Zmachine® Synergy

Clinician Instruction and Service Manual
Version 1.7

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 Synergy, 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 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 Cleveland, OH 44132, USA
Telephone	(888) 330-4424
General Information	Info@GeneralSleep.com
Technical Support	Support@GeneralSleep.com
Website	www.GeneralSleep.com

Note: This manual is applicable to the Zmachine Synergy running firmware version 1.1.5 and later.

Table of Contents

1

Introduction

Description

The Zmachine® Synergy is a high technology sleep monitor developed by General Sleep Corporation. The system records physiological signals from its on-board electroencephalographic (EEG) hardware, respiratory and body position sensors. The Zmachine Synergy was designed for use in the home or clinical environment. Signal data stored on the Zmachine Synergy can be uploaded via USB connection for later review.

The Zmachine Synergy acquires one channel of EEG via electroencephalograph with integrated impedance measurement technology, respiratory airflow and snore via temperature-compensated pressure transducer, oxygen saturation and pulse rate via pulse-oximeter, respiratory effort via thoracic respiratory inductance plethysmography belt, and body position via 3D accelerometer.

The patient and healthcare provider are both intended operators of the Zmachine Synergy.

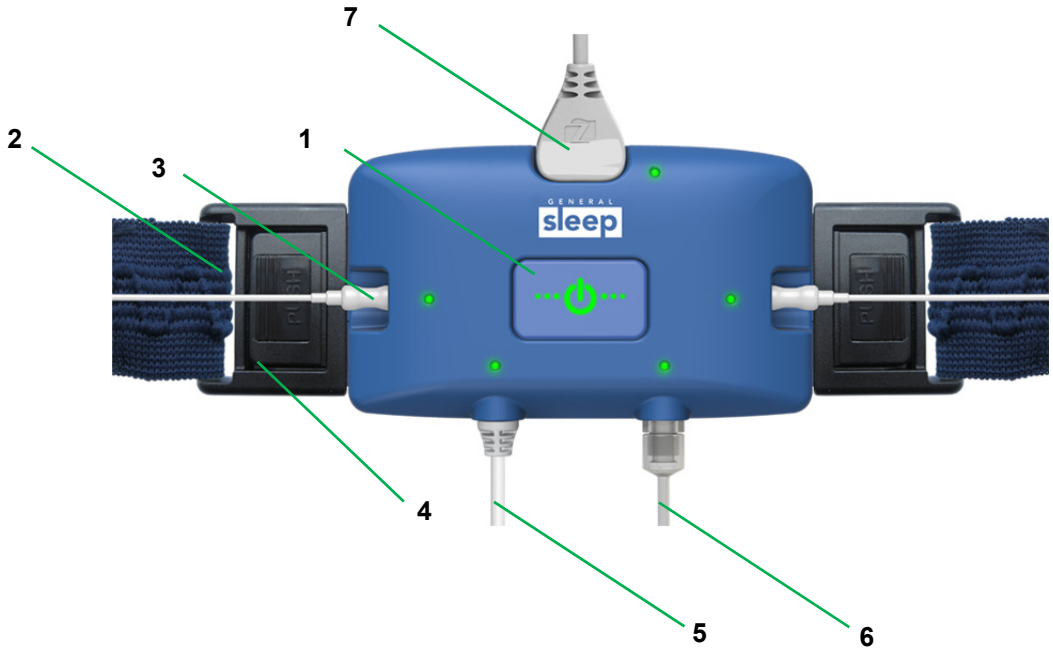
Indications for Use

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

Service Life

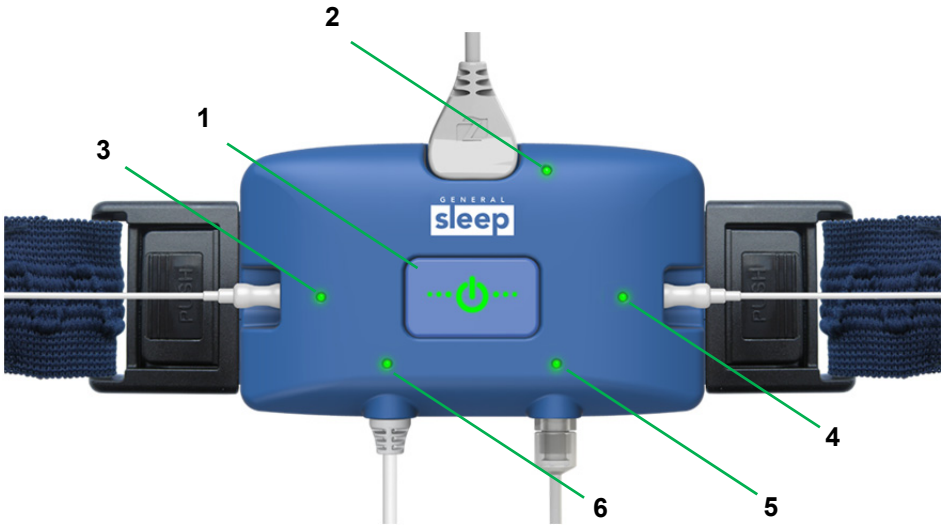
The Zmachine device has an expected service life of not less than two years. The cables, effort belt, and pulse oximeter finger probe have an expected service life of not less than one year.

The Zmachine Synergy Elements



Reference	Description
1	Power button
2	Inductance belt
3	Inductance belt cable
4	Inductance belt buckle
5	Pulse oximeter cable
6	Cannula
7	EEG/USB cable

The Zmachine Synergy Indicators

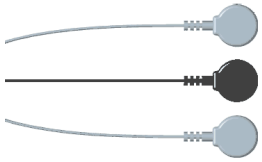


Reference	Description
1	Main system status
2	EEG sensor status
3	Inductance belt status
4	Inductance belt status
5	Airflow status
6	Pulse oximeter status

Description of Reusable Components

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

Zmachine Synergy
Rating: 5VDC ~ 500mA
GSC P/N 300-001



EEG Cable
Silicone jacket / 0.5m length
GSC P/N 300-011

Oximeter Finger Probe
GSC P/N 300-006

Effort Belt
Technology: Inductance
GSC P/N 300-010

Effort Belt Cables (set)
GSC P/N 300-003

Oximeter Belt Clip
GSC P/N 300-005

USB Cable
USB 2.0 Hi-Speed - 480Mbit/s
GSC P/N 300-004

Travel Case
GSC P/N 200-120

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 EEG Sensors
GSC P/N 200140-1

Alcohol Swabs
GSC P/N 200-060

Nasal Cannula
GSC P/N 300-032

Paper Tape
GSC P/N 300-034

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

Description of Documentation Components

The Zmachine system may include some or all of the documentation described below:

Patient Guide
GSC P/N 300-012

Clinician Manual
GSC P/N 300-016

Note: Documentation and software are also available for download from the support section of the General Sleep website (www.GeneralSleep.com)

Glossary of Symbols

Symbol	Definition of Symbol
	Read and understand the accompanying instructions before using the Zmachine Synergy.
	IEC 60601-1 Type BF applied parts.
	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.
	This system is not rated for use in wet conditions. Keep dry.

2

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 fragile or damaged skin. The self-adhesive EEG 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 system cables.

Advise patient to take care in arranging the system cables to avoid entanglement.

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

Do not modify the Zmachine and/or open Zmachine enclosure for any reason. The Zmachine contains no user serviceable parts and the internal Lithium Ion battery is not user replaceable. Service or repairs must be performed by General Sleep Corporation.

Do not perform service or maintenance activities while the Zmachine is in use.

The small parts and accessories of the Zmachine (such as EEG sensors and their clear backings) can present a choking hazard to small children and pets.

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.

Only use General Sleep approved parts and accessories.

The Zmachine employs high sensitivity amplifiers to acquire and analyze very low amplitude 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. 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.

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, damage to the Zmachine or accessories has been observed/suspected, 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, hypersensitivity, or an allergic reaction to the self-stick sensors or adhesive tape. 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 Zmachine and accessories should be cleaned between patients. Patient contact disposables (EEG sensors, cannulas, etc.) should be discarded and replaced with fresh.

The outer surfaces of the Zmachine Synergy may be cleaned between patients, or as needed, using 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.

The respiratory effort belt is machine washable (warm/gentle). Do not use bleach. Insert belt into protective pouch during tumble drying. Do not iron or dry clean. Make sure belt is thoroughly dry before use. No not soak in disinfectant.

To clean the pulse oximeter finger probe, wipe all patient contract surfaces with a soft cloth dampened with a mild detergent or a 10% bleach / 90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Allow the sensor to dry thoroughly before using.

The cannula and EEG sensors are disposable and should not be re-used.

Note: *The preceding Inspection and Cleaning activities should be performed prior to conveying the Zmachine to your Patient. The Patient has no maintenance responsibilities.*

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 electrical 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. 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 for devices containing lithium ion batteries.

4

Usage Overview

When the Zmachine Synergy is connected to a computer running Windows or Mac OS using a USB cable, the system will appear on the computer as a write-protected removable drive (same as a USB thumb drive). Because the data on the Zmachine is mounted in read-only mode, it is protected from corruption, virus infection, etc.

To facilitate communication between the Zmachine Synergy and attached computer without the possibility of corrupting the stored data, a serial data connection is automatically established over the USB link in which commands can be issued back and forth between the systems.

Charging

The Zmachine Synergy will charge whenever connected to a suitable USB device (computer, powered hub, or stand-alone charger). It takes approximately one hour to re-charge for each eight hours of recording.

Uploading data

When the Zmachine Synergy is connected to a PC, the system will provide the option of uploading data (assuming data is present on the Synergy). When data is successfully uploaded and verified from the Zmachine Synergy to a PC, the data on the Zmachine Synergy is deleted.

Pack Supplies for Patient to Take Home

Pack Zmachine Synergy Travel Case with the following supplies:

1. Zmachine Synergy system (fully charged)
2. Respiratory effort belt
3. Respiratory effort belt cables (2)
4. Pulse oximeter finger probe
5. Pulse oximeter belt clip
6. Patient EEG cable
7. EEG sensors (one package for each day, plus some extras)
8. Alcohol swabs (two swabs for each day, plus some extras)
9. Patient Guide

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

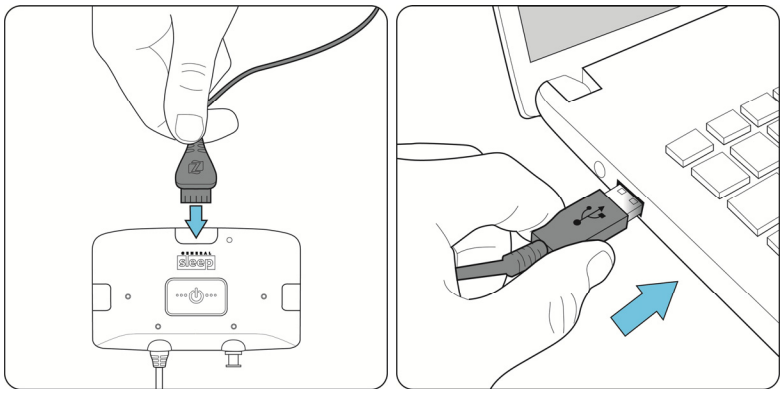
Familiarize Patient with the Zmachine

Review the Patient Guide and all accessories with your patient. To lessen the burden on the patient, use this opportunity to adjust the length of the thoracic effort belt for a snug, but not overly tight fit (should move with their breathing). Special attention should be given to instructing the patient in applying the EEG sensors and attaching to the sensor cable.

5

General System Setup and Operation

Charging the Zmachine



Plug the USB Cable into the Zmachine and the free end into a computer, powered hub, or dedicated charger. Charging will start and stop automatically.

With the Zmachine Synergy in a powered off state, plug the USB cable into the Synergy device, and then connect to a PC or charger.

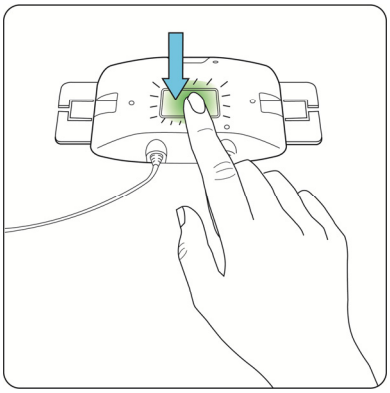
The Zmachine internal battery, when fully charged and operating within design parameters, can operate the Zmachine Synergy for at least 24 hours. It takes approximately three to four hours to charge a fully discharged battery (about 1 hour of re-charge per 8 hours of recording).

When the Zmachine is connected to a dedicated charger, powered hub, or computer, the perimeter indicator lights will pulse BLUE. While battery charging is in progress, the center button will show solid YELLOW. When charging is complete, the center button will change to solid GREEN.

Note: *Ensure that the Zmachine is fully charged before providing to a patient.*

Note: *The Zmachine will not overcharge. The system can safely remain connected to a charger until ready for use.*

Turning on the Zmachine



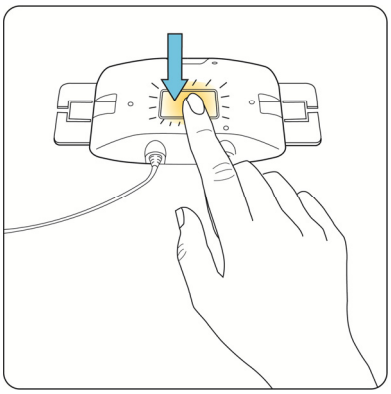
Press and hold the center button until the system lights appear (about 1 second).

If the system battery has sufficient power, the system will boot immediately and the system lights will illuminate. Otherwise, refer to the *Charging* section of this document.

In order to save battery power, the Zmachine automatically manages the LED brightness and will turn them off to save power when appropriate.

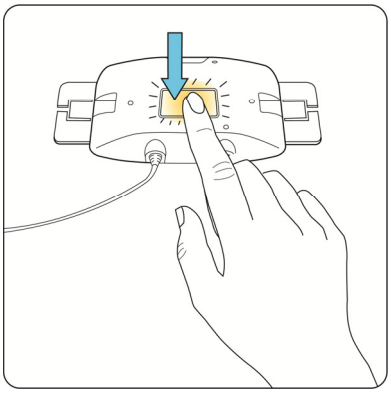
Hint: *Pressing the Power Button will re-illuminate the LEDs to display the current system status.*

Turning off the Zmachine



Press and hold the center button until the system beeps (about 3-4 seconds). All lights will glow orange, then turn off.

Forcing a system reset of the Zmachine



Press and hold the center button for 10 seconds. All system lights will be off when finished.

If the system becomes unresponsive and a system reset is needed, simply press and hold the button for at least 10 seconds, then release and wait another 10 seconds. This will force a system power shutdown sequence and should clear any fault condition(s).

If the problem persists, contact General Sleep for service for help (support@GeneralSleep.com).

6

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.	The wall charger may be faulty or the battery may have reached end of life. Try a different USB charger, or Contact General Sleep to arrange for battery replacement.
Noisy, corrupt, or missing signal(s)	The Zmachine may be affected by local EMI/RFI interference. If this is suspected, switch off or move equipment suspected of causing interference from the proximity of the Zmachine and re-try. If the problem persists, discontinue use and contact General Sleep for service.
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, contact General Sleep for service.
Zmachine system and/or accessories are damaged	Discontinue use immediately and contact General Sleep to arrange repair or replacement.
System does not boot when button pressed.	Battery may be fully discharged. Charge system and re-try. If problem persists, contact General Sleep for service.

Problem	Solution
System will not shut down when button held for 3-4 seconds.	Press and hold the button for at least 10 seconds to force system shutdown (there is a special circuit that will force a shutdown after 10 seconds). If problem persists, contact General Sleep for service.
System loses time and data.	The internal battery can hold the system time and date for at least three months between charging. Re-charge system and set correct time and date. If problem persists, contact General Sleep for service.

Zmachine Synergy Specifications

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

EEG Input Circuit	
Type	Fully differential
Coupling	AC
Voltage (non-distorted)	±500 µV
Voltage (maximum)	±40 V
Highpass Filter Cutoff	0.5 Hz
Lowpass Filter Cutoff	380 Hz
Impedance	10 GΩ || 800 pF
Sampling frequency	2500 Hz
Sampling resolution	16-bit
Linearity	± 1.5 LSB
Architecture	SAR
Effort Belt	
Type	Respiratory Inductance Plethysmography
Coupling	DC
Sampling frequency	500 Hz
Sampling resolution	16-bit
Linearity	± 1.5 LSB
Architecture	SAR
Airflow	
Type	Pressure transducer
Coupling	DC
Sampling frequency	125 Hz
Sampling resolution	14-bit
Accelerometer	
Type	Three-axis Linear Accelerometer
Coupling	DC
Sampling frequency	125 Hz
Sampling resolution	12-bit
Pulse Oximeter	
Type	Finger Pulse Oximeter
Coupling	DC
Sampling frequency	3 Hz pulse and SpO_2, 75 Hz for pleth

Battery	
Nominal Voltage	3.7 VDC
Chemistry	Lithium Ion
Capacity	900 mAh @ C/5 Rate @ 23 degC
Runtime	24 hrs
Charge time	3-4 hrs
Current Consumption (Nominal)	
Running	~30 mADC
Charging	~500 mADC
Sleeping	≤ 0.5 µADC
Data Storage	
Type	microSDHC
Capacity	4 GB
Data capacity	150 hrs
Mechanical	
Length	102 mm
Width	61 mm
Height	24 mm
Weight	93 g
Enclosure material	ABS Plastic
Standards	
Safety	60601-1
EMC	60601-1-2 Editions 2, 3 and 4
Home Healthcare	60601-1-11
FCC	47 CFR 15, Subpart B

Electromagnetic Compatibility (EMC) Summary Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Zmachine Synergy is intended for use in the electromagnetic environment specified below. The customer or the user of the Zmachine Synergy should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Zmachine Synergy uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Zmachine Synergy is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING:

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified in the clinical guide is not recommended. They may result in increased emissions or decreased immunity of the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zmachine Synergy is intended for use in the electromagnetic environment specified below. The customer or the user of the Zmachine Synergy should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Zmachine Synergy, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zmachine Synergy is used exceeds the applicable RF compliance level above, the Zmachine Synergy should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Zmachine Synergy.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Zmachine Synergy			
The Zmachine Synergy is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zmachine Synergy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zmachine Synergy as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $\boldsymbol{d = 1.2\sqrt{P}}$	**80 MHz to 800 MHz** $\boldsymbol{d = 0.35\sqrt{P}}$	**800 MHz to 2.5 GHz** $\boldsymbol{d = 0.70\sqrt{P}}$
0.01	0.012	0.035	0.07
0.1	0.38	0.67	0.22
1	1.2	0.35	0.70
10	3.8	1.1	2.2
100	12	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

As Zmachine Synergy does not have essential performance, all Zmachine Synergy immunity tests have been performed during Recording Mode and during USB Charging Mode.

7

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"). 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 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. 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. 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. 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. 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. 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. 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, for your use 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, GSC retains all ownership rights and title to the Licensed Software. 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 (1) 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 (2) 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.

Privacy Policy

For purposes of this Agreement ("Agreement"), the following terms have the following meanings: "User" means anyone using the Zmachine Synergy (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 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.