ADVANCED
BRAIN MONITORING

B-Alert X10

Technical Manual

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Chapter 1: Introduction and Safety Information

A. Indications for Use

The B-Alert System is not intended for the diagnosis or treatment of patients. They are intended for non-medical applications (e.g., human factors, ergonomics, neurogaming, neuromarketing, neuroleadership, team neurodynamics, brain computer interfaces, etc.) and IRB-approved human subject research.

B. About the X10

The X10 is an internally battery powered device intended for up to 12 hours of continuous use on a single charge. The X10 provides an integrated approach for wireless acquisition and recording of electroencephalographic (EEG), electrooculographic (EOG), and electrocardiographic (ECG) signals. The system utilizes the patented Sensor Headset and patented EEG sensors, which record high quality EEG, obtained with less than five-minutes of set-up time and no scalp abrasion required. The wireless technology allows the user to be un-tethered and move around the home or research environment while real time data is collected and displayed.

The X10 acquires nine channels of monopolar EEG recordings with a linked mastoid reference and optional channel for ECG, EOG, or EMG. The X10 consists of: (1) X10 Headset with a Bluetooth (BT) Receiving Unit for bi-directional transmission of digitized physiological signals, (2) a Neoprene Strap, and (3) a Strip with EEG sensors sites in the standard X10 format (POz, Fz, Cz, F3, F4, C3, C4, P3, and P4 with Linked Mastoids).

The Sensor Headset collects signals from the sensors placed on the participant and performs analog-to-digital conversion, encoding, formatting, and transmitting of all signals. The signals communicate using a 2.4 to 2.48 GHz radio transmitter. X10 acquisition utilizes the bi-directional capabilities of the system to initiate scalp-electrode impedance monitoring and monitors the battery capacity in the X10 Headset. A BT Receiving Unit is used as the base unit affixed to the PC workstation.

CAUTION! Read this manual carefully before using the X10.

C. Meaning of symbols


Warning or Caution


Refer to instruction manual/booklet


Manufactured by


Non-ionizing electromagnetic radiatio


European conformity

Model number

Serial number

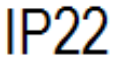

Charge between uses


Do not re-use


Dispose properly


GITEKI (MIC) Mark


Keep Dry



Limit objects, water ingress


Temperature Limitation


Humidity Limitation


Atmospheric Pressure Limitation

D. Safety

The X10 is designed to be applied and operated by a trained technician. There are a number of warnings and cautions throughout this manual: **Read them carefully, they are important to the use of the product.** 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.
- To avoid applying current to a participant with a pacemaker, only dispense the ECG cable when the dual-lead connector is set to ECG mode.

CAUTIONS – General

- Do not use the X10 System as a substitute for clinical electrocardiography, electromyography or critical care. The X10 is NOT intended to be used:
  - as a cardiac monitor
  - to assess neuromuscular diseases
  - for life supporting equipment which requires alarms
- Do not use the X10 System:
  - with high frequency (HF) surgical equipment or in a surgical suite,
  - in proximity to a Magnetic Resonance Imaging system,

- 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:
  - As the X10 System includes an internal battery, do not use the device in any way that could cause an explosion such as, but not limited to, use around an open flame, another battery device, an electrical device, or any high heat device.
  - The X10 System rechargeable battery should only be replaced by an authorized distributor and/or the manufacturer.
  - Local ordinances must be followed for disposal of all electronic equipment.
  - Do not use the X10 System in the presence of flammable anesthetics or gases.
- Electrical Shock Hazard:
  - Avoid touching the ExG sensor snaps when the USB cable is connected to the X10 System and an AC powered source (i.e., PC workstation, USB hub, or USB wall charger).
  - Only use an IEC 60601-1 compliant USB wall charger (Wall charger input 100-240 VAC 50/60Hz 0.35A and Output 5VDC ⎓ 1.0A) when charging from an AC power source.
  - The PC used with the X10 must be placed outside the participant/client environment (more than 3 meters or 10 feet).
- This device has been tested and found to comply with the limits for commercial devices to the applicable CE marking directives. These safety standards are designed to provide reasonable protection against harmful interference in a typical facility.
- The operating temperature of the X10 System may increase:
  - when it is connected to a computer.
  - when data is being transferred from the device memory to the host computer.
  - when device is being charged
- 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 6 hours, or until the device is within safe operating temperatures (5°C to 40°C), prior to use.
- Limitations of Use:
  - The sensors are intended for single participant use.
  - Inspect and then disinfect the sensor strip, enclosure(s) and sensor strap according to the recommended guidelines.
  - The X10 is not waterproof. Do not spray, pour, or spill any liquid on the X10 System, its connectors, switches, or openings as such application of liquids may cause permanent damage and will void the Warranty.
  - 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 and do not use in vicinity of more than 6 other Bluetooth devices.

- Limitations of Use with Accessories: Additional equipment connected to the participant must comply with the requirements of the applicable CE marking directives.
- The X10 System 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, on the X10 System as such use of cleaning agents may cause permanent damage and will void the Warranty.
  - Advanced Brain Monitoring is not responsible for any damage to the X10 System resulting from improper replaceable components i.e., battery, sensor strip, and flash card components.

CAUTIONS – Participant Use

- Do not use the X10 System if it appears to be damaged in any way or if the LED does not properly illuminate during startup.
- Discontinue use of the X10 System in case of any significant pain.
- Possible allergic reaction or skin irritation from device components, e.g. silicone and adhesive sensors, and neoprene/Velcro strap.

CAUTIONS – Limitations Affecting Use

- The X10 System is not recommended for use by participants 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).

  Use of the X10 System by participant with any of these conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.
- X10 System use under any of the following conditions may result in poor signal quality that could lead to a misdiagnosis by the physician.
  - Strap not adjusted properly; too loose or too tight.
  - Head not prepared according to instructions (e.g., makeup, lotion or hair under the sensor).
  - Not using the recommended Synapse® conductive cream.

CAUTIONS – Batteries

- For optimal performance, use a fully recharged battery.
- Only use approved Lithium Polymer rechargeable battery replacements.
- Electrical Shock Hazard: Do not allow the participant to recharge the X10 System with an AC Power Source.
- The X10 System 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

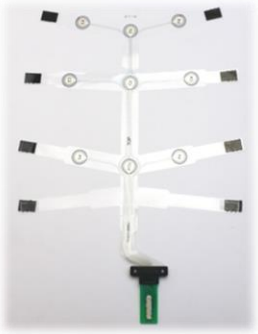
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including the battery. The battery might leak or explode if it is used or disposed of improperly. The X10 device and strip are classified under EWC code 16 02 10* as containing PCBs 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.

E. Minimum System Requirements

- Personal computer (PC) with minimum Pentium™ 2.4 GHz processor;
- Minimum of 2 GB of installed RAM memory and 4 MB virtual memory;
- Windows 7, Windows 8, or Windows 10 operating system;
- .NET framework version 3.5 installed
- Minimum of 50 MB hard disk space per 5-hour session;
- One CD-ROM drive;
- VGA or higher resolution video adapter;
- Two available USB ports (three for validation)
- Monitor size between 15” and 21” required for Baseline acquisition.

F. Items Required for Use

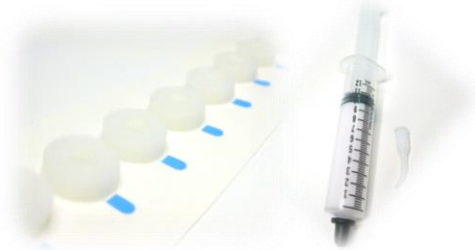
✓ X10 Headset



✓ X10 Sensor Strip

✓ Tape Measure

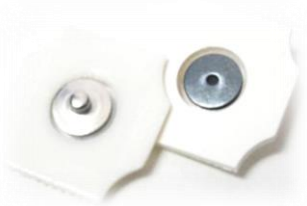
✓ Tweezers



✓ Foam Sensors
✓ 12cc Syringe with caps and curved tips

✓ Synapse Cream Bottle & Tube

✓ 2-pin ECG Leads
✓ 3-pin Mastoid Leads



✓ ECG/EMG/EOG/mastoid disposable electrodes

✓ BT Receiving Unit

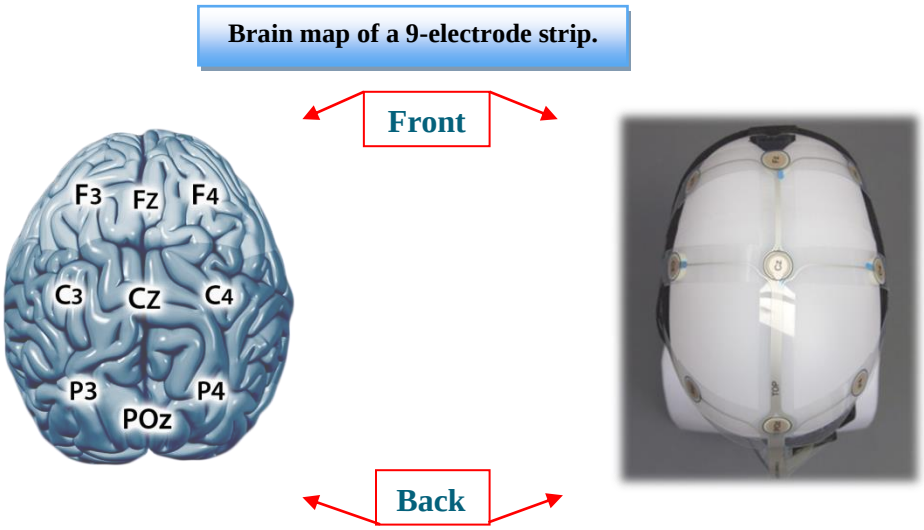
✓ USB Charging Cable

✓ Neoprene Strap

✓ Short Neoprene Strap

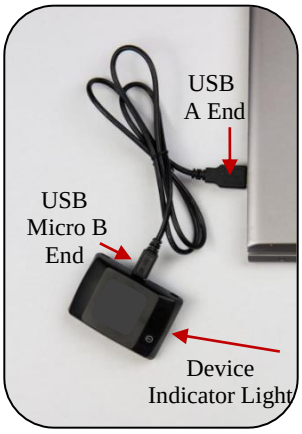
Chapter 2: Sensor Headset Use

This chapter presents a detailed, written process of a standard participant setup. For an additional demonstration, refer to the instructional videos provided with the included software.



A. Charging

The X10 Sensor Headset is advised to be charged to full battery before first use. For ongoing usage, it is recommended that you charge the headset the night before using. To recharge the Headset, follow the steps below.



1. Verify the Headset is in the off position. Plug the Micro-B end of the charging cable into the sensor headset.

2. Plug the USB-A end into your computer's USB port or an IEC 60601-1 approved wall charger.

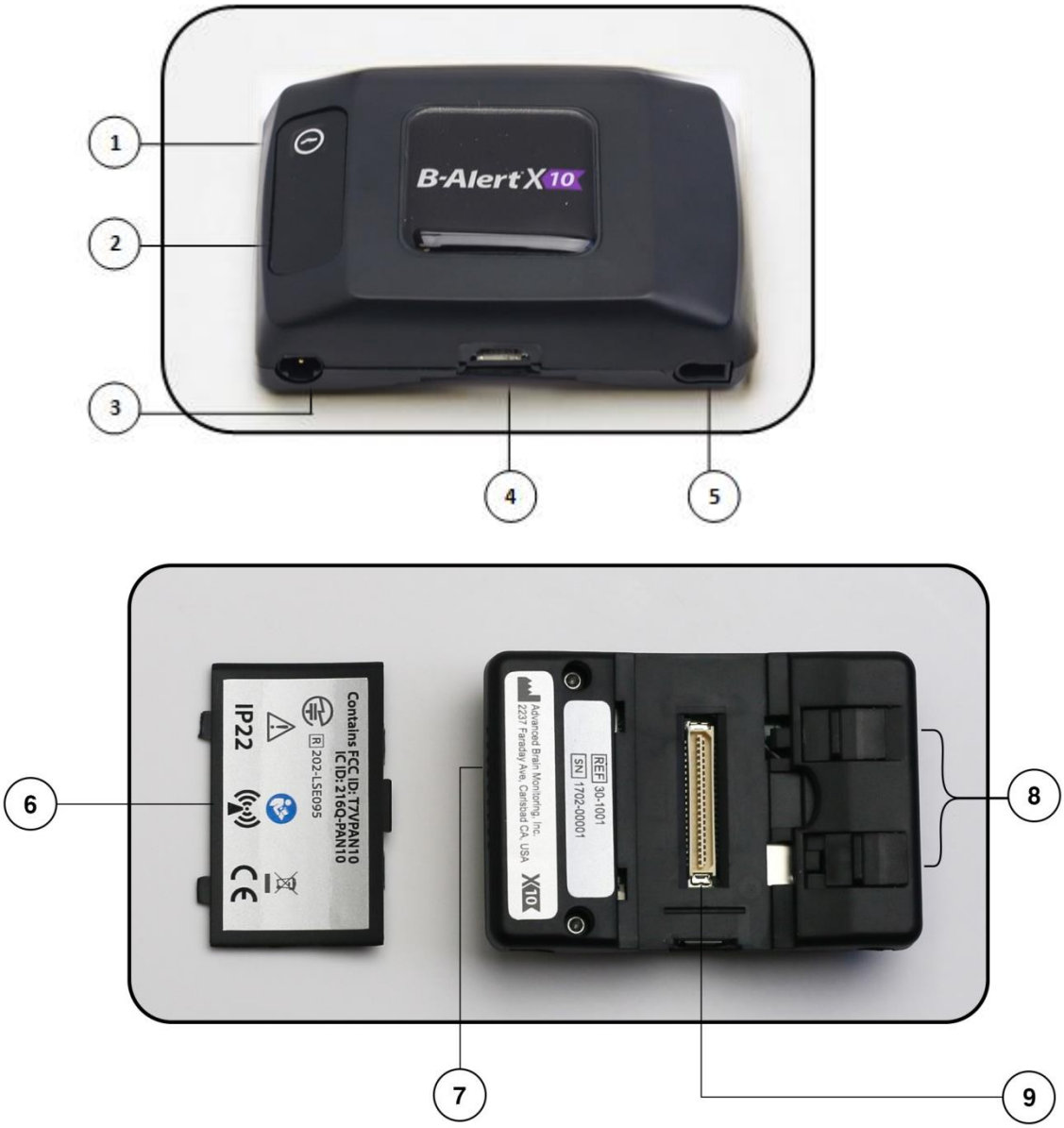
3. Once power is recognized, a voice message will state: "*Caution: the device is charging*." The green indicator light on the headset will flash twice per second.

4. Charging will automatically terminate once the batteries are fully charged, confirmed by a voice message that will state: "*Charging complete*" followed by a single blinking green LED pattern every other second.

B. Device Components

It is important to be familiar with all components of the device before administering the device on a participant. The X10 device components are shown in the diagrams below.

1	On/Off Switch	**4**	USB Micro-B Charging Input	**7**	Speaker
2	LED Indicator	**5**	2-Pin ECG/ EMG/ EOG Input	**8**	Sliding Locks
3	3-Pin Mastoid Input	**6**	Backdoor with Plastic Loop	**9**	Connector Input



C. Visual and Audio Feedback

Device Mode	Green LED	Amber LED	Audio Message
Device powered on	Blinking 3/sec	Off	"Device has been powered on."
Device not synced	Blinking 3/sec	Off	"Waiting to establish wireless communication."
Device synced	On	Off	"Wireless communication established."
Device in acquisition mode	On	Off	"Acquisition started."
Acquisition error or dropped blocks	Blinking	Off	N/A
Low battery	Off	Blinking 1/sec	"The battery is too low to continue without recharging."
Charging in progress	Blinking 2/sec	Off	"Caution: the device is charging."
Charging completed	Blinking 1/ every 2 sec	Off	"Charging complete"

D. Preparation

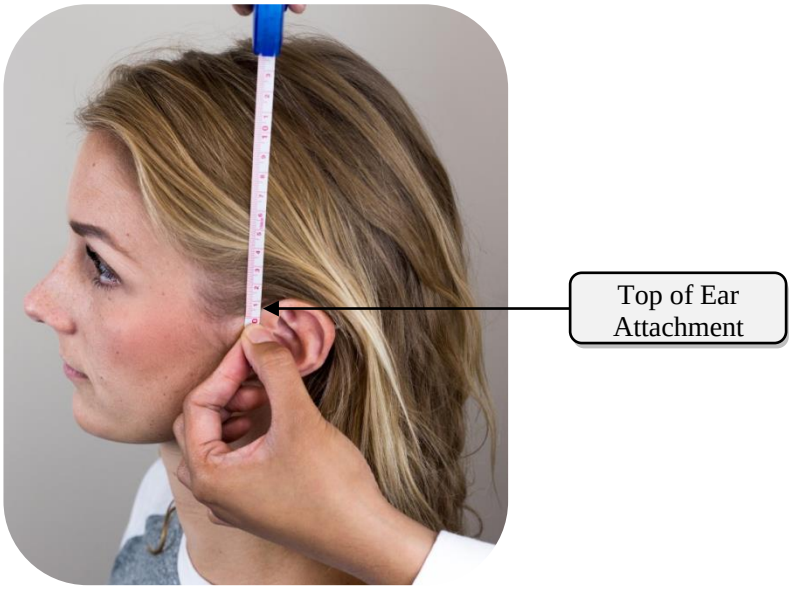
Preparation consists of measurement, strip setup, and head setup.

1. Measurement

a. First, locate the **occipital bone** by asking the participant to gaze upwards. Begin at the nape of the neck and slowly walk your fingers from the participant's head upwards until you have reached the slight bump at the back of the skull.

b. Then locate the **nasion**, right above the eyebrows. Measure the distance from the nasion to the occipital, and record this value.

c. Then, proceed to measure laterally from **the top attachment of the ear** on the left (where the ear intersects with the head) to the top of the ear on the right. Record this value.



d. The **Strip Sizing Chart** is to be used to determine what strip size is appropriate for each participant. This Chart is provided in the Quick Start Guide that is included with your hardware for reference. Locate the values on the Y-axis for Nasion to occipital and the values on the X-Axis for the left to right top of the ear attachment measurements.

		Left to Right Top of Ear Attachment to Head																			
Nasion to Occipital Protuberance		24.5	25	25.5	26	26.5	27	27.5	28	28.5	29	29.5	30	30.5	31	31.5	32	32.5	33	33.5	34
	30.5	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	-	-	-	-	-	-	-	-	-
	31	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	-	-	-	-	-	-	-	-	-
	31.5	XS	XS	XS	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	-	-	-
	32	XS	XS	XS	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	-	-	-
	32.5	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	S	M	M	M
	33	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	M	M	M	M	M	M
	33.5	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	M	M	M	M	M	M
	34	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	S	M	M	M	M	M	M
	34.5	XS	XS	XS	S	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M
	35	XS	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M
	35.5	XS	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M
	36	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M	M
	36.5	-	S	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M	M
	37	-	-	-	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M	M
	37.5	-	-	-	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M	M

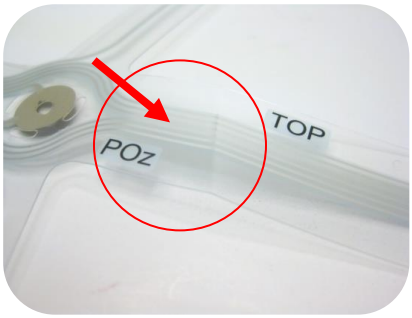
e. If values fall within the RED range shown below, then measure circumference.

Nasion to Occipital Protuberance \ Left to Right Top of Ear Attachment to Head	24.5	25	25.5	26	26.5	27	27.5	28	28.5	29	29.5	30	30.5	31	31.5	32	32.5	33	33.5
30.5	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	-	-	-	-	-	-	-	-
31	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	-	-	-	-	-	-	-	-
31.5	XS	XS	XS	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	-	-
32	XS	XS	XS	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	-	-
32.5	XS	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	S	M	M
33	XS	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	M	M	M	M	M
33.5	XS	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	M	M	M	M	M
34	XS	XS	XS	S	S	S	S	S	S	S	S	S	S	S	M	M	M	M	M
34.5	XS	XS	XS	S	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M
35	XS	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M
35.5	XS	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M
36	XS	XS	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M
36.5	-	S	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M
37	-	-	-	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M
37.5	-	-	-	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M

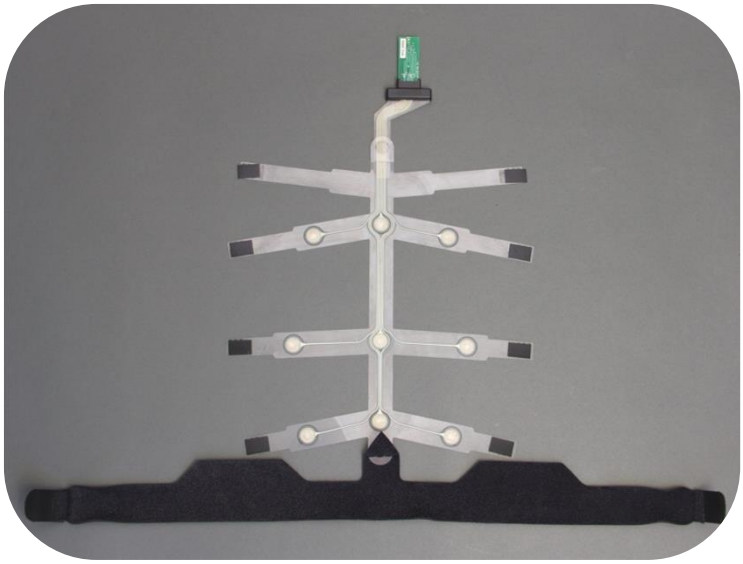
Also measure **circumference**. Downsize *if*: - circumference measures < 56cm, use Small Strip.
- circumference measures < 52cm, use XSmall Strip.

2. Preparing the Strip

a. After selecting the appropriate sized strip, inspect the entire Strip and verify there are no rips or hard creases; pay special attention to spots prone to rips and crease.



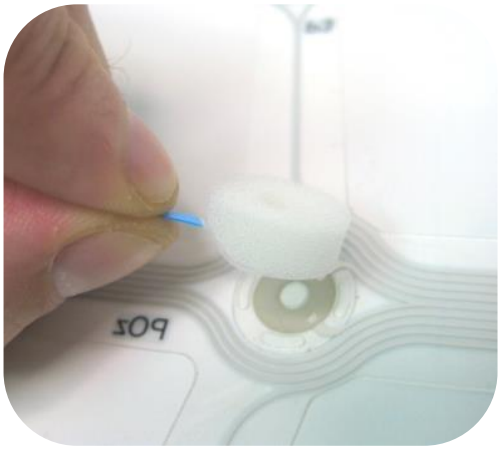
b. Lay down the Neoprene Strap with the fuzzy side facing down. Then, take the X10 strip and place it on the strap with the electrodes facing up.



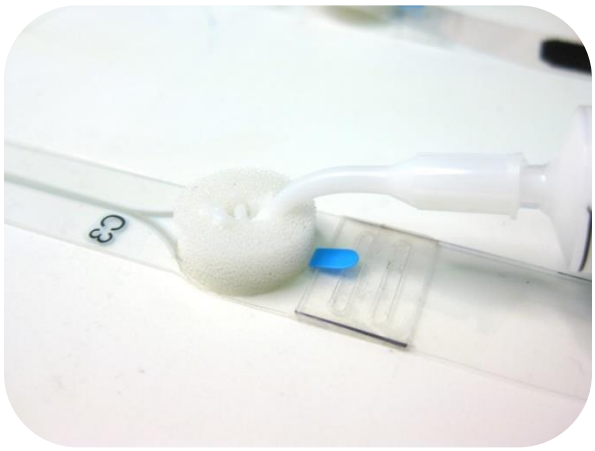
c. Feed the Velcro tabs of the strips through the slots on each end of the Strip.

d. Attach the Strip to the Neoprene Strap by feeding the triangular tip through the hole adjacent to site Fz making sure that the tip is coming through from the bottom.

e. Attach the foam pieces to the sensor sites. Ensure the foam is centered on the Strip to maximize the contact surface between the sensor site and the foam.



f. Using the provided syringes with curved tip attached, fill each foam piece with Synapse cream by placing the syringe in the hole of the hole and dispense the gel. You should see the gel begin filling the center of the foam.



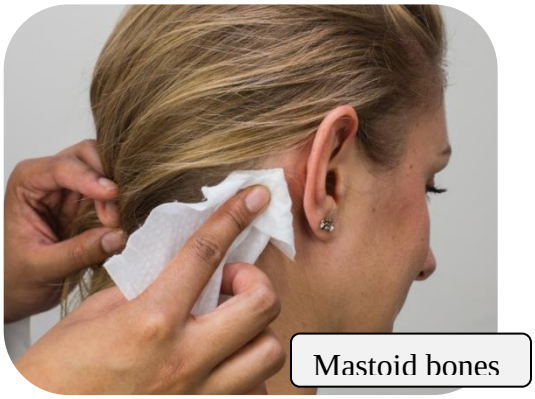
g. Be sure to completely fill foam piece. The foam should be saturated with gel and the center hole should be filled to the top.

h. With the flat surface of the syringe, gently press on each sensor site to allow sensor foam to absorb as much cream as possible.

i. Refill each sensor site and repeat these steps one or two more times.

CAUTION!
Synapse cream should be used with all sensors and electrodes to avoid signal quality problems.

3. **Preparing the Participant**
    a. Wipe the participant's head with a 70% isopropyl alcohol making broad and thorough strokes. Ensure that all of the following areas shown below and on the right are wiped down, in addition to the following:
        - All temporal sites
        - ECG sites (left and right collarbone)



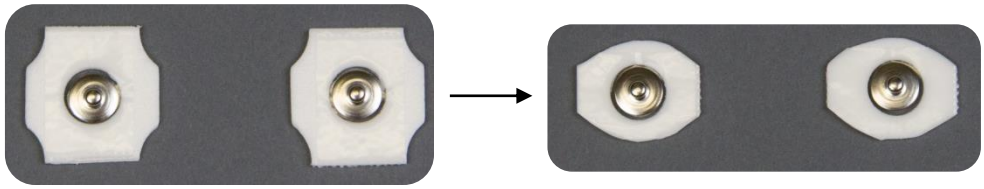
E. Application

Application consists of applying mastoid electrodes, ECG electrodes, sensor strip and neoprene strap, and the headset.

1. **Applying the Mastoid electrodes**

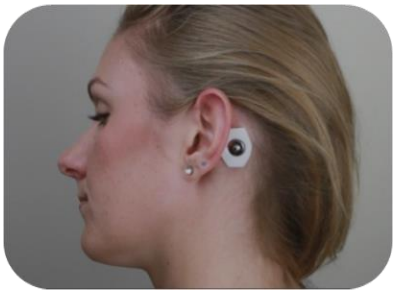
The linked mastoids are used as the reference to the electrodes. They are originally referenced internally, then against all other EEG sensor sites to estimate the Reference (linked mastoid) impedance. Improper set up at all EEG sites may result in inaccurately high impedances for the linked mastoid impedances. Impedance values will typically decrease over time, so it is best to place the mastoid electrodes on first.

a. For easier placement and improved subject comfort, use scissors to cut down the size of the 2 adhesive electrodes. This can also be done before the subject arrives.



b. Peel to expose the adhesive, then apply a small dab of cream on the center of the electrode.

c. Apply to each mastoid bone site.



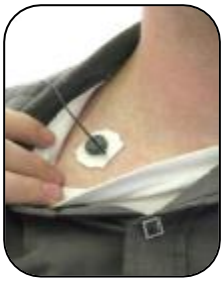
NOTE:
Proper mastoid placement is critical, so ensure adhesive is on the bony area behind the ear. Avoid hair and muscle for optimal data quality and comfort.

2. Applying ECG electrodes

The ECG Leads are color coordinated to distinguish between the left and right leads. Ensure that they are placed on the correct side.

a. Snap 2 adhesive electrodes onto the ECG leads.

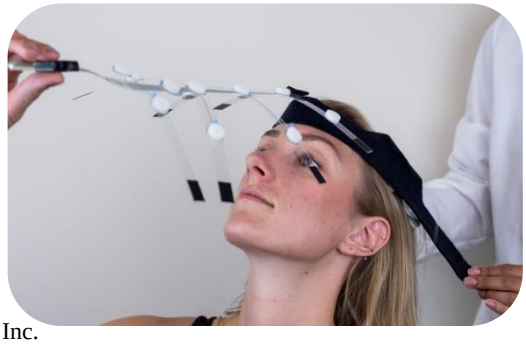
b. Peel to expose the adhesive, then apply a small amount of synapse cream to the centers.



c. Position the grey ECG lead on the participant's right collar bone, and the blue ECG lead on the left collar bone.

3. Applying the Sensor Strip and Neoprene Strap

a. Place the strip and strap on the subject's head, just above the brow bone, aligning the triangular piece of the neoprene strap with the center of the participant's eyebrows.



TIP: While holding both sides of the strap, ask the participant to hold the connector in front of his/her face while you fasten the strap around the participant's head.

b. After tightening to a comfortably snug fit, check both sides to ensure the strap sits just above the top of the participant's ears.

c. Carefully bring the Strip over the top of the participant's head from front to back, verifying that the Strip is centered. Pull the strip back so it is taut and snug against the scalp to prevent buckling/bunching of the strip.

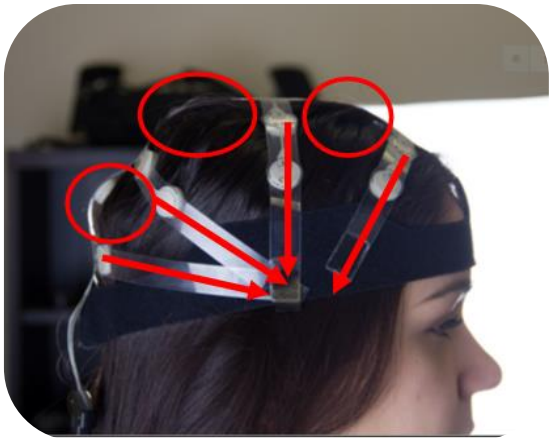
Simultaneously, lightly fasten the furthest back 2 arms down onto the strap.

d. Fasten the remaining strip arms in pairs, from the **back to the front**, ensuring the foam sensors lay flat against the subject's head, while maintaining the correct alignment on the scalp.

NOTE:
Excessive pressure can have negative effects on both signal quality and participant comfort, including the cause for headaches.

e. Ideal fit of the strip is achieved when all arms converge at the same point. **For the final arm set with the P3/P4 sites, prioritize flat sensor placement and affix them either slightly forward or back to find the best fit.** The fit should be *snug*, but not too tight, similar to the fit of a bicycle helmet.

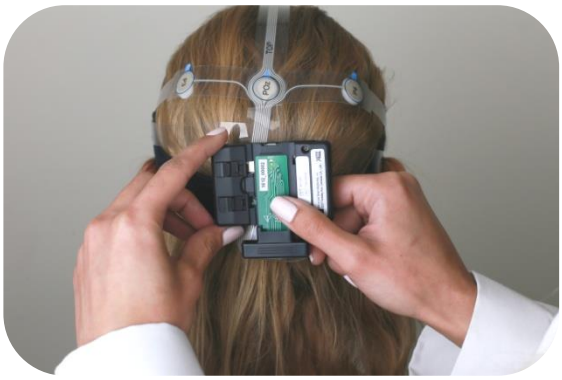
This photo on the right is an example of a good setup with the X10 strip. The strip arms (colored green) are pointing at the spot above the top of ear attachment and the P3 and P4 strip are curved to the shape of the participant's head. The strip is pulled back taut so that the strip does not buckle on any part of the midline. The fit of the strip and the strap should feel like the participant is wearing a bicycle helmet---snug and comfortable, but not too tight.



The buckling shown in the red circles can be caused by choosing the incorrect strip size for the participant; the photo shows a strip that is too large for the participant.

4. Applying the Headset

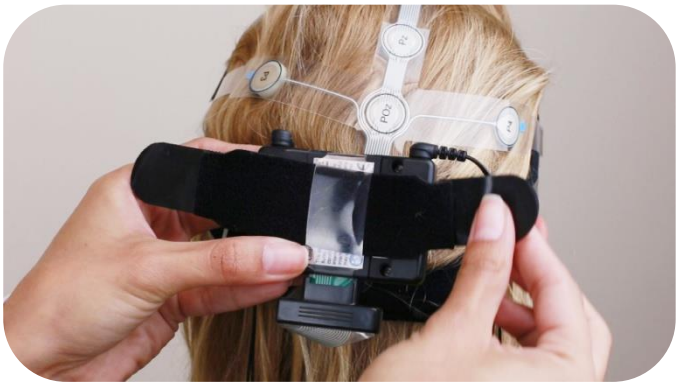
i. With the headset in your hand, remove the door by sliding the tabs away from the center.



ii. Hold the headset with the USB facing up and flip the strip upwards, then align the connector with the underside of the headset. Incorrect alignment of the two connectors can cause permanent damage to the device and strip.

iii. Reattach the device door and lock it in place by sliding the tabs toward the center of the device. Connect the 3-pin linked mastoid cable and optional 2-pin leads, to the device.

iv. Using the small neoprene strap, slip it through the clear plastic loop with the fuzzy Velcro side facing away from the head.



v. Flip the headset down and attach the Velcro to the other neoprene strap on the subject's head. Note: the headset should sit off-center in order to minimize bending of the strip.

vi. Ensure that the strip is still laying flat on the head and the strip is not creased in any areas.

F. Syncing to Bluetooth Receiving Unit

1. Plug in the X-Series BT Receiving Unit (i.e. Dongle) to an available USB port on the computer running the necessary software.

2. Verify the Sensor Headset is synced to the BT Receiving Unit by switching on the Sensor Headset.

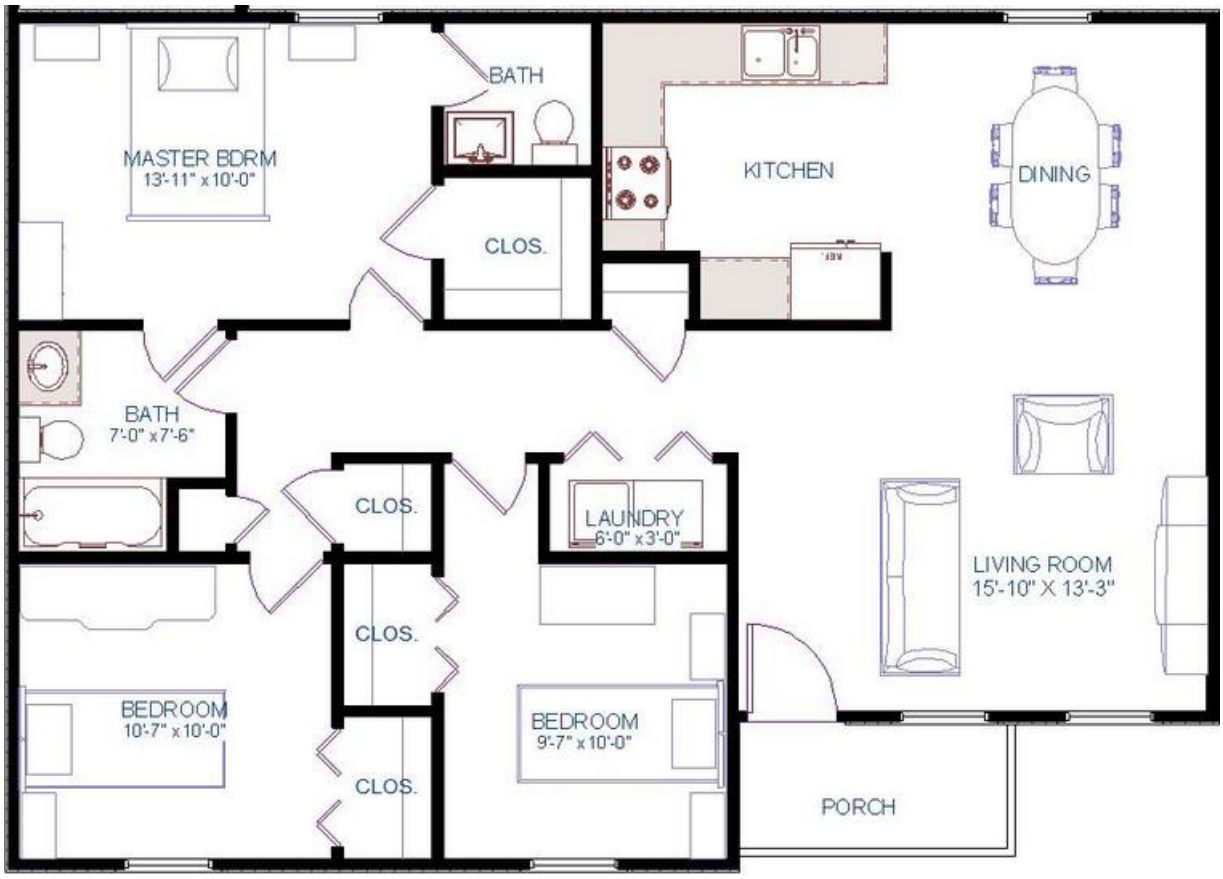
3. See **Section C: Visual and Audio Feedback** for a table that summarizes LED patterns and Audio messages from the headset.

G. Maintaining BT Signal Quality

1. **Guidance for Participants**
    - Line of site for best transmission (Laptop with receiving unit should be visible)
    - Less than 30 feet (10 m) from BT Receiving Unit to participant for best transmission
    - Remain at least a pace away from the receiving unit and laptop.

2. **Guidance for Technicians**
    - Make sure the Sensor Headset and BT Receiving Unit are within 30 ft (10 m) of each other. (10 paces for a normal height individual will give you an approximate distance of 30 feet.)
        i. *Device can transmit over 15M, but 10M is recommended for minimizing data loss due to BT transmission.*
    - Place the receiving unit and laptop at least 3 feet away from the participant and headset.
    - Reduce the obstructions between and avoid metal objects in the line-of sight of the head and host units.
    - Provide guidance to Participant on limitation of wireless coverage in the home environment.
    - Visually confirm via software that data is being transmitted to PC with Receivng Unit
    - Adjust placement of Laptop with receiving unit if necessary for optimizing signal quality

See sample guidance for mobile placement in a 3 Bedroom Home.



Dependent on the primary location of the participant in a mobile environment three optional Receiving Unit Locations are shown that provide different optimal coverage areas. Additional locations not shown could be used by the technician and/or repositioned during a data collection for optimizing signal quality.

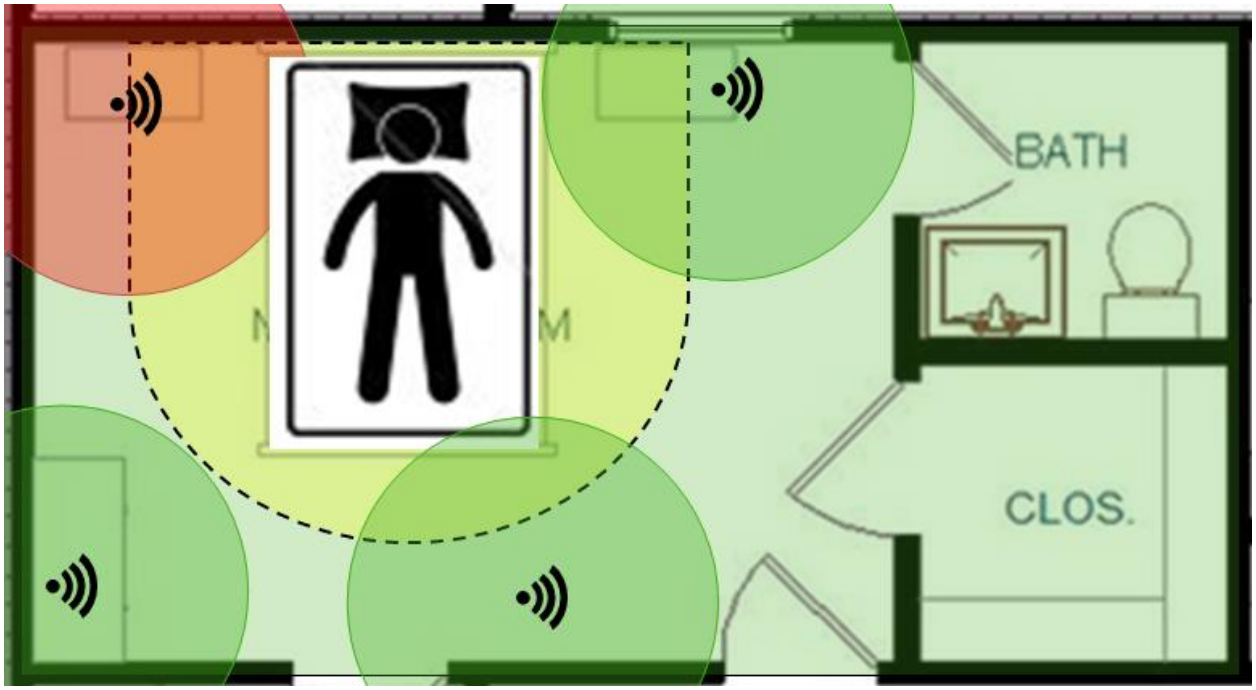
LEGEND	
	Optimal Coverage
	Average Coverage
	Bad Coverage
	Receiving Unit with 3 Foot Clearance.

Option 1

Option 2

Option 3

While the above options provide guidance for a mobile environment, see below sample of receiving unit placements in relation to a participant in a bed. In the sample below yellow represents the clearance area around the participant, the green circle represents the acceptable placement of the receiving unit and laptop, and the red circle represents a bad placement of the receiving unit.



H. Post-Study Procedures

1. Removing Disposable Components after Participant Use

The sensors are intended for single participant use and should be removed and disposed of between each use. The sensor strip, strap, cables, and device enclosure are to be disinfected between uses. It is recommended that the Strips be replaced after twenty-five (25) uses, or if there is a consistent pattern of poor signal quality or damage to the strip (see below for strip replacement instructions).

a. Remove the Sensors:

i. Use the tweezers to remove all foam pieces by grasping the blue tab and pulling it back over the foam. Ensure adhesive ring is removed with foam.

b. Remove the Strip:

i. Position the device so the Strip side is facing upward.

ii. To remove the Enclosure Cover from the device, slide the Cover Latches toward the edge of the device and gently lift the Enclosure Cover from the device. NOTE: Be sure that the latches are completely unlocked to prevent breaking them when removing the cover.

iii. Place index finger beneath Strip Board and thumb on top of Strip Board, apply light upward pressure and lift strip straight up away from device.

iv. When the Sensor Strip is removed from the device, the Female Strip Connector on the Strip and the Male Strip Connector on the device will be visible.

2. Disinfecting After Use

a. Materials:

i. 70% isopropyl alcohol wipe
ii. Dish Soap
iii. Disposable gloves

b. Sensor Strip:

i. Remove any remaining gel with a tissue. Wipe down the entire strip with a 70% isopropyl alcohol (IPA) wipe, ensuring that all gel is removed from sensor sites. All areas should remain wet with 70% IPA for a minimum of 15 seconds.
ii. If any visible soil or gel remains on the device, repeat step 2 as needed.
iii. Allow to air-dry.

c. Neoprene Strap:

i. Submerge the strap in a solution of 1 teaspoon of dish soap (e.g., Dawn detergent) per gallon of water.
ii. Agitate slightly for 1 – 2 minutes.
iii. Rinse under warm clear water for 1 minute.
iv. Wring and allow to air-dry.

d. Enclosures:

i. Using a 70% Isopropyl Alcohol (IPA) wipe, thoroughly clean the top, sides, and bottom of the enclosures. All areas should remain wet with 70% IPA for a minimum of 15 seconds. DO NOT saturate the device with 70% IPA or use wipes with chemicals other than 70% IPA for cleaning the device as this can result in damage to the device.
ii. If any visible soil remains on the device, repeat step 1 and needed.
iii. Allow to air-dry. Do not attempt to charge or turn on the device until it is completely dry.

Chapter 3: Acquisition Troubleshooting

A. Common Headset and Sensor Issues

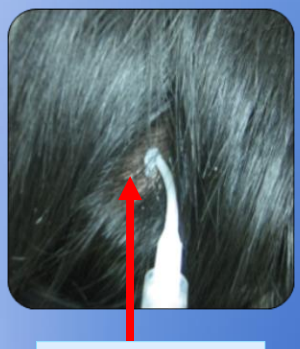
The following topics describe critical troubleshooting methods to undertake when encountering problems during the setup session of a participant.

Excessive EMG

Hands should be away from Face!

- **Is patient grinding their teeth, chewing gum, or furrowing brows?**
  - Teeth grinding is most noticable in the C3 and C4 channels.
  - Chewing gum will appear across channels.
  - Brow furrowing will appear mostly in the F3, F4, and Fz channels.
- **Possible adjustments:**
  - Ask the patient to relax their forehead, stop clenching their teeth ,or biting their lip(s).
  - Adjust their posture (i.e., desk, computer, chair, etc.) to make them more comfortable.
  - Ensure the patient is not resting their head on their hand.
  - Adjust the temperature of the room, especially if the patient is drowsy.

High Sensor Impedances



Part thick hair and add cream.

Try the steps below in order:

- Ensure the sensors are seated evenly and properly on the strip
- Tighten loose sensor strap arms.
- Lift up each strip arm and use the syringe tip to part the hair and expose the scalp under the sensor.
- Part the hair, apply synapse gel to the site, tighten down the strip arm while ensuring that the electrode is making contact with the scalp.
- If all channel sites still display high impedances after performing necessary troubleshooting procedures, replace the mastoid electrodes.

Sensor Placement and Comfort

- **Alignment hole does not match up with the nasion?** Pull the strap anterior so the strap sits closer to the eye brows or move to the left or right to line up.
- **Patient feels pinching or pulling on hair?** Confirm hair is not trapped between the strip and the sensor, Remove hair under the sensor strap across the forehead.

NOTE: The recommendations are not necessarily listed in a logical sequence. Use best judgment to determine which trouble-shooting tips are most relevant to the problem(s).

Chapter 4: Product Information

A. X10 B-Alert Specifications

<table>
<tr><th colspan="5">System Specifications of the X10 – subject to change</th></tr>
<tr><td>Brand names</td><td colspan="4">B-Alert</td></tr>
<tr><td>Operating Modes</td><td colspan="4">
<table>
<tr><th>Mode</th><th>Description</th></tr>
<tr><td colspan="2">Standard</td></tr>
<tr><td>Monitoring mode</td><td>Transmits via Bluetooth (BT)</td></tr>
<tr><td>Hibernation</td><td>Device turned off</td></tr>
<tr><td>Disconnect</td><td>Long term storage</td></tr>
</table>
</td></tr>
<tr><td>Signals acquired</td><td colspan="4">
<table>
<tr><th>Signal</th><th>Number of channels</th><th>Default dynamic range</th><th>Default samples per sec</th><th>Interfaced to PCB/electronics</th></tr>
<tr><td>EEG</td><td>9</td><td>± 1000 µV</td><td>256</td><td>PET strip</td></tr>
<tr><td>ECG, EMG, EOG, EEG</td><td>1</td><td>± 1000 µV</td><td>256</td><td>Touch-proof two-lead cable</td></tr>
<tr><td>Actigraphy</td><td>3</td><td>-180 to 180°</td><td>10</td><td>On device</td></tr>
</table>
</td></tr>
<tr><td>Signal Processing</td><td colspan="4">
<table>
<tr><th>Signal</th><th>Resolution for full dynamic range</th><th>Processing/Filtering</th></tr>
<tr><td>EEG</td><td>16 bit</td><td>0.1 Hz High Pass, firmware
67 Hz Low Pass, hardware</td></tr>
<tr><td>2-pin connector</td><td>16 bit</td><td>0.1 Hz High Pass, firmware
67 Hz Low Pass, hardware</td></tr>
<tr><td>Actigraphy</td><td>12 bit</td><td>Down sampled from 100 Hz to 10 Hz</td></tr>
</table>
</td></tr>
<tr><td>Typical Signal Accuracy and Resolution</td><td colspan="4">
<table>
<tr><th>Signal</th><th colspan="2">Accuracy (typical)</th></tr>
<tr><td>EEG</td><td colspan="2">3.0 µV peak-to-peak, resolution 0.038 µV</td></tr>
<tr><td rowspan="2">Optional 2-pin connector</td><td>ECG</td><td>3.0 µV peak-to-peak, resolution 0.06 µV</td></tr>
<tr><td>EOG/EEG/EMG</td><td>3.0 µV peak-to-peak, resolution 0.038 µV</td></tr>
<tr><td>Actigraphy</td><td colspan="2">+/- 3 degrees in +/-60 degrees range</td></tr>
</table>
</td></tr>
<tr><td>EEG Impedance Monitoring</td><td colspan="4">Impedance monitoring is not performed on ExG 2-pin channels
In monitoring mode when initiated by host computer</td></tr>
<tr><td>EEG Input Impedance</td><td colspan="4">500MΩ, typical</td></tr>
<tr><td>EEG Common Mode Rejection</td><td colspan="4">-115dB Common Mode Rejection Ratio, typical</td></tr>
<tr><td>Calibration</td><td colspan="4">The X10 device does not require calibration</td></tr>
<tr><th colspan="5">Battery</th></tr>
<tr><td>Battery Charging</td><td colspan="4">Via USB cable connected to
• USB port, 5V/0.5 A, or
• USB wall charger IEC 60601-1 approved, Input 110/220V, Output 5V/0.5A up to 5V/1.0A</td></tr>
<tr><td>Power Supply</td><td colspan="4">One 600mAh (or 650mAh) 3.7V Lithium Polymer Battery</td></tr>
<tr><td>Typical Power Consumption and Operating Time by Mode</td><td colspan="4">
<table>
<tr><th>Mode</th><th>Consumption (typical)</th><th>Hrs of Use (range)
0-4 days after charge</th><th>Hrs of Use (range)
5-10 days after charge</th></tr>
<tr><td colspan="4">Standard Modes</td></tr>
<tr><td>Monitoring</td><td>45 mAh</td><td>10.5 to 12.5</td><td>9.5 to 12.0</td></tr>
<tr><td>Hibernation</td><td>0.1mAh</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Disconnect</td><td>None</td><td>N/A</td><td>N/A</td></tr>
</table>
</td></tr>
<tr><th colspan="5">User Interface</th></tr>
<tr><td>User Control</td><td colspan="4">ON/OFF tactile switch</td></tr>
<tr><td>Visual feedback</td><td colspan="4">Green, Amber</td></tr>
</table>

Dimensions	2.8” long x 1.9” wide x 0.8” deep		
Weight	0.071kg with batteries		
Materials of Data Acquisition Device			
Case Material	ABS		
Enclosure strap	Neoprene with loop fastener		
EEG Sensor	Foam Sensor (100 PPI Natural Color Filter Foam) with Kustomer Kinetics Clear Conductive Cream		
ECG Sensor	MBS (3BF3) disposable Ag/AgCl sensors with adhesive		
EEG Flex Strip	Polyester film		
Cleaning	Cleaned and disinfected by rubbing with isopropyl alcohol		
USB Specification			
USB Standard	USB 2.0		
USB Data Transfer	USB Flash Disk		
Wireless Specification			
Wireless Module	Bluetooth v2.1+EDR compliant to IEEE 802.15.1		
Operating Frequency	2.4 to 2.48 GHz (ISM Band)		
Antenna	On-board		
Transmission Mode	Bi-Directional		
Output Power	Maximum 4 dBm		
Limitations of Operation	Maximum range 10 meters line of sight		
	Maximum 7 in-band Bluetooth transmitters in vicinity using Bluetooth spectrum management		
Data Throughput	Typical 10KB/sec, maximum 30 KB/sec		
Latency	Depends on PC Bluetooth, up to 300ms from data sample acquisition until received by PC.		
Data Integrity	Bluetooth protocol ensures data integrity by retransmitting corrupted data packets, X10 Communication Protocol recognizes and inserts zeros for missed samples.		
Quality of Service	Average data loss <0.1%		
Security Characteristics	X10 Communication Protocol establishes and Bluetooth protocol maintains secure transmission between X10 master and PC slave device.		
Software Performance			
Compatibility for client workstation	Personal computer with Pentium 4, 1GB RAM or higher processor (or equivalent) with Windows 7, 8, or 10 Operating Systems		
Estimated File Size	1 MB/min, 480 MB per 8 hrs		
Environmental Conditions	**Operation**	**Transportation**	**Storage**
Temperature / Relative Humidity	5ºC to 40ºC (41ºF to 104ºF), relative humidity 15% to 90%, non-condensing and water vapor pressure up to 5kPa	-25ºC to 5°C (-13ºF to 41ºF), 5°C to 35°C (41ºF to 95ºF) with relative humidity up to 90%, non-condensing, >35°C to 70ºC (95ºF to 158ºF) at water vapor pressure up to 5kPa	-25ºC to 5°C (-13ºF to 41ºF), 5°C to 35°C (41ºF to 95ºF) with relative humidity up to 90%, non-condensing, >35°C to 70ºC (95ºF to 158ºF) at water vapor pressure up to 5kPa
Synapse Cream Temperature	7ºC to 20ºC 45ºF to 68ºF	7ºC to 20ºC 45ºF to 68ºF	7ºC to 20ºC 45ºF to 68ºF
Altitude	-382m to 3,012 m -1,253 ft. to 9,882 ft.	-382m to 3,012 m -1,253 ft. to 9,882 ft.	-382m to 3,012 m -1,253 ft. to 9,882 ft.
Atmospheric Pressure	70 kPa to 106 kPa 21 in. Hg to 31 in. Hg	70 kPa to 106 kPa 21 in. Hg to 31 in. Hg	70 kPa to 106 kPa 21 in. Hg to 31 in. Hg
Temperature Limitations			
Max external surface temperature during charging at ambient temperature of 22.8ºC	Less than 57°C (135°F)	N/A	N/A
Max temperature of accessible parts during recording at ambient temperature of 22.2 ºC	Less than 45°C (113°F)	N/A	N/A

Max temperature of applied parts during recording at ambient temperature of 22.2 ^{o}C	Less than 41°C (106°F)	N/A	N/A

General Compliance	
Item	**Compliant With**
Equipment classification	Class B, EN 55011:2009+A1:2010
Degree of protection against electrical shock	Low Voltage Directive
Mode of operation	Continuous
Degree of protection against ingress of water/liquids	IP22
Electromagnetic compatibility	Electromagnetic Compatibility Directive, EN 301 489-1, EN 301 489-17
Electrostatic Discharge	EN 61000-4-2
Radio Frequency Electromagnetic Field Amplitude Modulated	Radio Equipment Directive EN 61000-4-3
Proximity Field from Wireless Transmitters	EN 61000-4-3
Power Frequency Magnetic Field	EN 61000-4-8

Essential Performance

The X10 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 X10 device has an expected service life of five years. The sensor strip, battery, strap, and sensors 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 uses. 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 strap does not have an expected service life, but is recommended to be replaced after 25 uses. The sensors are considered single-use disposable components and must be replaced after each use. The AgCl sensors and synapse cream have a limited shelf life and are labeled with an expiration date. The device, sensor strip, battery, and foam sensors do not have an expected shelf life. 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, and Canadian ICES-003. *Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.* 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 X10 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X10 System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The X10 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 X10 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 X10 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X10 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	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X10 System requires continued operation during power mains interruptions, it is recommended that the X10 System be powered from an uninterruptible power supply or a battery.

	<5 % *U*T (>95 % dip in *U*T) for 5 s		
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 X10 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X10 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 X10, 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 X10 System is used exceeds the applicable RF compliance level above, the X10 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 X10 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 X10 System			
The X10 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X10 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X10 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.			

CAUTION: Changes or modifications not expressly approved by Advanced Brain Monitoring, Inc. could void the user's authority to operate the equipment.

C. Standard Warranty, Terms, Conditions and Limitations on Use

1. **Parties.** This Standard Warranty, Terms and Conditions and Limitations on Use ("Standard Warranty") is between Advanced Brain Monitoring, Inc. (ABM) and purchaser (referred to as the "Customer," "You," or "Your") for the X10 B-Alert System covered by this Standard Warranty ("Product"). The term Product includes the software and/or firmware in machine-readable form which is pre-installed on the Product. The software and/or firmware in machine-readable form which is pre-installed on the Product is separately referred to as the Software. By your use of the Product, You agree to this Standard Warranty. If you do not agree, do not use the Product and return it to ABM for a refund.

2. **Product Coverage. This is a limited warranty.** ABM warranties the Product to be free from defects in workmanship and to be in a condition suitable for normal use, and in material compliance with all published product specifications, from date of shipment for a period of: a) twenty-four (24) months for electronic components enclosed within the serialized device, and b) twelve (12) months for replacement components (e.g., battery(s), removable memory card within the enclosure. "Normal use" is defined as regular, ordinary, and routine use of the Product under normal operating conditions as intended and/or recommended by ABM. The following conditions or events and any resulting damage or defect are explicitly excluded from the Standard Warranty:
   a. On-Site or in-house service;
   b. The service, maintenance, repair or replacement necessitated by any loss or damage resulting from any cause other than normal usage, including without limitation, to loss or damage resulting from misuse, abuse, use outside of the specifications, or improper installation or maintenance. Non-normal Product failures explicitly excluded from warranty coverage include:
      - Detachment of the connector(s) inside the enclosure – damage typically occurs when the cable connector is improperly forced into place;
      - Shorted microcontroller - failure can occur under extremely dry climate conditions resulting in an electro-static discharge coupled with the user not inserting or removing a cable only when the Device is OFF;
      - Items attached to the enclosure (i.e., strips, headband, and sensors).
      - Use with disposables not supplied by ABM.
   c. Service made necessary by any external cause, including fire, theft, acts of God, alteration, non-normal patient use, problems arising from software or hardware not supplied by ABM, power failures or shortages, improper shipping, common carrier equipment and/or facilities;
   d. Service or repair by persons other than those trained or authorized by ABM to service the Product;
   e. Service or repair made necessary by use of or damage caused by third party products.

3. **Software License:** This Standard Warranty grants You a personal, non-exclusive license ("License") to use the Software. You are only licensed to use the Software on the Product on which it was pre-installed. The Software is licensed, not sold. The Software is owned by ABM and/or its suppliers and is protected by United States copyright laws and international treaty provisions. You may not copy the Software or the written materials accompanying the Software. You may not decompile, disassemble, or otherwise derive Source Code from the Software. You may not reverse engineer the Software or attempt to determine its underlying algorithms. You may not use the Processed Data derived from the Sleep Profiler Software to assist in Your development or validation of methods, procedures, software, or commercial or non-commercial technologies intended to characterize sleep architecture or sleep continuity without ABM's express written permission. This License is effective until terminated. This License will terminate immediately without notice from ABM or judicial resolution if you fail to comply with any provision of this License. Upon such termination, you must destroy the Software and all accompanying written materials and all copies thereof.

4. **Software Coverage:** 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.

5. **How to Obtain Service.** You may obtain Service for the Product, or request additional information, by contacting ABM at (866) 677-2737.

6. **Return of Product.** To return a Product to ABM under a warranty claim or under a refusal to agree to the terms herein, the Purchaser must first contact ABM's Customer Support at (866) 677-2737 and receive a Return Merchandise Authorization (RMA) number. Purchaser must place the RMA number on the outside of the package containing the products being returned and ship the package to ABM's facility at your expense. The package should contain a short description of the defect and a contract number to discuss equipment concerns with the licensee. Any returned Product received by ABM without a RMA number shall be sent back to the Purchaser. If a claimed problem cannot be identified or reproduced in Service, You agree to pay shipping cost for the return of the Product to you.

7. **Eligibility.** ABM reserves the right to require an inspection of the Product at Your expense prior to the acceptance of this Standard Warranty to verify that the Product is in unaltered, operable condition and in good working order suitable for normal use. Acceptance of this Standard Warranty is expressly conditioned upon prior payment by You. You agree to notify ABM if Product is lost, stolen, or sold.

8. **Repair or Replacement:** ABM will provide all parts and labor necessary to service and repair the Product covered under Warranty. In the event ABM is unable to repair a defective Product, it shall, at its option, replace any Product with one of equivalent value or functionality or refund the purchase price pro rata. In the case of a pro rata refund, the amount of the refund will be the purchase price reduced by the percentage of the warranty period that has passed (measured in days). For example, if 146 days of a two

year (730 days) warranty has passed, the refund would be the purchase price reduced by twenty percent (146 days divided by 730 days). The foregoing remedies shall be Purchaser's sole and exclusive remedies under this warranty.

9. **Payment for Non-Warranty Work**: In the event a repair is not covered by the Standard Warranty, you will be notified within five (5) business days upon receipt of the Product. If you authorize ABM to perform any services excluded under this Standard Warranty, You agree to pay ABM its usual and customary fees for such work.

10. **LIMITATION OF WARRANTIES.** ABM DOES NOT REPRESENT OR WARRANT THAT THE PRODUCT WILL MEET YOUR REQUIREMENTS OR THAT THE OPERATION OF THE PRODUCT WILL BE UNINTERRUPTED OR ERROR FREE. TO THE MAXIMUM EXTENT PERMITTED BY LAW, EXCEPT AS EXPRESSLY PROVIDED IN THIS STANDARD WARANTY, PRODUCTS ARE PROVIDED "AS IS" WITHOUT WARRANTY. ABM DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, THAT ARE NOT EXPRESSLY PROVIDED IN THIS STANDARD WARRANTY INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

11. **LIMITATION OF LIABILITY**. IN NO EVENT SHALL ABM, ITS RESPECTIVE PARENT OR AFFILIATE COMPANIES OR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR SUBCONTRACTORS, BE LIABLE UNDER ANY THEORY OF TORT, CONTRACT, STRICT LIABILITY OR OTHER LEGAL THEORY FOR LOST PROFITS, LOST REVENUES, LOST BUSINESS OPPORTUNITIES AND INFORMATION, BUSINESS INTERRUPTION, EXEMPLARY, PUNITIVE, SPECIAL, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EACH OF WHICH IS HEREBY EXCLUDED BY AGREEMENT OF THE PARTIES, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE OR WHETHER ABM HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. ABM'S CUMULATIVE LIABILITY FOR ALL LOSSES, CLAIMS, SUITS, CONTROVERSIES, BREACHES, OR DAMAGES FOR ANY CAUSE WHATSOEVER (INCLUDING, BUT NOT LIMITED TO, THOSE ARISING OUT OF OR RELATED TO THIS STANDARD WARRANTY) AND REGARDLESS OF THE FORM OF ACTION OR LEGAL THEORY SHALL BE THE AMOUNT YOU ACTUALLY PAID FOR THE PRODUCT, AS EVIDENCED BY WRITTEN RECEIPTS OR OTHER WRITTEN EVIDENCE. BECAUSE SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

12. **GOVERNING LAW**. This Warranty shall be governed by and construed in accordance with the laws of the State of California (without regard to its choice of law provisions). YOU IRREVOCABLY WAIVE ANY AND ALL RIGHTS YOU MAY HAVE TO A TRIAL BY JURY IN ANY JUDICIAL PROCEEDING INVOLVING ANY CLAIM RELATING TO OR ARISING UNDER THIS STANDARD WARRANTY.

13. **DISPUTE RESOLUTION**. Any dispute, controversy, or claim against ABM or its parent or affiliate companies arising out of or relating to this Standard Warranty, its interpretation, or the breach, termination or validity thereof, or any related purchase shall be resolved exclusively and finally by arbitration administered by the American Arbitration Association (AAA) under its rules (www.adr.org). You may file for arbitration at any AAA location in the United States upon the payment of any applicable filing fee. The arbitration will be conducted before a single arbitrator, and will be limited solely to the dispute or controversy between you and ABM. The arbitration shall be held in any mutually agreed upon location in person, by telephone, or online. Any decision rendered in such arbitration proceedings will be final and binding on each of the parties, and judgment may be entered thereon in a court of competent jurisdiction. The arbitrator shall not award either party special, exemplary, consequential, punitive, incidental or indirect damages, or attorneys' fees and each party irrevocably waives any such right to recover such damages. The parties will share the costs of the arbitration, (including the arbitrator's fees, if any) in the proportion that the final award bears to the amount of the initial claim. No action, regardless of form, arising out of or in conjunction with the subject matter of this Standard Warranty may be brought by either party more than one (1) year after the cause of action arose.

14. **ENTIRE AGREEMENT**. This Standard Warranty constitutes the entire agreement between you and ABM pertaining to the subject matter hereof and supersedes in their entirety all written or oral agreements between the parties pertaining to the subject matter hereof. This Standard Warranty is intended to be understood in conjunction with the Standard Warranty, Terms, Conditions and Limitations on Use which is included in the Sleep Profiler Portal Technical Manual.

D. Additional Information

Customer Support

If you have any questions regarding this product, please first refer to this User's Manual. To speak with a Customer Service Representative, please dial the telephone number below. Be prepared to provide: 1) your name, address and telephone number, 2) the X10 model and serial numbers, and 3) an explanation of the problem.

Telephone:	(760) 720-0099 or Toll-Free (866) 677-2737 Monday – Friday 8:30 AM to 5:00 PM Pacific Time
Fax:	(760) 476-3620
Email:	support@b-alert.com
Web:	http://www.AdvancedBrainMonitoring.com
Mailing Address:	2237 Faraday Avenue, Suite 100, Carlsbad, CA 92008

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