Sleep Profiler™ and PSG2 LE X8 Hardware Technical Manual

Sleep Profiler model

PSG2 model

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I. Regulatory and Safety Information

A. System Description

The X8 System ('Device') is an internally battery powered (IEC 60601-1 Classified) Type BF device that acquires physiological signals during wake and sleep and monitor signal quality to optimize the quality of acquired signals. The system can be affixed by the patient and enables configurable acquisition of up to five channels of electrophysiological signals [electroencephalographic (EEG), electromyographic (EMG), electrooculographic (EOG), and electrocardiographic (ECG) signals], a photoplethysmographic (PPG) signal, sound, and movement and position. The system can "record" data to internal memory for download with Sleep Profiler software, wirelessly transmit within a defined coverage area to Sleep Profiler software designed to interactively "monitor" and save the data, or simultaneously record and monitor. The acquired signals are saved in a universal data format (European Data Format – EDF) and intended to be analyzed with Sleep Profiler software. The device can optionally record two channels of respiratory effort, airflow with a cannula and nasal pressure transducer, and/or oxygen saturation and pulse rate with a pulse oximeter, which can be analyzed with Sleep Profiler software to detect sleep disordered breathing.

B. Indications for Use

The X8 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. All X8 models (SP40, SP29, and XS29) acquire, record, transmit, and/or display electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals with optional accelerometer, acoustical, and photoplethysmographic signals. Model SP29 additionally includes a nasal pressure transducer and cannula (for airflow), thoracic and abdomen respiratory effort, and pulse rate and oxyhemoglobin saturation from the finger. The X8 System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision, and reliability.

Contraindications: None

C. Meaning of symbols

								IP22
Refer to instruction manual/booklet	Adults only	Dispose properly	Keep Dry	Non-ionizing electromagnetic radiation	Temperature limitation	Humidity limitation	Atmospheric pressure limitation	Limit objects, water ingress
								
GITEKI (MIC) Mark	European conformity	Type BF Applied Part	Prescription required in USA	Catalogue/Model number	Serial number	Lot/Batch Number	Medical device	Manufactured by
								
Manufacture date	Use-by date	Caution, consult accompanying documents	Do not re-use	Importer	Keep away from sunlight	Non-sterile	Electronic Instructions for Use	

D. Safety

The device should be prepared for patient use by a trained technician. Below are warnings and cautions for the trained technician. Read them carefully, they are important for the effective and safe use of the product. In the event of a serious incident, notify the manufacturer and, if applicable, your local EU competent authority.

The information in this manual has been carefully checked and is based on our best judgment at this time. In the interest of continued product development, Advanced Brain Monitoring reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

WARNING:

- Do not wear the device while it is connected to an AC Power Supply.
- Possible strangulation from cables or headband; possible choking hazard if small parts are detached and swallowed.

CAUTIONS – General

- Do not use the device as a substitute for clinical electrocardiography, electromyography, or critical care. The device is NOT intended to be used:
  - as a cardiac monitor
  - to assess neuromuscular diseases
  - for life supporting equipment
- Do not use the device:
  - with high frequency (HF) surgical equipment or during surgery,
  - or in proximity to a Magnetic Resonance Imaging system.
- Device is not defibrillator proof. EEG Leads, Strips, and Sensor interfaces are not protected against the effects of defibrillation. Damage to the device is possible if worn during defibrillation.
- Explosion Hazards:
  - The device includes an internal battery and optional external battery. Do not use the device in any way that could cause an explosion (e.g. near an open flame or high heat device).
  - The device internal rechargeable battery should only be replaced by an authorized distributor or the manufacturer.
  - Local ordinances must be followed for disposal of all electronic equipment.
  - Do not use the device in the presence of flammable anesthetics or gases.
- Electrical Shock Hazard:
  - Avoid touching the ExG (i.e. EEG/ECG/EMG/EOG) sensor snaps when the USB cable is connected to the device and an AC powered source (i.e., PC workstation, USB hub, or USB wall charger).
  - The device must only be charged with an IEC 62133 compliant external battery while being worn by the patient.
  - Do not affix the external battery to a wall charger when the device is being worn.
  - Only use a medical IEC 60601-1 compliant USB wall charger (Wall charger Output 5VDC ⎓ 1.0A) when charging from an AC power source.
- This device has been tested and found to comply with the requirements for medical devices to the IEC 60601 standards. These safety standards are designed to provide reasonable protection against harmful interference in a typical medical installation.
- The operating temperature of the device may increase:
  - When it is connected to a computer.
  - When data are being transferred from the device memory to the host computer.

  - When the internal battery is being charged.
- Do not attempt to charge the device if room temperature is above 40°C (104°F).
- Device may not charge properly if in direct sunlight or if room temperature is above 30°C (86°F). Charging will automatically terminate when an unsafe operating temperature is detected.
- If device is stored or transported at temperatures < 5°C or > 40°C, the device must be kept in a room with an ambient temperature of 20°C for at least 6 hours, or until the device is within safe operating temperatures (5°C to 40°C), prior to use.
- Limitations of Use:
  - The sensors and cannula are intended for single patient use.
  - Inspect and then clean and disinfect the sensor strip, enclosure(s), and headband according to the recommended guidelines.
  - The sensor strip and headband should be replaced after 50 nights of use or earlier if an inspection shows that the surface that comes in contact with the forehead is cracked or pitted.
  - The device is not waterproof. Do not spray, pour, or spill any liquid on the device, its connectors, switches, or openings as such application of liquids may cause permanent damage and will void the Warranty.
  - IP22: Device is protected against objects greater than 12.55 mm and against dripping water when tilted up to 15 degrees.
  - Do not position conductive parts of the ExG sensors and cables so that they contact other conductive parts and earth.
  - In wireless mode, do not exceed maximum distance of 10 meters.
  - For PSG2, inspect and then clean and disinfect the respiratory effort belts and SpO2 sensor according to the respective manufacturer's recommended guidelines.
- Limitations of Use with Accessories:
  - All equipment connected to the patient must comply with the requirements of IEC 60601-1-1.
  - PSG2: Only use validated respiratory effort belts with the device. The device has been validated with the Philips/Pro-Tech ezRIP Respiratory Effort Sensor, Philips/Pro-Tech CT2 Piezo Sensor, and SleepSense PVDF (Piezo) Sensor.
- The device should be prepared for use by a trained technician.
  - Do not use caustic or abrasive cleaning agents, or any cleaning agents other than those listed in the cleaning section below, on the device as such use of cleaning agents may cause permanent damage and will void the Warranty.
  - Advanced Brain Monitoring's warranty does not cover damage caused to the device while the customer is changing replaceable components.
- U.S. Federal law restricts this device to sale by or on the order of physician.

CAUTIONS – Patient Use

- Do not use the device if it appears to be damaged in any way or if the LED does not properly illuminate during startup.
- Discontinue use of the device in case it causes any significant pain.
- Possible allergic reaction or skin irritation from device components, e.g., silicone and adhesive sensors, cannula, and neoprene/Velcro headband. Wearing the device may result in a mark on your forehead that usually disappears in a few hours; on extremely rare occasions the mark may remain for 2-5 days.
- To avoid damage not covered by warranty, keep the device dry and clean, and out of reach of children and pets.

- The device should only be worn by a patient during unassisted use after having read the written instructions regarding product use approved by Advanced Brain Monitoring.

CAUTIONS – Limitations Affecting Use

- The device is not recommended for unassisted use by patients with the following conditions:
  - Deafness
  - Blindness
  - Severe arthritis which limits use of both hands
  - Dementia
  - Supplemental oxygen use at night
  - Cardiac arrhythmia
  - Atrial fibrillation
  - Tics or tremors of the head

  Unassisted use of the device by patient with any of these conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.
- The device is not recommended for use by or on patients with the following conditions:
  - Sensitivity of skin or scalp and/or open wounds on the forehead or scalp
  - Allergic reactions to extended exposure to synthetic fabrics (e.g., polyester, rayon).
  - Upper respiratory infection or congestion
  - Head circumference less than 21 or greater than 25 inches.
  - Forehead vertical measurement (top of eyebrows to hairline) less than or equal to 2 inches or horizontal measurement (hairline to hairline) less than or equal to 6 inches.

  Use of the device by patients with any of these conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.
- The proper unassisted use of the device requires patients to be dexterous in both hands, capable of reading and comprehending instructions, and able to see and hear the audio and visual indicators. If the patient cannot meet these requirements the result may be poor signal quality leading to a misdiagnosis by the physician. Such patients require assistance in order that the device provides accurate data.
- Device use under any of the following conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.
  - Headband not adjusted properly (i.e. too loose or too tight).
  - Forehead not prepared according to instructions (e.g., makeup, lotion, or hair under the sensor),
  - Loud snoring bed partner or significant ambient noise.

CAUTIONS – Batteries

- For optimal performance, use a fully recharged battery.
- Only use approved Lithium Polymer rechargeable battery replacements.
- Electrical Shock Hazard: The device external battery is approved for patient use. Do not allow the patient to recharge the device with an AC Power Source or anything other than the approved external battery.
- The device internal rechargeable battery should only be replaced by an authorized distributor and/or the manufacturer.
- When charging is completed, remove the device from the power supply to extend the life of the battery.

CAUTIONS – Disposal

- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including the battery. The battery might leak or explode if it is used or disposed of improperly. The device and sensor strip are classified under EWC code 16 02 10* as containing PCBs and must be disposed of properly. The battery is classified under EWC code 16 06 05 as a lithium-ion battery and must be disposed of properly. Follow third party device instructions for proper disposal methods.

E. Device Terminology

"X8 System" is the regulatory clearance name for the hardware device, which is configured for use in the models Sleep Profiler and PSG2. This manual only applies to X8 devices with "LE" on the label.

II. Getting Started

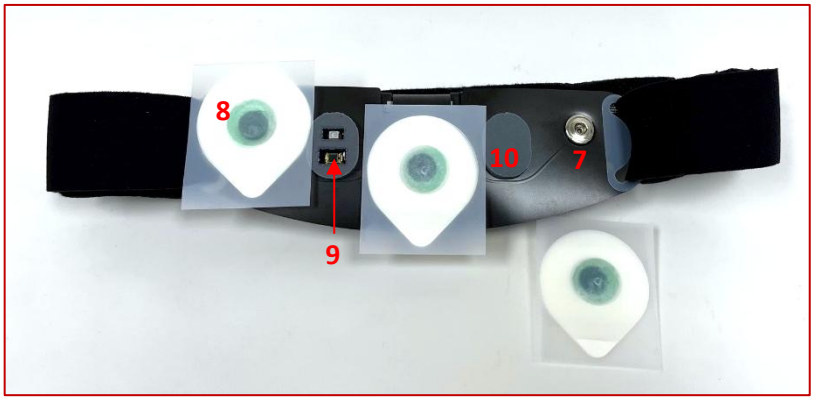
Go to the following link to access helpful instructions for conducting your first study and additional documents and forms needed to use the Sleep Profiler/PSG2.
www.advancedbrainmonitoring.com/sleepprofiler/gettingstarted

III. Using the Device

A. Components

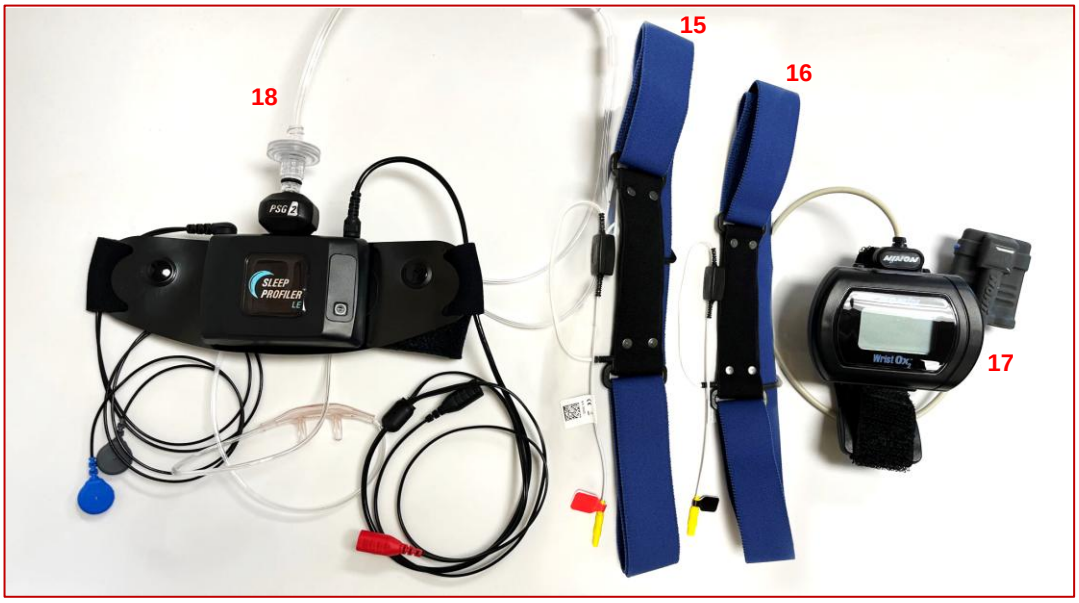
The components for the Sleep Profiler model are shown in the figures and table below.

Components – Sleep Profiler model	
1	X8 Device
2	On/Off Switch
3	LED Indicator
4	Sleep Profiler Strip
5	Sleep Profiler Headband
6	2-Pin Dual-lead Cable*
--	3-pin Dual-lead Cable* (not shown)
7	Sensor Snap
8	Forehead EEG Sensors*
9	Optical Sensor
10	Gray strip pad
11	40 inch (1 m) USB cable
12	Measuring tape
--	External battery/cable* (not shown)
* Purchased separately	



The PSG2 model includes the additional components shown in the figures and table below.

Additional Components – PSG2 model	
13	PSG2 Airflow Adapter
14	3-Pin Effort Belt Cable
15	Effort Belt (Abdomen)*
16	Effort Belt (Chest)*
17	Nonin Pulse Oximeter (Wrist Device with Finger Sensor)
18	Nasal Cannula**
* SleepSense 139411-Kit PVDF Effort Sensor Kit by S.L.P. Ltd. Israel. Note: Philips/Pro-Tech ezRIP and Piezo belts previously provided are not shown, but are still compatible.	
** Purchased separately	



B. Setup Options

The Sleep Profiler software allows the device to be configured for the following applications for use in conjunction with the self-application instructions.

Device Configurations		Patient Instruction Link
Sleep Profiler	Sleep Profiler	Sleep Profiler Patient Instructions
	Sleep Profiler with ECG	
	Sleep Profiler with Chin EMG	
	Sleep Profiler with Chin/Arm EMG	
PSG2	PSG2 with ezRIP Effort Belts	PSG2 Patient Instructions
	PSG2 with ezRIP Effort Belts and ECG	
	PSG2 with ezRIP Effort Belts and Chin EMG	
	PSG2 with Piezo Effort Belts	
	PSG2 with Piezo Effort Belts and ECG	
	PSG2 with Piezo Effort Belts and Chin EMG	
	PSG2 without Effort Belts (PM3)	

C. Fitting the Sleep Profiler

Setting the Headband:

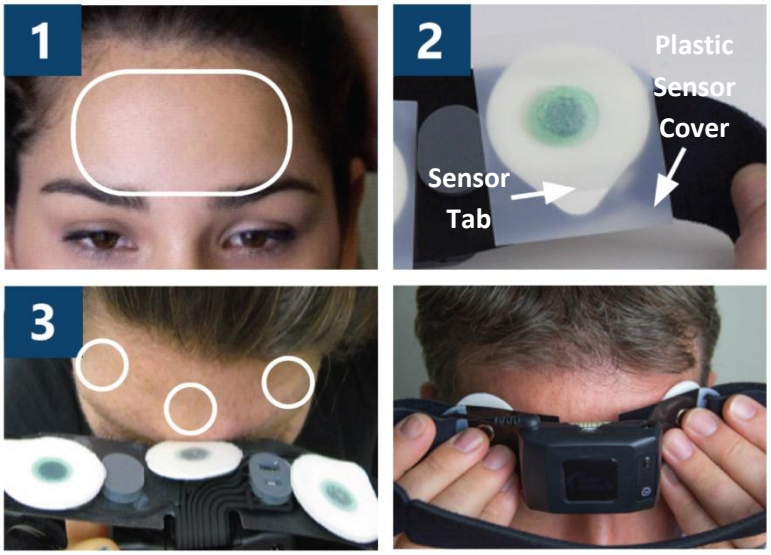
1. For long hair, pull it back in a way that is comfortable and away from the forehead (e.g. low ponytail).
2. Measure the distance around the head with the measuring tape just above the ears. Use the lookup table and set the headband to the appropriate V-cut setting.
3. When adjusting the headband setting, keep the cables inside the headband loop as shown

Head Measurement			Head Size	Headband V-cut Setting
	Inches	Centimeters		
Less than	22	56	S	S
Between	22-23	56-58.5	M	M
Greater than	23	58.5	L	L

NOTE: Leave the sensor covers ON when showing the patient how to self-apply the device.

Applying the Device:

1. Scrub the entire forehead with an alcohol swab for 15 seconds. Air-dry.
2. Grasp the sensor tab and peel the plastic covers from the sensor. Remove the covers from all 3 sensors.
3. Center the middle sensor just above the eyebrows and press the middle sensor against the forehead. Press the left and right sensors to the skin.
4. Pull the black headband over the head.
5. Press firmly on the outer edges of all 3 sensors to ensure complete contact with the forehead.
6. Firmly press the ON/OFF button down for 1-second and release.
7. The voice alert will notify you if the impedance test passed or if you need to repeat steps 1 – 6.



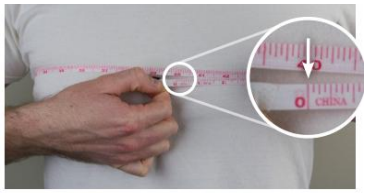
D. Fitting the PSG2 Components (if applicable)

Nasal Cannula (PSG2):

1. Insert the cannula tips into the nose.
2. Slide the slip tube down toward the back of your head.
3. Tighten so cannula tube lays over the headband.
4. Gently pull out on the cannula. If the cannula tips can be pulled away from the nose more than 1/4 inch or 7 mm, then tighten the slip tube.

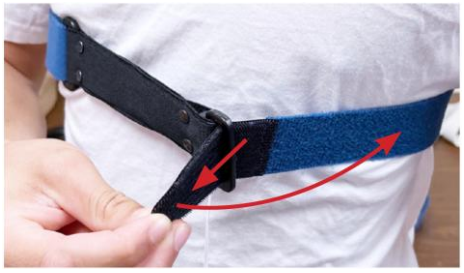
Thorax and Abdomen Effort Belts (PSG2):

Applying the Philips/Pro-Tech Belts:



1. Wrap the tape measure around the chest just under your arms to determine the thorax ("THX") belt length.
2. Use the "0" for the measurement reference and not the end of the tape (see image to the right).
3. Wrap the tape measure around your abdomen, just above your navel (belly button) to determine the abdomen ("ABD") belt length.
4. Write down the thorax and abdomen measurements.
5. Adjust the belts to be 4 inches (10 cm) less than the thorax and abdomen measurements.
6. Apply the **Thorax belt (BLACK sticker)** around the chest just under your arms. The belts should be worn over nightclothes.
7. Apply the **Abdomen belt (RED sticker)** just above your navel (belly button).
8. *(*RIP *Belts only)*: Insert the black connectors from the "THX" box into the holes in the chest effort belt buckle and the black connectors from the "ABD" box into the holes in the abdomen effort belt buckle.
9. Follow effort belt cable steps below.

Applying the SleepSense (S.L.P.) Velcro Belts:



1. The belts should be worn over nightclothes.
2. Apply the **Thorax belt (BLACK sticker)** around the chest just under your arms as shown. To apply the belt, unhook the Velcro tab, insert the tab through one of the black sensor loops (with Velcro facing away from sensor), then pull the tab towards your back and attach the Velcro to the belt. Repeat for the other side of the belt. The white cable should hang down from the bottom edge of the belt.
3. Apply the **Abdomen belt (RED sticker)** just above your navel (belly button).
4. Tighten the belts until they are snug and secure. You should feel some resistance when breathing.
5. Follow effort belt cable steps below.

Connecting the Effort Belt Cables:

1. Insert the key-shaped connector from the **Thorax belt** into the **BLACK** end of the effort cable.
2. Insert the key-shaped connector from the **Abdomen belt** into the **RED** end of the effort cable.

Wrist Oximeter with Finger Sensor (PSG2):

1. Slip the device over the non-dominant hand with the label up.
2. Tighten the wrist strap.
3. Place the index finger into the gray sensor with the cable facing up.

E. Audio Messages

All Operation
Device has been powered on.
Device is powered off.
Caution, the device is charging.
Charging complete.
The battery is too low to continue without recharging.
Acquisition started.
Turn out the light, go to sleep.
Signal Calibration
Device signal quality testing may take several minutes, do not move. Forehead sensor test now starting.
Forehead sensor test passed.
Forehead sensor test completed. (Note 1)
PSG2 Signal Calibration
PSG2 adapter is required to continue the study. (Note 2)
Wrist device test failed. Wrist device is required to continue the study. (Note 2)
Wrist device test passed.
PSG2 Bad Signal Quality Alert (Notes 2 ,3)
Nasal cannula test failed. Insert the nasal cannula tips into your nose, tighten the slip tube to the back of your head.
Wrist device Test failed. Make sure the gray sensor from the wrist device is properly placed on your index finger.
Note 1: Indicates that signal quality test failed, but recording will start anyway. Note 2: Indicates that the component is not connected or there is poor signal detected. Note 3: Bad signal alerts may be sounded at startup or during the overnight recording.

F. Visual Indicator Patterns

LED Mode	Green LED	Amber LED
Device powered on	Blinking 3/sec	Off
Device recording	On	Off
Recording/Acquisition error	On	On
Hardware problems	Off	On
Low battery	Off	Blinking
Charging in progress	Blinking 2/sec	Off
Charging completed	Blinking 1/ every 2 sec	Off
Charging Error	Blinking 2/sec*	Blinking

*Charging error only activates Amber LED and will not change Green LED operation.

Note: Device uses green and amber LED light indicators and sound to indicate operational status. These indicators do not indicate hazardous situations or alert conditions and should not be taken as alarm indicators.

IV. Preparing the Device for Reuse

A. Charging the Device

CAUTION: Charging the device via an AC Power Source should only be performed by a trained technician.
Note: If the device is unplugged immediately after connecting to the computer, it may start acquisition.

Charge Device via USB:

1. Connect the USB-micro connector to the device and USB-A connector into a 5-volt power supply (Computer USB port, External battery, or IEC 60601-1 compliant AC wall charger with output 5VDC 1.0A).
2. When initially connected, a voice message will indicate device is charging, and the green indicator light will flash twice per second.
3. When charging is completed, a voice message will play, and the green indicator light will flash once every other second.

For PSG2 Only:

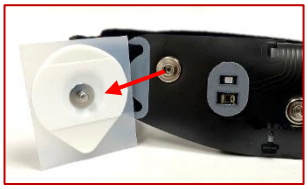
1. Carefully disconnect the airflow adapter from the device before charging.
2. For the Wrist Oximeter, replace the two AAA batteries in the wrist device prior to reuse. The Wrist Device will turn off during the study if the batteries do not have sufficient battery power. **Remove the batteries from the wrist device if it will not be used for > 30 days.**

B. Cleaning the Device after Use

Removing Sleep Profiler Components

Notes:

- The sensors are intended for single night use and must be replaced and disposed after each night of use.
- The sensor strip, headband, cables, and enclosures must be cleaned between uses. It is recommended that the Sleep Profiler Strip be replaced every fifty (50) nights, if the gray pads become pitted, or if there is a consistent pattern of poor signal quality (see Section E for strip replacement instructions).
- It is recommended that the Sleep Profiler headband be replaced every 25-50 nights, or if the headband is damaged.



1. Remove and dispose of the single use sensors.

2. Remove the headband for subsequent cleaning.
3. When applicable, remove the 2-pin and 3-pin cables.

Removing PSG2 Components

Note: The Nasal Cannula is intended for single patient (multi-night) use and must be replaced and disposed of between patients.

1. Detach the cannula from the airflow adapter by twisting the cannula counter-clockwise.
2. Remove the cannula from the headband Velcro tabs and discard it.
3. Detach the airflow adapter from the USB connector.
4. Detach the 3-pin cable and effort belts.

Cleaning Between Uses

Materials:

1. 70% Isopropyl Alcohol (IPA) wipes
2. Dish soap
3. Disposable gloves

To avoid damage - DO NOT use chemicals other than instructed and DO NOT saturate the Device when cleaning.

Sensor Strip:

1. Using a 70% IPA wipe, thoroughly wipe the top, base and surfaces of both gray rubber pads. All areas should remain wet with 70% IPA for a minimum of 15 seconds.
2. With a new 70% IPA wipe, clean the entire surface area of both sides of the plastic strip and snaps. All areas should remain wet with 70% IPA for a minimum of 15 seconds.
3. If any visible soil remains, repeat steps 1 and 2 as needed.
4. Allow to air-dry.

Device Enclosure and Cables:

1. Using a 70% IPA wipe, thoroughly clean the top, sides, and bottom of the enclosure and cables. All areas should remain wet with 70% IPA for a minimum of 15 seconds.
2. If any visible soil remains, repeat step 1 as needed.
3. Allow to air-dry. Do not charge or turn on the device until it is completely dry.

Neoprene Headband:

1. Submerge the headband in a solution of 1 teaspoon of dish soap (e.g., Dawn detergent) per gallon of water.
2. Agitate slightly for 1 – 2 minutes.
3. Rinse under warm clean water for 1 minute.
4. Wring and allow to air-dry.

Carrying Case:

1. Using a 70% IPA wipe, thoroughly clean the insides of the carrying case. All areas should remain wet with 70% IPA for a minimum of 15 seconds.

2. If any visible soil remains, repeat step 1 as needed.
3. Do not place the device or other components in the case until it is completely dry.

PSG2 Philips/Pro-tech Effort Belts:

According to the manufacturer, the following cleaning products should not degrade the belts or shorten the useful life: Amphyl Hospital bulk Disinfectant Cleaner, DisCide ULTRA Disinfectant, CaviCide.

1. (RIP Belts Only): Detach the white boxes from the belts before cleaning.
2. Avoid contact of the cleaning solution with the connector(s).
3. The belt may be safely soaked in warm water (do not use hot water) with a hospital grade laundry detergent for cleaning. Allow to air dry.
4. For additional information or questions, reference the belt manufacturer instructions provided.

PSG2 SleepSense Effort Belts:

According to the manufacturer, the following cleaning products should not degrade the belts or shorten the useful life: SaniZide Plus® Germicidal Wipes, CaviWipes™ Disinfecting Toweletes, Super Sani-Cloth® Germicidal Disposable Wipes, Protex® Ultra Disinfectant Wipes, Opti-Cide3® Surface Wipes, Meliseptol® Wipes Sensitive, OptiCide Max® Wipes or Spray, Isopropyl Alcohol 70% or Ethyl Alcohol (Ethanol) 70%.

1. Avoid contact of the cleaning solution with the connector(s).
2. Sensor/cable: Wipe with approved cleaning solution. Do not submerge/soak the sensor or cable.
3. Band: Machine wash in gentle cycle with household laundry detergent. Attach the Velcro tabs to band before washing.
4. Allow to air dry.
5. For additional information or questions, reference the belt manufacturer instructions provided.

PSG2 Electronic Component Enclosures:

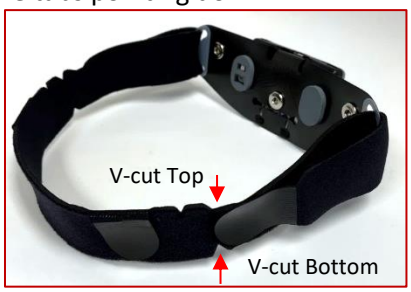
Caution: DO NOT immerse any of the Electronic Components in liquids

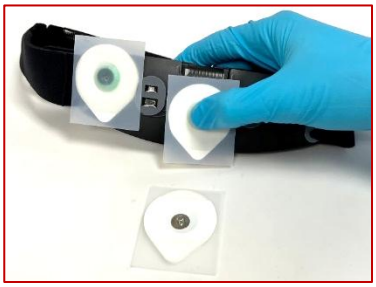
1. Using a 70% IPA wipe, thoroughly clean the top, sides, and bottom of the enclosure. All areas should remain wet with 70% IPA for a minimum of 15 seconds.
2. If any visible soil remains, repeat step 1 as needed.
3. Allow to air-dry. Do not use the components until it is completely dry.
4. Make sure to wipe the inside of the finger sensor (a).

C. Applying Disposables

Sleep Profiler Disposables:

1. Reapply the headband with the Velcro tab set to the middle V-cut.
2. Snap new sensors onto the strip with the tabs pointing down.

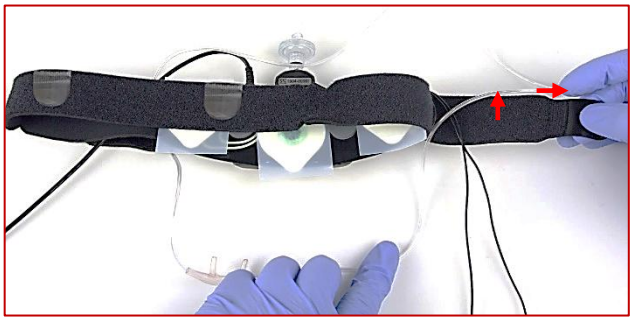




3. When applicable, slip the 2-pin (and/or 3-pin) cable through the left (right) loop of the headband and connect it to the device. Connect the EMG/ECG sensors to the two snaps.

PSG2 Disposables:

1. Gently insert the airflow adapter into the USB connector.
2. Affix the cannula luer lock to the airflow adapter luer lock by twisting clock-wise; do not over-tighten.

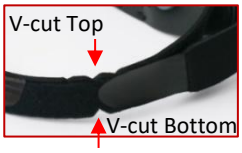


3. Route the cannula tubing through the headband following the steps below.

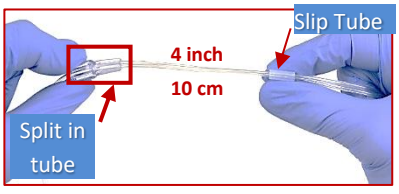
a. Temporarily detach one Velcro end-tab.

b. Holding the cannula tips with one hand, route the cannula tube across the headband opening.

c. Reattach the Velcro with the edge aligned with the top and bottom V-cuts.



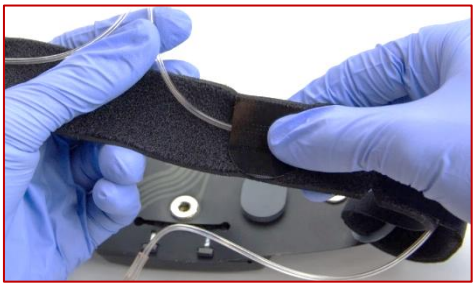
d. Repeat steps a-c to route the cannula tube on the opposite side of the headband.



e. Pull the slip tube 4 inches (10 cm) from the split in the tube.

f. Temporarily detach one cannula Velcro tab.

g. Position the cannula tubing beneath the Velcro tab and reattach the cannula Velcro tab.



h. Repeat to secure the cannula tubing on the opposite side. The slip tube should rest between the two cannula Velcro tabs.

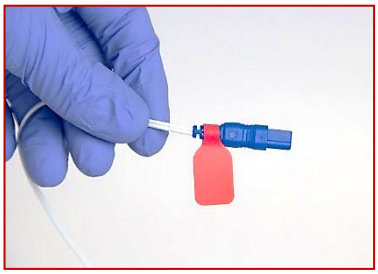
4. Route the 3-pin effort belt cable connector through the right loop of the headband to acquire respiratory effort.

D. Packing the Carrying Case for Home Use

Sleep Profiler Carrying Case:

1. Place the device, sensors, and patient instructions in the case.
2. Depending on the selected study condition, include the following:
   - Measuring tape,
   - Extra sensor pouches,
   - Alcohol wipes,
   - External battery,
   - Sleep Profiler questionnaire, sleep diary, etc.

PSG2 Carrying Case:



1. Wrap the **red** sticker around the end of the RIP effort belt cable labeled "**Abd**" or one of the Piezo belt cables. Wrap the **black** sticker around the RIP effort belt cable labeled "**Thx**" or one of the Piezo belt cables.
2. Fold and place the belts and the cables in the right-side cut-out.
3. Replace the batteries in the wrist device and place it and the finger sensor in the left-side cut-out.
4. Place the Sleep Profiler device with airflow adapter in the left-side cut-out.
5. Include as appropriate:
   - Measuring tape
   - Extra sensor pouches
   - Alcohol wipes
   - EMG/ECG cables and sensors
   - User instructions

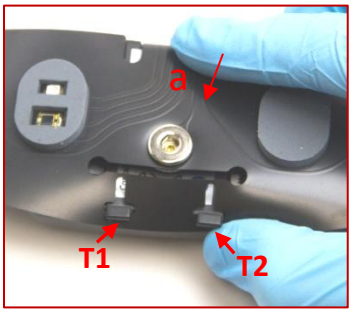
E. Replacing the Sensor Strip

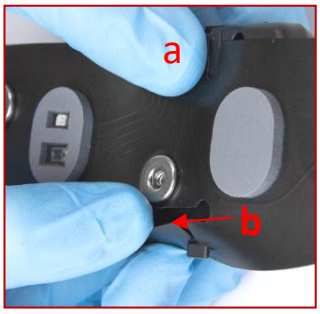
CAUTION: To avoid compromise in signal quality, replace the Sensor Strip after 50 nights.
Note: Forcing the Slide Locks open or closed or attempting to forcefully remove the Enclosure Door while the slide locks are closed may result in damage to the slide locks and enclosure door.

The link below provides a video demonstrating how to properly replace the sensor strip:
https://advancedbrainmonitoring.app.box.com/s/fj4mjq7csgw89l74r45jwhzc81lyibgl

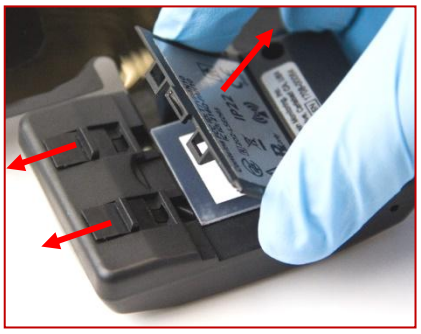
Removing the Strip

1. (PSG2 Only): Remove the airflow adapter before replacing the strip.
2. Gently press down on the Sensor Strip **(a)** and slide the Strip toward the T-Slots **(T1 and T2 below)**.
3. Place finger through the slot in the Strip **(b)**, and gently unhook the Strip Tabs from the T-slots .
4. Fold strip back so that it appears as the image below.





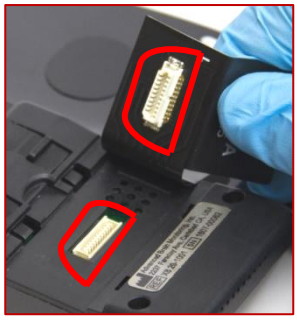
5. **Press firmly down on the edge of the Enclosure Door near the slide locks (c)** and slide the Slide Locks toward the edge of the device until they are fully unlocked **(d)**. Then gently lift the Enclosure Door.



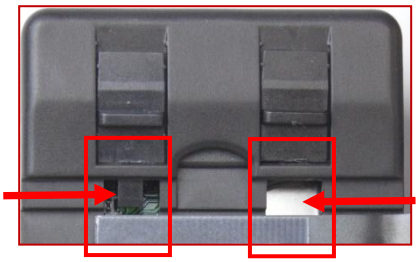
6. Grasp the strip removal tab **(e)** on the strip and lift the strip straight up away from device.


Replacing the Sensor Strip

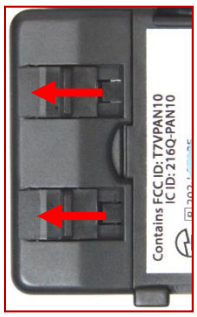
1. Align the “D” shaped connectors on the Female Strip Connector and the Male Strip Connector and affix the connector.
2. Press down on the Strip Removal Tab to ensure the Strip Connector is fully seated.




3. Confirm the slide lock tabs are not broken and do not need to be replaced.



4. Slide the Slide Locks away from the folded strip removal tab.
5. Insert the right edge of the Enclosure Door into the device enclosure. **Ensure the Slide Locks are completely open, then press down on Enclosure Door,** and while pressing on the Enclosure Door, slide the Slide Locks toward the center of the device until fully seated into the Enclosure Door Hooks. **Do not force the Slide Locks closed, as this could damage the Slide Locks or Enclosure door.**





6. Fold the Sensor Strip Over the Sleep Profiler Device and affix the T-Slots onto the Strip Tabs.



V. Product Information

A. Technical Specifications

System Specifications

Brand names / Model	Sleep Profiler, PSG2

Operating Modes

Mode	Description
Recorder	Records to SD card
Monitor	Transmits wirelessly
Hibernation	Device turned off
Disconnect	Long term storage

Configurations

Configuration	Description
Sleep Profiler	Recorder Mode: basic signals acquired
PSG2	Recorder Mode: basic signals, airflow, oximetry and effort acquired

Signals acquired

Signal	Number of channels	Dynamic range (typical)	Samples per sec	Interfaced to PCB/electronics
EEG	3	± 1000 µV	256	Kapton strip
Infrared (880 nm)	1	0 to 200 nA	100	
2-pin connector	ECG	± 2000 µV	256	Touch-proof two-lead cable
	EMG	± 1000 µV		
Actigraphy	3	-90 to 90°	10	On device
Acoustic microphone	1	20 to 80 dB	10	On device
3-pin connector (EMG)	1	± 1000 µV	256	Touch-proof three-lead cable
PSG2 Components				
Airflow	1	± 1" H_20	64	USB connector
Oxygen saturation	1	0 – 100%	1	Wireless
Pulse rate	1	20 – 250 BPM	1	Wireless
Respiratory Effort	1 or 2 belts	± 10,000 µV	256	Touch-proof three-lead cable

Signal Processing

Signal	Resolution for full dynamic range	Processing/Filtering
EEG	16 bits	0.1 Hz High Pass, firmware 67 Hz Low Pass, hardware
2-pin and 3-pin connectors	16 bits	0.1 Hz High Pass, firmware 67 Hz Low Pass, hardware
PPG	16 bits	Optional ~3Hz Low Pass firmware filter
Actigraphy	12 bits	Down sampled from 100 Hz to 10 Hz
Acoustic microphone	16 bits	Down sampled from 2560 Hz to 10 Hz RMS

Typical Signal Accuracy and Resolution

Signal	Accuracy (typical)	
EEG	Resolution 0.03 µV, typical noise 3.7 µVpp (EEG circuit 3.0 µVpp)	
Optional 2-pin connector	ECG	Resolution 0.06 µV, typical noise 4.0 µVpp
	EMG	Resolution 0.03 µV, typical noise 3.7 µVpp
Pulse Rate	+/- 5 bpm	
Actigraphy	+/- 3 degrees in +/-60 degrees range	
Acoustic microphone	+/- 4dB at mid-range	

EEG Impedance Monitoring	Performed in Monitor mode when initiated by software. Performed in Recorder mode at study record start and every 15 minutes thereafter. High Impedance indicates poor connection between scalp and EEG electrode, but might be also caused by disconnected electrodes, leads, or strips, and may result in poor signal quality. Impedance monitoring is not performed on ExG 2-pin channels.
EEG Offset Voltage	± 600mV
EEG Input Impedance	500MΩ, typical

<table>
<tr><td>EEG Common Mode Rejection</td><td>-115dB Common Mode Rejection Ratio, typical</td></tr>
<tr><td>Calibration</td><td>The Sleep Profiler device does not require calibration.</td></tr>
<tr><td colspan="2">Battery</td></tr>
<tr><td>Battery Charging</td><td>Via USB cable connected to 5 volt power supply (Computer USB port, External battery, or IEC 60601-1 compliant AC wall charger with output 5VDC 1.0A)</td></tr>
<tr><td>Internal Power Supply</td><td>650mAh 3.7V Lithium Polymer Battery</td></tr>
<tr><td>Typical Power Consumption per Operating Mode</td><td>
<table>
<tr><th>Mode</th><th>Consumption (typical)</th><th>Hours of Use (0-4 days after charge)</th><th>Hours of Use (5-10 days after charge)</th></tr>
<tr><td>Recorder</td><td>15 mAh</td><td>30 to 34</td><td>28 to 32</td></tr>
<tr><td>Recorder (PSG2)</td><td>22 mAh</td><td>26 to 30</td><td>24 to 28</td></tr>
<tr><td>Monitor</td><td>16 mAh</td><td>28 to 32</td><td>26 to 30</td></tr>
</table>
</td></tr>
<tr><td colspan="2">User Interface</td></tr>
<tr><td>User Control</td><td>ON/OFF tactile switch</td></tr>
<tr><td>Acoustic audio feedback</td><td>Internal speaker</td></tr>
<tr><td>Visual feedback</td><td>Green, Amber LED</td></tr>
<tr><td>Dimensions</td><td>2.8” long x 1.9” wide x 0.8” deep</td></tr>
<tr><td>Weight</td><td>0.071 kg (Sleep Profiler Device with battery, strip, and headband)</td></tr>
<tr><td colspan="2">Device Materials</td></tr>
<tr><td>Device Enclosure</td><td>ABS</td></tr>
<tr><td>Headband</td><td>Neoprene with loop fastener</td></tr>
<tr><td>EEG Sensor Strip</td><td>Kapton film</td></tr>
<tr><td>EEG Sensor</td><td>Vermed (Graphic Controls) Custom EEG sensor – Polyethylene Foam, Acrylic, Conductive Gel</td></tr>
<tr><td>Optical sensor pad</td><td>Silicone / Silicone Rubber</td></tr>
<tr><td>Cables</td><td>PVC</td></tr>
<tr><td colspan="2">PSG2 Components</td></tr>
<tr><td>Respiratory Effort Belt</td><td>See Third Party Specifications</td></tr>
<tr><td>Wrist Oximeter</td><td>See Third Party Specifications</td></tr>
<tr><td>Nasal Cannula</td><td>PVC</td></tr>
<tr><td colspan="2">Cleaning</td></tr>
<tr><td>Cleaning Chemicals</td><td>Cleaned and disinfected by rubbing with 70% isopropyl alcohol (IPA); water and dish soap for headband</td></tr>
<tr><td colspan="2">USB Specification</td></tr>
<tr><td>USB Standard</td><td>USB 2.0</td></tr>
<tr><td>USB Data Transfer</td><td>USB Flash Disk</td></tr>
<tr><td colspan="2">Wireless Specification</td></tr>
<tr><td>Wireless Module</td><td>Laird/Ezurio BL652 5.0 compliant to IEEE 802.15.1</td></tr>
<tr><td>Operating Frequency</td><td>2.4 to 2.48 GHz (ISM Band)</td></tr>
<tr><td>Antenna</td><td>On-board</td></tr>
<tr><td>Transmission Mode</td><td>Bi-Directional</td></tr>
<tr><td>Output Power</td><td>Maximum 4 dBm</td></tr>
<tr><td>Limitations of Operation</td><td>Maximum range 10 meters line of sight</td></tr>
<tr><td>Data Throughput</td><td>Typical 10KB/sec, maximum 30 KB/sec</td></tr>
<tr><td>Data Integrity</td><td>Wireless protocol ensures data integrity by retransmitting corrupted data packets, communication protocol recognizes and inserts zeros for missed samples.</td></tr>
<tr><td>Quality of Service</td><td>Average data loss <0.1%</td></tr>
<tr><td>Security</td><td>Wireless encryption is enforced during transmission</td></tr>
<tr><td colspan="2">Software</td></tr>
<tr><td>Operating System Support</td><td>
<table>
<tr><th>OS</th><th>Requirements</th><th>Supported Software</th></tr>
<tr><td>Windows</td><td>Windows 8 and up
Quad Core processor, 4 GB RAM</td><td>Sleep Profiler Desktop Software
Sleep Profiler Portal</td></tr>
<tr><td>Mac</td><td>Mac OS 11 and up</td><td>Sleep Profiler Portal</td></tr>
</table>
</td></tr>
<tr><td>Recording File Size</td><td>Approximately 17 MB per hour</td></tr>
</table>

Environmental Conditions*	Operation	Transportation	Storage
Temperature / Relative Humidity	5°C to 40°C (41°F to 104°F), relative humidity 15% to 90%, non-condensing and water vapor pressure up to 5 kPa	-25°C to 5°C (-13°F to 41°F), 5°C to 35°C (41°F to 95°F) with relative humidity up to 90%, non-condensing, >35°C to 70°C (95°F to 158°F) at water vapor pressure up to 5 kPa	-25°C to 5°C (-13°F to 41°F), 5°C to 35°C (41°F to 95°F) with relative humidity up to 90%, non-condensing, >35°C to 70°C (95°F to 158°F) at water vapor pressure up to 5 kPa
Altitude	-382m to 3,012 m -1,254 ft. to 9,882 ft.	-382m to 3,012 m -1,254 ft. to 9,882 ft.	-382m to 3,012 m -1,254 ft. to 9,882 ft.
Atmospheric Pressure	70 kPa to 106 kPa 20.6 in. Hg to 31.3 in. Hg	70 kPa to 106 kPa 20.6 in. Hg to 31.3 in. Hg	70 kPa to 106 kPa 20.6 in. Hg to 31.3 in. Hg

*Note that these environmental conditions apply to the X8 Sleep Profiler device and PSG2 airflow adapter. For environmental limitations of third-party components, see the third-party labels and/or user manuals.

Device Safety Limits	
Max external surface temperature during charging at ambient temperature of 25°C	Less than 49°C (120°F)
Max temperature of accessible parts during recording at ambient temperature of 25°C	Less than 40°C (104°F)
Max temperature of applied parts during recording at ambient temperature of 25°C	Less than 40°C (104°F)

General Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1, CSA 601.1 UL 60601-1, EN 865, IEC 60601-1-2, 60601-1-11
Type of protection	Class II, internally powered by battery
Degree of protection against electrical shock	Type BF – Applied part
Mode of operation	Continuous
Degree of protection against ingress of water/liquids	IEC 60601-1, sub-clause 11.6 IP22
Degree of Safety in presence of flammable mixtures	UL 60601-1
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table DII of Appendix D
Attention Symbol, consult accompanying documentation	IEC 60601-1 Symbol 9 of Table DI of Appendix D, and 60601-1-11
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(b)
Case mechanically strong	IEC 60601-1 and 60601-1-11
Electromagnetic compatibility	IEC 60601-1, sub-clause 17 IEC 60601-1-2, EN 301 489-1, EN 301 489-17
Electrostatic Discharge	IEC 60601-1-2, EN 61000-4-2
Radio Frequency Electromagnetic Field Amplitude Modulated	IEC 60601-1-2, EN 61000-4-3
Proximity Field from Wireless Transmitters	IEC 60601-1-2, EN 61000-4-3
Power Frequency Magnetic Field	IEC 60601-1-2, EN 61000-4-8

Essential Performance

The X8 System is a diagnostic device that does not have any essential performance that would lead to an unacceptable risk. If the device were to fail, it would be easily detected, and the study would need to be repeated.

Expected Service Life

The Sleep Profiler X8 device has an expected service life of five years. The sensor strip, battery, headband, airflow adapter, effort belts, cables, and oximeter finger sensor are considered replaceable components and are expected to be replaced during the service life of the device. The sensor strip has an expected service life of 25 studies (50 nights). The battery has an expected service life of two years, which can be compromised by leaving the device on a charger for extended periods when the battery is fully charged. The headband does not have an expected service life but is recommended to be replaced after 25-50 nights. The sensors are considered single-use disposable components and must be replaced after each use. The cannulas are considered single-patient-use disposable components and must be replaced after each patient. Expected service life of third-party devices such as the pulse oximeter and effort belts are provided by the original manufacturer. The sensors have a limited shelf life and are labeled with an expiration date on the sensor pouch. The expected service life is not a guarantee (see warranty information below).

B. FCC

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) This device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesirable operation.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The X8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X8 System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The X8 System 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 X8 System 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.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The X8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X8 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	2, 4, 6 and 8 kV (±) Contact Discharge 2, 4, 8 and 15kV (±) Air Discharge	2, 4, 6 and 8 kV (±) Contact Discharge 2, 4, 8 and 15kV (±) Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X8 System requires continued operation during power mains interruptions, it is recommended that the X8 System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (Both 50Hz and 60Hz field)	30 A/m (Both 50Hz and 60Hz field)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity			
The X8 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X8 System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the X8, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *Not Applicable*
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 0.4\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 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: 
NOTE 1 At 80 MHz, the higher frequency range applies. NOTE 2 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 X8 System is used exceeds the applicable RF compliance level above, the X8 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the X8 System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the X8 System			
The X8 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X8 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X8 System is 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 *Not Applicable*	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$
0.01	*Not Applicable*	0.04	0.07
0.1	*Not Applicable*	0.1	0.22
1	*Not Applicable*	0.35	0.70
10	*Not Applicable*	1.11	2.21
100	*Not Applicable*	3.5	7
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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Device operation, primarily EEG/ECG/EMG signal acquisition and wireless communication, may be affected by strong electromagnetic fields created by wireless equipment (e.g. Wi-Fi, wireless and mobile phones - especially 5G, wireless chargers), office/household light sources, television and computer screens, electric radiators/heaters, hairdryers, microwave ovens and other kitchen appliances. Please allow at least 0.15 meter (0.5 feet) distance from such equipment for proper operation. Please allow at least 1 meter (3 feet) from such equipment for optimal operation.

C. Customer Support, Warranty, and Terms of Use

1. Customer Support

ABM will provide up to ten (10) hours of telephone technical support to assist with hardware technical problems not covered by the Technical Manual or Training Video(s) within one year from the date of shipment.

To speak with a Customer Service Representative, please dial the telephone number below. Be prepared to provide: 1) your contact information, 2) device details (e.g. serial #), and 3) an explanation of the problem.

Telephone:	+1 (760) 720-0099
	+1 (866) 677-2737 (Toll-free: USA and Canada only)
Hours:	Monday – Friday, 8:30 AM to 5:00 PM, Pacific Time
Fax:	+1 (760) 476-3620
Email:	SleepProfiler@advanced-sleep.com
Website:	http://advancedbrainmonitoring.com/sleep-profiler/
	https://www.advancedbrainmonitoring.com/sleep-profiler-psg2
Mailing Address:	2237 Faraday Avenue, Suite 100, Carlsbad, CA 92008, USA

2. PSG2 Re-order Information for Oximeter and Effort Belts

Nonin Medical (Wrist-Worn Pulse Oximeter) - http://www.nonin.com/CustomerService

WristOx$_2$, Model 3150 BLE	PN: 3150BLE-0101

SleepSense (Respiratory Effort Belts) - https://www.sleepsense.com/

Replacement Band	PN: 1341 Large (Dark blue)
	PN: 1342 Small (Light blue)
Replacement PVDF Piezo Belt	Contact Advanced Brain Monitoring

Philips Respironics (Respiratory Effort Belts) - http://www.protech.respironics.com/contact

ezRIP Adult Kit. 249, 16”/20”	PN: 1099517 (1 Abd module, 1 Thx module, 2 zRIP DuraBelts)
zRIP DuraBelt, Adult, 24” – 74”	PN: 1073622 (zRIP DuraBelt only)
ezRIP Module, Abdomen, 249, 20”	PN: 1094920 (ezRIP Abdomen Module only)
ezRIP Module. Thorax, 249, 16”	PN: 1094921 (ezRIP Thorax Module only)
CT2 piezo sensor adult, (Embleta)	PN: P1800 (1 adult Piezo belt)

3. Warranty and Terms of Use

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D. Additional Information

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CH REP

Importer

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