as this may interfere with the sensitive EEG amplifiers.*
- *Do not allow the conductive parts of the Zmachine sensors and connectors to contact other conductive parts, including earth ground.*
- *The Zmachine may not work adequately for some patients, such as those with highly fragmented sleep, or an abnormal EEG signal. Some medications that affect the EEG signal could affect Zmachine performance.*
- *In order for the Zmachine to product accurate results, the patient must have achieved some sleep.*
- *The Zmachine is not protected against ingress of water or particulate matter. Care should be exercised to avoid exposing the Zmachine to liquids or particulate matter.*
- *Do not immerse the Zmachine in liquid to clean.*

- *Do not sterilize the Zmachine or accessories.*
- *The Zmachine is designed for indoor use only. After shipping or transportation, allow the Zmachine system to reach room temperature before using.*
- *The function or safety of the equipment could be impaired if it has been subjected to unfavorable conditions or mishandling. If, at any time, function or safety is thought to be impaired, or any damage to the Zmachine or accessories has been observed, the Zmachine device should be taken out of operation and secured against unintended use. Contact General Sleep for service.*
- *Some patients may experience skin irritation or hypersensitivity from the sensors. Advise patient that if this occurs, to discontinue use and consult their healthcare provider.*

3

Care and Maintenance

Inspection

The Zmachine should be inspected regularly for damage to the system and accessories. If, at any time, function or safety is thought to be impaired or any damage to the Zmachine or accessories has been observed, then the Zmachine device should be taken out of operation and secured against unintended use. Contact General Sleep for information regarding service and technical support.

Cleaning

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

Interference

The Zmachine will continue to operate in the presence of radio frequency magnetic fields (RF) and during electrostatic discharges according to the requirements specified in IEC/UL 60601-1-2.

The Zmachine employs high sensitivity amplifiers to acquire and analyze very low amplitude EEG signals. As such, it is possible that there may be some unavoidable interference from radio frequency magnetic fields, electrostatic discharges and low frequency magnetic fields. This interference may alter the results from the Zmachine system. Mobile phones, transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields should not be used in close proximity of the Zmachine. Electric blankets should not be used with the Zmachine.

Although the Zmachine meets the standards for electromagnetic compatibility (IEC/UL 60601-1-2), the device may cause interference when used in close proximity with sensitive electrical equipment. It is advised that if interference on sensitive electrical equipment is observed that the equipment is switched off or moved from the proximity of the Zmachine.

Environmental Parameters for Shipping and Storage

The Zmachine and its accessories can be stored, shipped and operated within the following environmental limits. Conditions outside these ranges could affect performance and reliability.

Temperature: 0°C to 40°C (32°F to 104°F)
Humidity: 15% to 93% (non-condensing)
Pressure: 800mm-360mm Hg (1500 feet below sea level to 20,000 feet above sea level)

Protect the Zmachine from sudden temperature changes that can lead to condensation within the device. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the Zmachine to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

Environmental Parameters for Operation

The Zmachine is designed to operate safely under the following conditions. Conditions outside these ranges could affect reliability.

Temperature: 10°C to 40°C (50°F to 104°F)
Humidity: 15% to 93% (non-condensing)
Pressure: 800mm-360mm Hg (1500 feet below sea level to 20,000 feet above sea level)

Disposal of Equipment

When the Zmachine has reached the end of its operating life, it should be disposed of in accordance with local waste regulations.

4

Usage Overview

Understanding the Zmachine

This description is based on the Zmachine DT-200, running sleep staging algorithm version 2.1.0. To see what version your Zmachine is running, refer to page 30.

Patients should be advised to apply the sensors at least 30 minutes before bedtime. This will allow sufficient time for the sensor gel to soak into the skin and lower the sensor impedances without use of abrasive skin preparation. When the patients are ready to go to bed and try to sleep, they should snap the sensor cable onto the sensors. When in bed, the sensor cable should be plugged into the Zmachine. Upon connection of the sensor cable, the Zmachine will turn on, check the sensor impedances, and begin recording.

Every patient will have unique EEG patterns that are related to their age, skull thickness, medical history, medication use, etc. Rather than making assumptions about the exact nature of these differences, the Zmachine relies on a self-tuning algorithm which automatically adjusts its internal parameters to the unique EEG patterns of each patient. These internal parameters are called a *sleep signature*.

Individualization of the sleep signature is the key to realizing the accuracy of the Zmachine. While this is a revolutionary concept in automated sleep staging, individualization is routinely performed when polysomnographic (PSG) records are visually scored. When an experienced sleep technologist begins the process of scoring a night of sleep, they will often page through the record to familiarize themselves with the “look” of the signals. This allows the human brain to see the unique patterns for that particular patient. Rarely would an experienced technologist immediately score the record, from start to finish, in a linear fashion. They often page forward and back and sometimes return to change a previous score as more is learned about the unique morphology of the sleep record. Is the patient a good alpha producer or a weak producer? Does the patient exhibit alpha throughout the record or only prior to sleep onset? Does the EMG activity behave as expected or does it persist throughout the night? What about the signal levels, are they strong and classically defined or weak and odd looking? This pre-scanning of the records by the sleep technologist is very similar to the process of creating a sleep signature.

When the Zmachine first begins recording a new patient, a sleep signature will not yet exist for that patient. So, the first data collected by the Zmachine will be used to generate a sleep signature, and this is called the *signature interval*. To generate the most accurate sleep signature, the signature interval needs to contain both wake and sleep. Other than simply using the Zmachine, the patient need *not* do anything special during the signature interval, nor tell the Zmachine when they were awake or asleep (the algorithm will figure this out itself). If either

wake or sleep are missing from the signature interval, then the sleep signature (and the resulting sleep staging output) would be less accurate.

In order to ensure that examples of both wake and sleep are captured in the signature interval, a minimum period of time and data are specified upon which the sleep signature will be calculated. By default, the Zmachine will generate a sleep signature after two days and at least twelve hours of data have been acquired. This signature interval is a *settable parameter* and can be increased or decreased as desired depending upon the environment in which the Zmachine is being used. It was only chosen in order to ensure, with a high probability, that some sleep data was captured during the signature interval (i.e. it is highly likely that the patient achieved some sleep during two days of use). Even a small amount of sleep achieved during the signature interval is sufficient for an accurate sleep signature to be generated.

Once the sleep signature has been generated, there is no further need to have examples of wake and sleep within the data. For example, with a sleep signature already generated, the Zmachine can be used on pure waking data with no loss of accuracy expected.

It is perfectly appropriate to run a sleep report before a sleep signature is generated (e.g. after a single night of sleep). The Zmachine will simply generate a *temporary* sleep signature based on all available data for the purposes of generating the report. Assuming that some wake and some sleep were present within the data, no loss of accuracy should be expected (remember, the signature interval was only defined to ensure that some wake and sleep were recorded).

Zmachine New Patient Setup

1. Boot the Zmachine (p.17)
2. Check *time and date* - change if needed (p. 19)
3. Prepare Zmachine for *New Patient* (p. 20)
4. (Insight+ only) Change *alert to get-out-of-bed* settings (p. 21)
5. (Insight+ only) Change *statistics to display* settings (p. 22)
6. Check *day break time* - change if needed (p. 23)
7. Charge the Zmachine (p. 16)

Pack Supplies for Patient to Take Home

Pack Zmachine Travel Case with the following supplies (p. 3):

1. Zmachine DT-200 (fully charged)
2. Sensor cable
3. Sensors (one package for each day, plus a few extras)
4. Alcohol swabs (two swabs for each day, plus several extras)
5. System Charger
6. Patient Guide

Note: *Be sure to provide your patient with a few extra packages of sensors and alcohol swabs to allow them to remove, clean, and re-apply sensors if needed.*

Familiarize Patient with the Zmachine

Review the instructions contained in the Patient Guide with your patient. Special attention should be given to applying the sensors and instructing the patient to connect their sensor cable to the Zmachine only when lying in bed and ready to attempt sleep.

Generate a sleep report and review

When your patient returns with their Zmachine:

1. Generate a *sleep report* (p. 24)
2. Remove the microSD card from the Zmachine (p. 25)
3. Insert card into USB-microSD Card Reader and connect to a personal computer (p. 25)
4. Use the Zmachine Data Viewer software to review the data
5. Return the microSD card to the Zmachine (p. 25)

If you are finished using the Zmachine with this patient, then stop here. Otherwise, continue with the next steps.

Adjust System Setup & Discuss

If you feel one or more of the Zmachine system settings should be changed, then make the adjustments as follows:

1. Boot the Zmachine (p.17)
2. (Insight+ only) Adjust the *alert to get-out-of-bed* settings (p. 21)
3. (Insight+ only) Adjust the *statistics to display* settings (p. 22)
4. Adjust *day break time* setting (p. 23)
5. Review any changes to the system settings with your patient so that they know what to expect from the Zmachine.

Re-Fill Zmachine Travel Case and Provide to Patient

Re-fill the Zmachine Travel Case with the equipment and supplies listed previously and provide to patient for continued use. See steps above.

Note: *If returning the Zmachine to a patient to continue their use, there is no need to erase data from the microSD or to prepare for a New Patient. Simply allow them to continue using the Zmachine system.*

General System Setup and Operation

Charging the Zmachine

The Zmachine internal battery, when fully charged and operating within design parameters, can operate the Zmachine for at least 12 hours. It takes approximately three hours to obtain a full charge.

To charge the Zmachine:

- i) Plug the Zmachine System Charger into a wall outlet.
- ii) Insert the free end of the Zmachine System Charger into the Zmachine Sensor/Charger Port.
- iii) Charging will start and stop automatically.



Plug the Zmachine System
Charger into a wall outlet



Insert the free end into the
Zmachine Sensor/Charger
Port

Charging Zmachine

Note: *The charge cable connector is keyed and can only be fully inserted when properly oriented.*


Note: *Ensure that the Zmachine is fully charged before providing to a patient for use. Advise patients to charge the Zmachine after each night of use.*

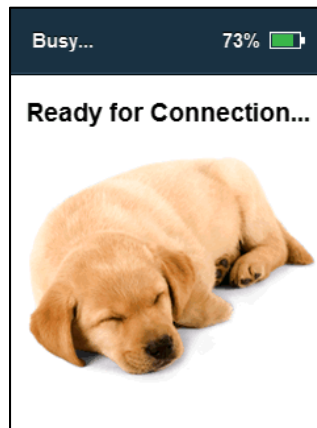
Note: *The Zmachine can safely remain connected to the charger until ready for use.*

Booting the Zmachine

Although the Zmachine will automatically boot and begin operation when the Zmachine Patient Cable is inserted, there may be times when you want to manually boot the Zmachine for operations such as checking/setting time and date, verifying the battery state of charge, preparing for a new patient, etc.

To boot the Zmachine:

- i) Press and release the  button.
- ii) If the system battery has sufficient power, it will boot immediately. Otherwise, refer to the *Charging* section of this document.



In order to save battery power, the Zmachine automatically dims the LCD backlight after 20 seconds, turns off the LCD backlight after 40 more seconds, and shuts down the system after an additional 60 seconds of inactivity.

Hint: *Pressing any button will restart the sequence described above.*

Accessing the Zmachine System Menu

To change any system setting requires access to the Zmachine System Menu. Access to the System Menu has been designed to be inaccessible to patients through the use of the Zmachine Clinician Key.

To access the Zmachine System Menu:

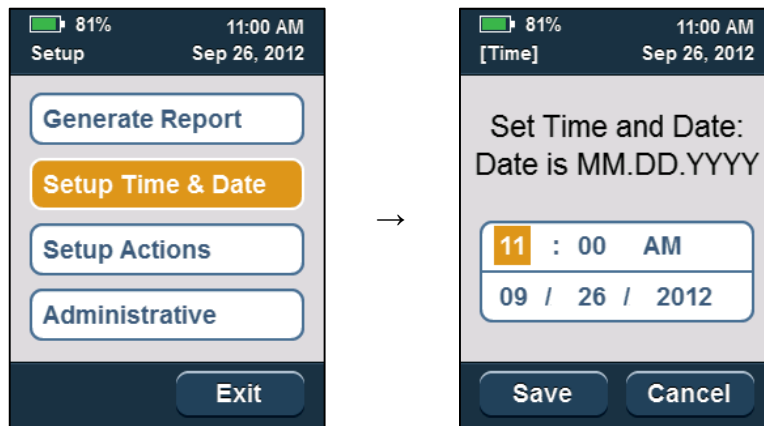
- i) Boot the Zmachine.
- ii) Insert the Zmachine Clinician Key into the Sensor/Charger Port.
- iii) The System Menu will be displayed when the Clinician Key is inserted and will disappear when the key is removed.



Setting the Time and Date

To set the time and date:

- i) Access the Zmachine System Menu.
- ii) Select *Setup Time & Date* and press **OK**.
- iii) Use the System Buttons to adjust the time and date fields.
 - a. **D** button will advance to the next field
 - b. **C** button will cycle through values in a field
 - c. **OK** will select selection of *Save* or *Cancel*
- iv) Select *Save* and press **OK** to commit changes and reboot the system.
Select *Cancel* and press **OK** to discard all changes.








Note: Whenever the time or date are manually updated and saved, the seconds are automatically zeroed at the moment **OK** is depressed, thereby enabling sub-second time synchronization.

Prepare the Zmachine for a New Patient

The Zmachine system uses a sophisticated learning algorithm to maximize accuracy. Therefore, the Zmachine *must* be cleared of all information before being used on each *different* patient.

To prepare the Zmachine for a new patient:

- i) Access the Zmachine System Menu.
- ii) Select *Administrative*
 - a.  will scroll through the menu choices
 - b. Pressing  will confirm the selection
- iii) Select *New Patient*
- iv) A confirmation screen will appear.
- v) Selecting  will permanently erase all data, sleep report, statistics, etc. and will prepare the Zmachine for a new patient.
- vi) Select *OK* (*bottom of system display*) and press  to run the operation and reboot the system.
Select *Cancel* (*bottom of system display*) and press  to cancel this operation.



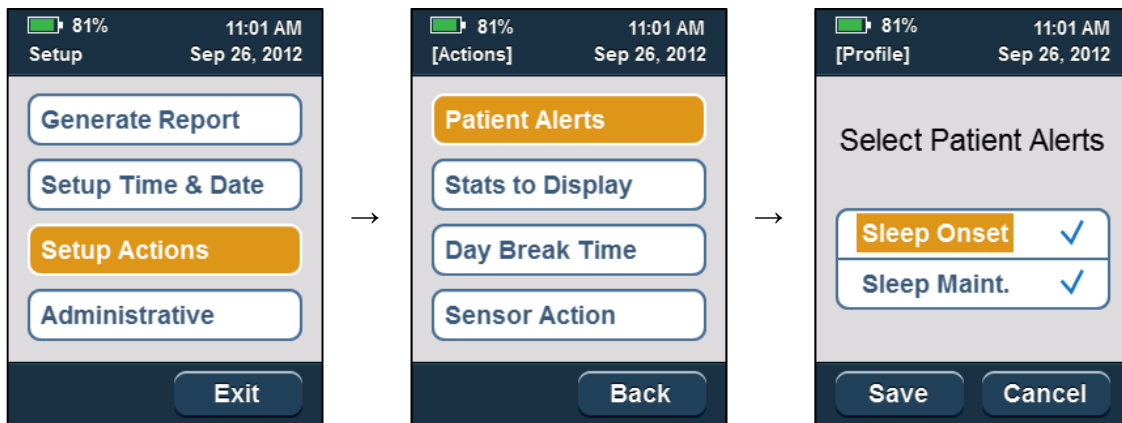
Note: The Zmachine must be prepared in this manner before providing to a new patient.

Setting the Alerts to Get-Out-Of-Bed (Insight+ only)

The Zmachine can be set to generate alerts to get-out-of-bed when the patient has not fallen asleep within the prescribed time interval (called a Sleep Onset alert), or when the patient has fallen asleep successfully, but woke and was unable to fall back to sleep within the prescribed interval (called a Sleep Maintenance alert).

To change the alerting:

- i) Access the Zmachine System Menu.
- ii) Select *Setup Actions*
- iii) Select *Patient Alerts*
- iv) Select *Sleep Onset* and press **OK** to toggle enabled/disabled.
 - a. A check mark indicates that the function is enabled.
- v) Select *Sleep Maint.* and press **OK** to toggle enabled/disabled.
 - a. A check mark indicates that the function is enabled.



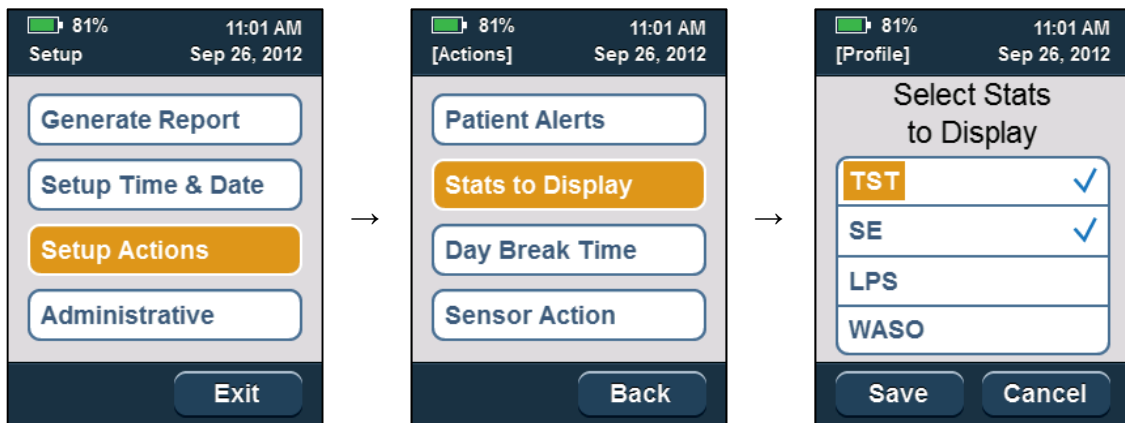
Note: A check mark indicates that the alert is enabled.

Setting the Statistics to Display (Insight+ only)

The Zmachine can be set to display statistics to the patient each time the sensor cable is disconnected.

To set which statistics will be displayed:

- i) Access the Zmachine System Menu.
- ii) Select *Set Actions*
- iii) Select *Stats to Display*
- iv) Select *TST* and press **OK** to toggle displayed/hidden
- v) Select *SE* and press **OK** to toggle displayed/hidden
- vi) Select *LPS* and press **OK** to toggle displayed/hidden
- vii) Select *WASO* and press **OK** to toggle displayed/hidden



Note: A check mark indicates that the statistic will be displayed when the sensor cable is disconnected.

Note: All statistics are calculated and displayed in the clinician report, regardless of the status of these display settings.

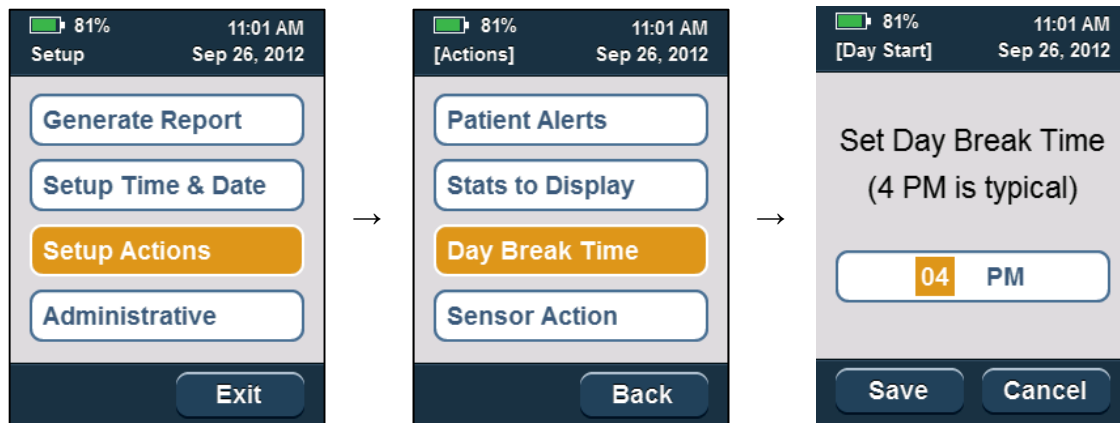
Setting the Day Break Time

The Day Break Time is the hour at which the system transitions from one day to the next. This is used by the statistics computation and reports. The default, 4:00 PM, is appropriate for most nocturnal sleepers.

If the patient sleeps through this time, then the resulting report will show their sleep as spanning two days (i.e. both sides of 4PM).

To change the Day Break Time:

- i) Access the Zmachine System Menu.
- ii) Select *Set Actions*
- iii) Select *Day Break Time*
- iv) Change the Hour and AM or PM.
- v) Select *Save* or *Cancel* and press **OK**.



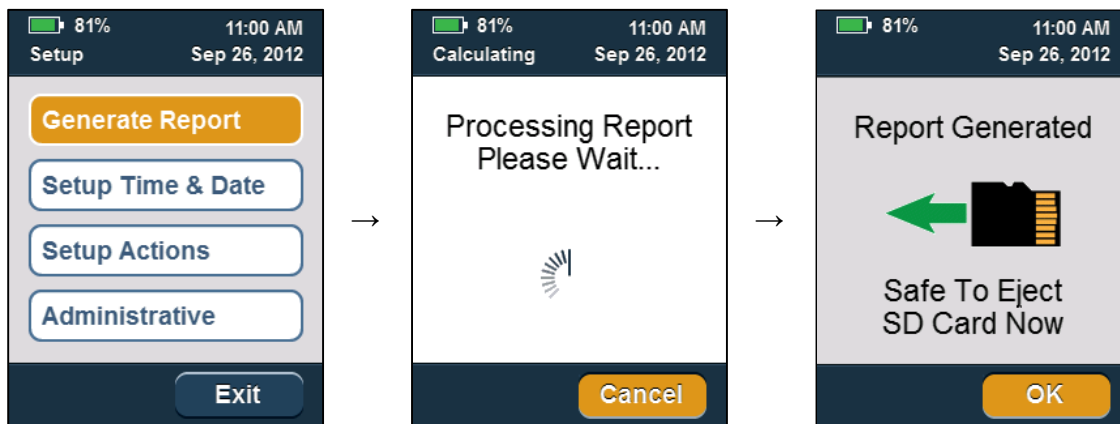
Note: *All statistics are calculated and displayed in the clinician report, regardless of the status of these display settings.*

Sleep Report and Statistics Files

Generate Sleep Report and Statistics

To generate the sleep report and summary statistics file:

- i) Access the Zmachine System Menu.
- ii) Select *Generate Report*

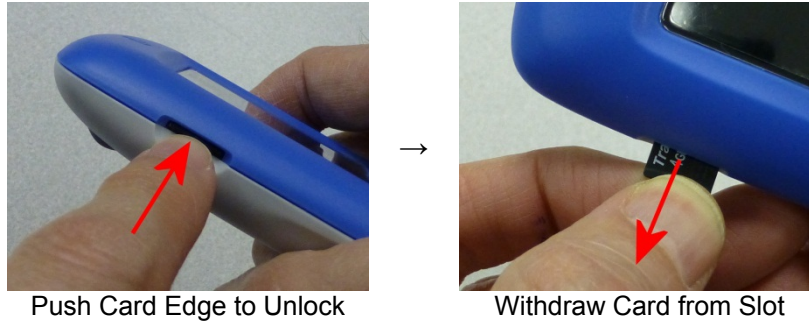


Note: *Following report generation, the microSD card can be ejected safely. If you do not wish to eject the microSD card at this time, simply press OK to return to the previous menu.*

MicroSD Card Operations (Eject, Copy Data, Insert)

The microSD card can only be ejected safely when the Zmachine is off, at the Main Screen (displaying either the sleeping puppy or sleep statistics) with the operating mode in the upper left corner indicating 'Ready', or following report generation. Otherwise, loss of data can result.

- i) Eject the microSD card by pressing inward on the edge of the card with your fingertip/ fingernail and releasing. If the card was depressed sufficiently, upon release, the card will protrude from the card slot sufficiently so as to allow it to be withdrawn.



Removing the microSD card

- ii) Insert microSD card into the supplied USB-microSD Card Reader.
- iii) Import data into your Zmachine Data Viewer software, or copy/paste files to your computer manually.



USB to MicroSD Card Reader

- iv) Reverse the above steps to insert the microSD card into the Zmachine (gold contacts facing down). Press the card into the card slot with your fingertip/ fingernail and release. If the card was depressed sufficiently, it will lock in place when released.

About the Sleep Report & Statistics Files

When generating a sleep report (which includes the summary statistics file), any previous reports on the microSD card will be overwritten. The sleep report and statistics files will appear in the root directory of the microSD card with the following file names:

score.csv
stats.csv

These are ASCII files in comma-separated-variable (csv) format that can be read by any text editor (such as Microsoft Notepad, Wordpad or Word) or directly imported into a spreadsheet (such as Microsoft Excel).

File: score.csv

Column definition:

1	2	3	4	5	6	7	8
Date	Time	Score	Session	Day	Events	Temporary Signature?	Arousal

Column 1: Date

This is the date of the start of the current 30-second epoch (mm/dd/yyyy format).

Column 2: Time

This is the start time of the current 30-second epoch (hh:mm:ss format).

Column 3: Score

This is the wake/sleep score of each 30-second epoch.

- 0 = Awake
- 2 = Light Sleep (N1 & N2)
- 3 = Deep Sleep (Slow Wave Sleep)
- 5 = REM Sleep
- 5 = Not Scored (sensor problem)

Column 4: Session

This is the recording session number (0, 1, 2, ... format). The session number will be automatically incremented each time the sensor cable is disconnected and reconnected.

Column 5: Day

This is the recording day number (0, 1, 2, ... format). The day number is incremented when the current time passes the *Day Break Time* (i.e. 4 p.m.).

Column 6: Events

These are events related to patient alerting (Insight+ only).

- 0 = Patient alerting is not enabled.
- 1 = Patient alerting is enabled.
- 2 = Patient woke from at least 5 minutes of sleep within a 6 minute sliding window, but not enough sleep to achieve sleep maintenance. Alerts will now be suspended for the next 10 minutes (this can happen no more than once per session).
- 3 = Patient achieved 10 minutes of sleep within a 12 minute sliding window. This suspends the sleep onset rule, and arms the sleep maintenance rule.
- 4 = Alert generated (audible and LCD message) for patient to leave bed.

Column 7: Temporary Signature?

This column is related to data requirements.

- 0 = Report generated normally with the data requirement satisfied (default: 2 days & 12 hours). This requirement can be changed using the Zmachine Data Viewer.
- 1 = Report generated with less data.

Column 8: Arousal

This column is related to the detection of an EEG arousal when the epoch is scored as sleep.

- 0 = No arousal detected.
- 1 = Arousal detected.

File: Stats.csv

This is an example of Stats.csv as viewed in a spreadsheet:

1	2	3	4	5	6	7
Day	Start Date	Start Time	SPT (hrs)	TST (hrs)	SE (%)	LPS (min)
8	9	10	11	12	13	14
WASO (min)	SPT2 (hrs)	TST2 (hrs)	SE2 (%)	LPS2 (min)	WASO2 (min)	Temporary Signature?
15	16					
Deep Sleep (hrs)	REM (hrs)					

Column 1: Day

This is the recording day number (0, 1, 2, ... format). Statistics are generated for each day.

Column 2: Start Date

This is the date of the start of each 30-second epoch (mm/dd/yyyy format).

Column 3: Start Time

This is the start time of each 30-second epoch (hh:mm:ss 24-hour format).

Column 4: SPT (hrs)

Sleep Period Time is the total recording time, reported in hours, *including* out of bed gaps, for each day. Periods of time when the impedance check shows failed sensor(s) are not included in this number.

Column 5: TST (hrs)

Total Sleep Time is the accumulation of all epochs determined to represent sleep. This statistic *includes* time spent out of bed.

Column 6: SE (%)

Sleep Efficiency is $100 \times (\text{TST}/\text{SPT})$ and reported as a percentage. This statistic *includes* time spent out of bed.

Column 7: LPS (min)

Latency to Persistent Sleep is the elapsed time, reported in minutes, until the beginning of the period in which 10 of 12 minutes are scored as sleep (start of Sleep Maintenance). This statistic *includes* time spent out of bed.

Column 8: WASO (min)

Wake After Sleep Onset is the total awake time, reported in minutes, following LPS. Awake must be 3 or more contiguous epochs in order to be counted. This statistic *includes* time spent out of bed.

Column 9: SPT2 (hrs)

Sleep Period Time is the total recording time, reported in hours, *excluding* out of bed gaps, for each day.

Column 10: TST2 (hrs)

Total Sleep Time is the accumulation of all epochs determined to represent sleep. This statistic *excludes* time spent out of bed.

Column 11: SE2 (%)

Sleep Efficiency is $100 \times (\text{TST2}/\text{SPT2})$ and reported as a percentage. This statistic *excludes* time spent out of bed.

Column 12: LPS2 (min)

Latency to Persistent Sleep is the elapsed time, reported in minutes, until the beginning of the period in which 10 of 12 minutes are scored as sleep (start of Sleep Maintenance). This is also known as Latency to Persistent Sleep. This statistic *excludes* time spent out of bed.

Column 13: WASO2 (min)

Wake After Sleep Onset is the total awake time, reported in minutes, following LPS. Awake must be 3 or more contiguous epochs in order to be counted. This statistic *excludes* time spent out of bed.

Column 14: Temporary Signature?

This column is related to data requirements.

0 = Statistics generated normally.

1 = Statistics generation was forced by the clinician when insufficient data was available for the report (a warning screen was displayed). A temporary patient signature is generated for the purposes of generating the report.

Column 15: Deep Sleep (hrs)

Total Deep Sleep reported in hours.

Column 16: REM (hrs)

Total REM Sleep reported in hours.

System Utilities

Display System Information

To display the Zmachine system information:

- i) Access the Zmachine System Menu.
- ii) Select *Administrative*
- iii) Select *About*
- iv) When done, press **OK**.



S/N = System serial number.

Hardware Ver = Version of the system hardware.

Firmware Ver = Version of the system firmware.

Staging Ver = Version of the sleep staging algorithm.

Feedback Ver = Version of the alert-to-get-out-of-bed and statistics algorithms (Insight+ only)

SD Free (Hrs) = Recording space remaining on the microSD card in hours.

Odometer = Accumulated EEG acquisition time in hours.

Update Firmware

Updates to the Zmachine system firmware may be released by General Sleep Corporation (GSC) from time to time.

To install a firmware update on your Zmachine system:

- i) With the Zmachine off, eject the microSD card.
- ii) Using the microSD card reader and PC, copy the firmware update file to the microSD card **(do not change the name of this file)**.
- iii) Properly eject the microSD card reader from the PC.
- iv) Return the microSD card containing the firmware update file to the Zmachine
- v) Press **OK** to boot the Zmachine
- vi) Access the Zmachine System Menu.
- vii) Select *Administrative*
- viii) Select *Update Firmware*
- ix) If the firmware update was successful, the Zmachine will reboot when the operation has completed. Otherwise, an error screen will be displayed.



Hint: Following a firmware update, it is always a good idea to access the Zmachine System Menu → *Administrative* → *About* to verify that the correct firmware update was installed.

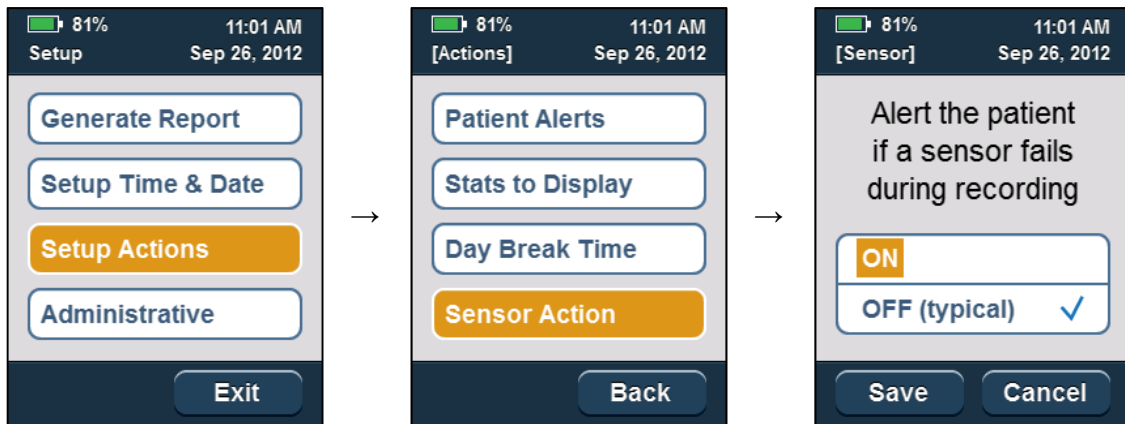
Setting the Failed Sensor Alert

Throughout the recording session, the Zmachine can periodically measure and limit test the sensor impedance values (default is every 15 minutes). If the Zmachine detects a failed sensor, it can either stay silent (default), or can produce an immediate alert to the patient with instructions presented on the system display indicating which sensor(s) need to be replaced. Regardless which setting is selected, the detection of a failed sensor will always be noted in the report.

Note: *If Sensor Action is enabled (i.e. ON), then a failed sensor will cause the Zmachine to produce an immediate audible alert that will potentially wake your patient. This may not be desirable in some clinical applications.*

To change the impedance alert behavior:

- i) Access the Zmachine System Menu.
- ii) Select *Setup Actions*
- iii) Select *Sensor Action*
- iv) Select *ON* or *OFF* and press **OK**.



Note: *The default time interval between measurements, pass/fail impedance limits, and many other advanced settings can be viewed and changed using the Zmachine Data Viewer software.*

Troubleshooting and Specifications

Troubleshooting

Troubleshooting solutions for some problems you may encounter with the Zmachine system are listed below. If none of the corrective actions provided solve your problem or if your problem is not listed, then discontinue use immediately and contact General Sleep.

Problem	Solution
The Zmachine can no longer run for at least 12 hours on a full charge.	The battery has reached end of life. Contact General Sleep to arrange for battery replacement.
The Zmachine does not indicate a full charge after 5 hours of charging or the LCD indicates Charge Fault.	The wall charger may be faulty or the battery may have reached end of life. Contact General Sleep to arrange for battery or charger replacement.
Zmachine display indicates microSD card full.	Prepare the Zmachine for a New Patient (<i>System Menu</i> → <i>Administrative</i> → <i>New Patient</i>). This operation will clear all data from the microSD. If this does not resolve the problem, the microSD card may be defective. Contact General Sleep to arrange for microSD card replacement.
Sensor check indicates that one or more sensors need to be replaced.	Replace the failed sensors according to the Patient Guide. If the problem persists, then a faulty sensor cable may be the cause. Contact General Sleep to arrange for replacement.
Zmachine system and/or cable are damaged.	Discontinue use immediately and return to General Sleep for repair or replacement.
Sleep report does not match the patient report.	Patient self-reporting is highly subjective and may or may not be accurate. However, if you suspect a problem with the Zmachine system then discontinue use and contact General Sleep.

Zmachine Insight & Insight+ Specifications

The Zmachine is a Class II, type BF, internally powered, medical device and is rated for continuous operation.

Input Characteristics

Type	Fully differential
Coupling	AC
Voltage (non-distorted)	$\pm 500 \mu\text{V}$
Voltage (maximum)	$\pm 40 \text{ V}$
Highpass Filter Cutoff	0.5 Hz
Lowpass Filter Cutoff	380 Hz
Impedance	$10\text{G}\Omega \parallel 800\text{pF}$

Analog-to-Digital Conversion

Sampling frequency	2.5 kHz
Sampling resolution	16 bit
Linearity	$\pm 1.5 \text{ LSB}$
Architecture	SAR

Battery

Nominal Voltage	3.7 VDC
Chemistry / Cell type	Lithium Ion / Secondary
Capacity	900 mAh @ C/5 Rate @ 23 degC (standard) 1800mAh @ C/5 Rate @ 23 degC (extended)
Runtime	12-18.5 hrs (standard battery) 24-29.5 hrs (extended battery)
Charge time	$\leq 5 \text{ Hr}$ (standard battery) $\leq 8 \text{ Hr}$ (extended battery)

Current Consumption (Nominal)

Running	$\sim 70 \text{ mADC}$
Charging	$\sim 600 \text{ mADC}$
Sleeping	$\leq 0.5 \mu\text{ADC}$

Data Storage

Type	microSDHC
Capacity	16 GB (Standard)
Data capacity	900 Hr

Mechanical

Length	116 mm
Width	68 mm
Height	21 mm
Weight	102 g (standard battery) 122 g (extended battery)
Enclosure material	ABS Plastic
Window material	Lexan

Standards

Electrical Safety	IEC/UL 60601-1
Electromagnetics	IEC/UL 60601-1-2
FCC	47 CFR 15, Subpart B

Clinical Performance

Clinical Performance Summary

A ninety-nine subject (99) clinical study was conducted in which polysomnographic (PSG) data was acquired and analyzed by polysomnographic technologists, and simultaneously data from the differential mastoids were acquired and processed by the Zmachine algorithm.

Each PSG record was scored independently by at least two (2) certified polysomnographic technologists (3 records scored by 2 technologists, 16 records scored by 3 technologists, and 80 records scored by 4 technologists) using the Rechtschaffen & Kales (R&K, 1968) visual sleep scoring rules. The performance of the Zmachine was evaluated by comparing the Zmachine algorithm to the consensus of human scorers.

Analysis demonstrates substantial agreement between the Zmachine and the consensus of polysomnographic technologists. The P1 (the probability that Zmachine will correctly assign an epoch when the PSG Consensus assigns the epoch to a particular stage) and P2 (when the Zmachine assigns an epoch to a particular stage, the probability of such assignment is correct) values for the detection of Wake, Light Sleep, Deep Sleep and REM for the Zmachine algorithm (staging version 2.1) are summarized in the following table:

	Wake	Light Sleep	Deep Sleep	REM
P1	0.928	0.825	0.783	0.723
P2	0.838	0.855	0.743	0.749

The P1 and P2 values were also computed for each subject individually (99 P1 and 99 P2 values were obtained for each stage). The mean and interval estimation (95% confidence level) is summarized the following table:

	Wake	Light Sleep	Deep Sleep	REM
P1	0.933 ± 0.012	0.822 ± 0.016	0.730 ± 0.063	0.719 ± 0.037
P2	0.814 ± 0.027	0.854 ± 0.017	0.722 ± 0.072	0.751 ± 0.033

The overall Kappa agreement between the Zmachine Algorithm and the PSG Consensus for 85,206 epochs of data is 0.722, which is well above the 0.6 threshold for good agreement. The Kappa score was also computed for each subject individually (99 Kappa scores were obtained). The interval estimation with 95% confidence level for the Kappa score is 0.708±0.020.

In conclusion, the Zmachine Algorithm shows good performance in sleep staging from a single-channel of EEG data. A copy of the full Technical Report is available upon request.

Legal Notices

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, Euclid, 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 Patent: 2201694, 2516093, 2783015
European Patent: 1124611, 2512573
Japanese Patent: 4532739, 4721451, 5684828
Other patents pending

User Agreement

This User Agreement (“Agreement”) sets forth the terms of use by and between Consolidated Research of Richmond, Inc. dba General Sleep Corporation (“GSC”), an Ohio corporation, whose address is 26250 Euclid Avenue, Suite 709, Euclid, OH 44132, and the user of the subject equipment known as the Zmachine (“User”).

1. 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 that User and all others using the Zmachine shall abide by and conform to, all laws and governmental orders, rules and regulations, including any future amendments thereto, controlling or in any manner affecting operation, or use or of the Zmachine.
2. 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.
3. GSC warrants to the initial User that the Zmachine will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year (“Warranty Period”) from the date of its initial 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 Warranted Product (or part thereof) to GSC. GSC shall determine whether to repair or replace Products and parts covered by this warranty and 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 or part thereof. If GSC reasonably determines that a repair or replacement is covered by the warranty, GSC shall bear the costs of shipping the repaired or replacement 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 products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the warranted product, including but not limited to failure of or faulty electrical power; that have been used in violation of GSC's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than GSC; or that have been disassembled, serviced, or reassembled 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 THE SOLE AND EXCLUSIVE WARRANTY FOR GSC'S PRODUCTS, EXTENDS ONLY TO THE USER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GSC'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY GSC IN CONNECTION THEREWITH. GSC SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

4. All notices and other communications required by this Agreement shall be in writing and shall be delivered either by personal delivery or by mail. If delivered by mail, notices shall be sent by

Express Mail or by certified or registered mail, return receipt requested, with postage and charges prepaid.

5. The Parties agree that every dispute or difference between them arising under this Agreement, including a failure to reach a decision as described in this Agreement, shall be settled first by a meeting of the parties attempting to confer and resolve the dispute in a good faith manner.

6. This Agreement shall be governed in accordance with the laws of the State of Ohio and each party: (a) consents to the exclusive jurisdiction and venue of the federal and state courts located in Ohio; (b) waives any objection it might have to jurisdiction or venue of such forums or that the forum is inconvenient; and (c) agrees not to bring any such action in any other jurisdiction or venue to which either party might be entitled by domicile or otherwise.

7. No waiver by any party of any breach of the terms and conditions of this Agreement shall constitute a waiver of any subsequent breach of the same or any other terms or conditions of this Agreement.

8. This Agreement shall be binding upon and it shall inure to the benefit of the parties hereto and their respective heirs, agents, representatives, successors and assigns.

9. The invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions hereof and this Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted.

Software License Agreement

The computer software (“Licensed Software”) loaded on the Zmachine (the “System”) is licensed, not sold, to you for use only under the terms of this license. Consolidated Research of Richmond, Inc., dba General Sleep Corporation (“GSC”) reserves any rights not expressly granted to you. While you may possess the System, but GSC retains all ownership rights and title to the Licensed Software itself.

You are hereby granted the non-exclusive right to use the Licensed Software solely with the specific System on which the Licensed Software was provided to you.

You shall not transfer the Licensed Software in any manner from the System to any other computer or system without the prior written consent of GSC. You shall not distribute copies of the Licensed Software or its related documentation to others. You shall not modify or translate the Licensed Software or its related documentation without the prior written consent of GSC. The Licensed Software is proprietary; you may not decompile, reverse engineer, disassemble, or otherwise reduce the Licensed Software to a human-perceivable form. If you transfer the System, you have the right to transfer the Licensed Software provided that the transferee agrees to be bound by the terms and conditions of this License Agreement.

This License remains effective until terminated. This License will terminate automatically without notice from GSC if you fail to comply with any term or provision of this License. Upon termination of this License, you may not make any further use of the Licensed Software.

THE LICENSED SOFTWARE IS PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY WITH RESPECT TO ITS MERCHANTABILITY OR ITS FITNESS FOR ANY PARTICULAR PURPOSE. GSC DOES NOT WARRANT THAT THE FUNCTIONS CONTAINED IN THE LICENSED SOFTWARE WILL MEET YOUR REQUIREMENTS OR THAT THE OPERATION OF THE LICENSED SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE OR THAT SUCH ERRORS IN THE LICENSED SOFTWARE WILL BE CORRECTED.

GSC’S ENTIRE LIABILITY TO YOU FOR ACTUAL DAMAGES FOR ANY CAUSE WHATSOEVER, AND REGARDLESS OF THE FORM OF THE ACTION, AND YOUR EXCLUSIVE REMEDY SHALL BE LIMITED TO THE MONEY PAID FOR THE SYSTEM, WHICH INCLUDED THE LICENSED SOFTWARE. IN NO EVENT SHALL GSC BE LIABLE TO YOU (i) FOR ANY INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, AND THE LIKE) ARISING OUT OF THE USE OF OR INABILITY TO USE ANY LICENSED SOFTWARE EVEN IF GSC OR ANY AUTHORIZED GSC REPRESENTATIVE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR (ii) FOR ANY CLAIM BY ANY OTHER PARTY.

This License Agreement will be construed under the laws of the State of Ohio. If any provision of this License Agreement shall be held by a court of competent jurisdiction to be contrary to law, that provision will be enforced to the maximum extent permissible, and the remaining provisions of this Agreement will remain in full force and effect.

Should you have any questions concerning this License Agreement, you may contact GSC by writing to General Sleep Corporation, at 26250 Euclid Avenue, Suite 709, Euclid, Ohio 44132.