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

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

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

Web Site
www.GeneralSleep.com

Guide Revision: 1.9

Copyright © 2018 by General Sleep Corporation
All rights reserved
# Table of Contents

About this Guide  
Table of Contents  
Introduction  
Indication for Use  
Symbol Descriptions  
Description of Components  
The Zmachine Synergy Indicators & Elements  
Warnings and Cautions  
Disposal  
Cleaning  
Interference  
Using the System  
Step 1: Clean/Prepare Skin  
Step 2: Apply Sensor Pads  
Step 3: Setup Effort Belt  
Step 4: Connect Cable and Sensors  
Step 5: Connect the Cannula  
Step 6: Connect the Finger Probe  
Step 7: Review (not really a step)  
Starting the Test  
Stopping the Test  
Frequently Asked Questions  
Legal
Introduction

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

Indication for Use

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

Symbol Descriptions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition of Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>Read and understand the instructions before using this system.</td>
</tr>
<tr>
<td>☔️</td>
<td>This system is not rated for use in wet conditions. Keep dry.</td>
</tr>
<tr>
<td>🍼</td>
<td>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.</td>
</tr>
<tr>
<td>🤸</td>
<td>IEC 60601-1 Type BF applied parts.</td>
</tr>
<tr>
<td>✔️</td>
<td>Built according to RoHS (Restriction of Use of Hazardous Substances) regulations that limit or ban specific substances in new electronic and electric equipment.</td>
</tr>
<tr>
<td>🌐</td>
<td>Product tested and certified by SGS North America, Inc. to meet worldwide safety standards.</td>
</tr>
</tbody>
</table>
### Description of Components

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

<table>
<thead>
<tr>
<th>Zmachine Synergy</th>
<th>EEG Cable</th>
<th>Nasal Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effort Belt</td>
<td>Effort Belt Cables</td>
<td></td>
</tr>
<tr>
<td>Finger Probe</td>
<td>Sensor Pads</td>
<td>Alcohol Swabs</td>
</tr>
<tr>
<td>Paper Tape</td>
<td>Belt Clip</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Due to differences in brand and model numbers, part appearances may vary. Only use General Sleep approved parts and accessories.
# The Zmachine Synergy Indicators & Elements

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Description</th>
<th>Ref.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Main system status</td>
<td>4</td>
<td>Effort belt status</td>
</tr>
<tr>
<td>2</td>
<td>Sensor pads status</td>
<td>5</td>
<td>Cannula status</td>
</tr>
<tr>
<td>3</td>
<td>Effort belt status</td>
<td>6</td>
<td>Finger probe status</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Power Button: Turns the system on &amp; off</td>
</tr>
<tr>
<td>8</td>
<td>Effort Belt: Senses chest movements while breathing</td>
</tr>
<tr>
<td>9</td>
<td>Effort Belt Cable: Connects effort belt to system</td>
</tr>
<tr>
<td>10</td>
<td>Effort Belt Buckle: Holds effort belt</td>
</tr>
<tr>
<td>11</td>
<td>Pulse Oximeter: Senses heart rate and oxygen levels</td>
</tr>
<tr>
<td>12</td>
<td>Nasal Cannula: Senses airflow and snoring</td>
</tr>
<tr>
<td>13</td>
<td>EEG Cable: Senses sleep patterns</td>
</tr>
</tbody>
</table>
## Warnings and Cautions

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

<table>
<thead>
<tr>
<th><strong>Contraindications, Warnings and Cautions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not use the Zmachine on newborns, infants, or children. The Zmachine has only been tested on adults.</td>
</tr>
<tr>
<td>Do not use the Zmachine if you have fragile or damaged skin. The self-adhesive EEG sensors or paper tape could damage fragile skin.</td>
</tr>
<tr>
<td>Do not use the Zmachine in an oxygen rich or explosive atmosphere. The Zmachine could ignite flammable gases.</td>
</tr>
<tr>
<td>Do not use the Zmachine if you cannot free yourself if tangled with the system cables. This could present a strangulation hazard.</td>
</tr>
<tr>
<td>Take care in arranging the system cables to avoid becoming tangled during the night.</td>
</tr>
<tr>
<td>Do not expose the Zmachine to excessive heat, as the internal Lithium Ion battery may leak or explode.</td>
</tr>
<tr>
<td>Do not open the Zmachine enclosure or attempt to service for any reason. Otherwise, the safety and/or performance of the system could be compromised.</td>
</tr>
<tr>
<td>Keep all parts and accessories out of reach of children and pets. The small parts and accessories (such as EEG sensors and their clear backings) could present a choking hazard to small children and pets.</td>
</tr>
<tr>
<td>Only use General Sleep approved parts and accessories described in this guide. Other parts may not function correctly with the Zmachine and could pose a safety hazard or lead to poor performance.</td>
</tr>
<tr>
<td>The Zmachine records very small electrical signals. Do not use transmitters, power transformers, motors and similar equipment that generate strong electromagnetic fields near the Zmachine. This could interfere with the recorded signals.</td>
</tr>
<tr>
<td>Electric blankets should not be used with the Zmachine. They could interfere with the recorded signals.</td>
</tr>
<tr>
<td>Avoid exposing the Zmachine to any liquids or small particulates as this could damage the system.</td>
</tr>
<tr>
<td>Do not immerse the Zmachine in liquid for any reason as this could damage the system.</td>
</tr>
<tr>
<td>The Zmachine is designed for indoor use only. Allow the Zmachine system to reach room temperature before using.</td>
</tr>
<tr>
<td>The Zmachine could become damaged if it has been subjected to unfavorable conditions or mishandling.</td>
</tr>
</tbody>
</table>
### Contraindications, Warnings and Cautions

<table>
<thead>
<tr>
<th>If, at any time, the Zmachine or accessories is thought to be damaged or malfunctioning, stop using the Zmachine and contact your healthcare provider for further instructions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some patients may experience skin irritation, hypersensitivity, or allergic reaction to the self-stick sensors or adhesive tape. If this occurs, stop using and contact your healthcare provider for further instructions.</td>
</tr>
<tr>
<td>Do not connect the Zmachine to any equipment except as described in this guide.</td>
</tr>
<tr>
<td>Do not modify the Zmachine and/or open Zmachine enclosure for any reason. The Zmachine contains no user serviceable parts.</td>
</tr>
</tbody>
</table>

### Disposal

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

### Cleaning

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

### Interference

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

### Using the System

Closely perform the steps beginning on the next page to help ensure a comfortable night and a great recording.
Step 1: Clean/Prepare Skin

Use an alcohol swab to clean the three areas as shown below.

*Clean bony area under the left earlobe, right earlobe, & back of neck*

**Note:**  *Let skin air dry for about 20 or 30 seconds before proceeding to Step 2.*

**Hint:** *A mirror can be helpful for this and the next step.*
Step 2: Apply Sensor Pads

Remove clear backing.

Apply sensor pad to each of the cleaned areas.

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

Apply to bony area under the left earlobe, right earlobe, & back of neck

Hint: If sensors look very different from the picture, simply remove, discard, and repeat the steps above using a fresh sensor pad (never re-use a sensor pad).
Step 3: Setup Effort Belt

Attach effort belt to Synergy and adjust length to fit your body.

Click belt onto tabs, position just under your armpits and over night shirt. Adjust length for a snug but comfortable fit that hugs your chest and moves with your breathing.

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

It should look like this when finished.
Step 4: Connect Cable and Sensors

Insert free end of EEG Cable into Synergy.

Snap BLACK wire to NECK sensor.

*Very important for test accuracy that the black wire be connected to the neck sensor pad (not the ears).*

Snap the two WHITE wires to the two EAR sensors.

*Either white wire can be connected to either ear sensor.*
Step 5: Connect the Cannula

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

*Adjust slider just a little to remove some slack. Do not tighten.*

Apply small two pieces of tape as shown.

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

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

Screw the free end of the cannula onto the fitting until snug.

*Note: Depending on cannula tightness and your sleeping position, the cannula can leave temporary marks and/or indentations on your face.*
Step 6: Connect the Finger Probe

Insert a finger from either hand into finger probe, and apply a small piece of tape to secure cord.

*Be sure to leave a little slack in the cord for comfort.*

Clip the cord to effort belt.

*Clip to the side that gives you maximum cord length.*

**Hint:** If you notice the finger probe becoming uncomfortable during the night, it is acceptable to switch the probe during your test to another finger.
Step 7: Review (not really a step)

The complete setup should look similar to this...
Press and hold the button for approximately one second to turn on the system.

When any lights appear, the system is running and the button should be released.

**Note:** The Synergy will automatically check your sensors. A yellow light indicates that the corresponding sensor is not yet connected or needs further attention (green means good). Refer to the previous instructions and correct any problems.

**Hint:** All lights should be green. However, if you are unsuccessful in correcting a yellow indicator, simply continue with the test.

Go to bed when ready.

Sleep in any position that is comfortable. It is fine to lie on the wires or any other part of the system.
Stopping the Test

When you are ready to stop the test, press and hold the button for approximately three seconds to turn off the system.

Unhook yourself from the system.

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

Return all equipment as instructed.
Frequently Asked Questions

Can I get out of bed for a drink, to use the bathroom, etc. when connected to the Zmachine Synergy?
Yes. However, use caution around water to prevent water from entering the system.

Can I lie directly on the Zmachine Synergy system and cords?
Yes, lying on the system and cords is absolutely fine and will not influence the recording. Sleep in any position that is comfortable and representative of your normal sleep.

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

Do I need to charge the Zmachine Synergy if using for a second night?
No. When you receive the Zmachine Synergy it will be fully charged and can run for at least 24 hours, so no need to recharge before a second night.

What should I do if I find that a sensor has become dislodged or disconnected during the night?
Simply re-position / re-attach the affected sensors as soon as this has been discovered and continue using the system as before.
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.