B-Alert® X10

User Manual

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Chapter 1: Introduction and Safety Information

A. About the X10

The X10 is an internally battery powered Type BF device intended for continuous use (16-17 hours). 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 9 channels of monopolar EEG recordings with a linked mastoid reference. 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 X10 Standard format: POz, Fz, Cz, Pz, F3, F4, C3, C4, P3, P4.

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.

B. Indications for Use

The B-Alert wireless EEG systems are 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.

CAUTION! Read this manual carefully before using the X10.

C. Safety

The X10 is designed to be applied 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 believed to be accurate.

CONTRAINDICATIONS

- Do not use the X10 in an MRI environment.
- Do not use the X10 when alarms based on EEG classification are required.
- X10 has no alarm classifications (such as drowsiness). There are only alarms for indications of excessive artifact.

- Do not use the X10 as a substitute for clinical ECG. The X10 is a recording device, not a monitoring device.
- Do not use the X10 with high frequency (HF) surgical equipment.
- Do not use the X10 in an environment where Defibrillation is common.

WARNINGS

- Explosion Hazard. Do not use the X10 in an explosive atmosphere.
- Explosion Hazard. Do not use the X10 in the presence of flammable anesthetics or gases.
- Explosion Hazard. Do not use the X10 battery recharging system with non-rechargeable batteries.
- EEG Leads, Strips, and Sensor interfaces are not protected against the effects of defibrillation. Damage to the device is possible if worn during defibrillation.
- Not Defibrillator Proof.
- Additional equipment connected to the participant must comply with the requirements of IEC 60601-1-1.
- The PC used with X10 must be placed outside the participant environment (more than 3 meters or 10 feet), or the PC must comply with IEC 60601-1.1
- Permanent Damage and/or Warranty Voidance. X10 must be repaired by authorized personnel only. Any evidence of opening the system, field service by non-authorized personnel, tampering, or any kind of system misuse or abuse shall void the warranty.
- Synapse® Conductive Electrode Cream is recommended for use with the EEG sensors. Use of any conductive gel, cream, or electrolyte other than Synapse may affect signal quality or accuracy, or damage the EEG sensor.
- To comply with X10 Transportation and Storage Environmental Condition specifications, Synapse may need to be shipped separately.
- Avoid placement of EEG sensors or Synapse cream directly into an open wound.

CAUTIONS – General

- The X10 should only be applied by a trained technician. This model is not intended for in-home use without the assistance of a technician.
- Position conductive parts of the EEG, ECG, and EOG sensors so that they do not contact other conductive parts and earth.
- Do not spray, pour, or spill any liquid on the X10, its connectors, switches, or openings, as this will cause permanent damage and void the Warranty.
- Do not use caustic or abrasive cleaning agents on the X10 or on the Sensor Strip, as this will cause permanent damage and void the Warranty.
- This device has been tested and found to comply with the limits for medical devices to the IEC 60601 standards. These standards are designed to provide reasonable protection for safety and against harmful interference in a typical medical installation.
- To minimize the possible hazard caused by the summation of leakage currents when several equipments are interconnected, the X10 should be used in wireless mode only and should never be charged while being worn by the participant.

- Verify that all visible indicators illuminate during the startup (initialization) sequence. If any indicator is not lit, do not use the X10. Contact ABM for repair or replacement.

CAUTIONS – Batteries

- Do not charge the batteries while wearing the Sensor Headset.
- Do not recharge batteries that have been fully charged.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Batteries may leak or explode if used or disposed of improperly.
- The internal Li-Polymer batteries should only be replaced by the service department!

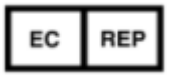

Warning or Caution, see instructions for use


See instructions for use


Manufactured by


Type BF classification


European conformity



European authorized rep

Model number

Serial number with year and month (YYMM) of Manufacture


Keep Dry


Single patient use


Dispose properly

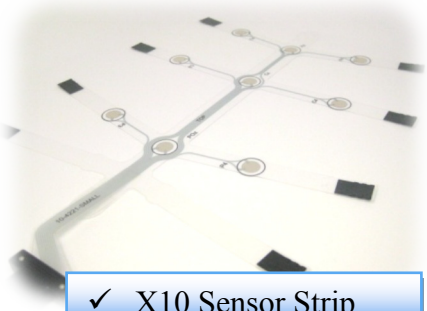
Limit objects, Water ingress

D. 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 or Windows 8 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;
- One available USB port.
- Monitor size between 15” and 21” required for Baseline acquisition.

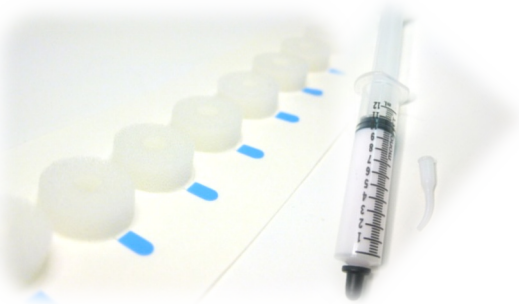
E. Items Required for Use

✓ X10 Headset



✓ X10 Sensor Strip

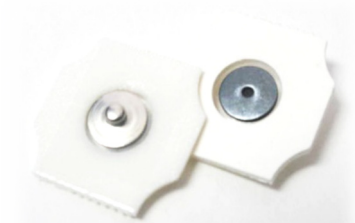
✓ Cleaning Tool - Tweezers



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

✓ Synapse Cream Bottle & Tube

✓ 2 pin ECG Leads (left)
✓ 3 pin Mastoid Leads (right)



✓ Disposable ECG/EMG/EOG and Mastoid Electrodes

✓ BT Receiving Unit Dongle (left)
Optional ESU-MC (right)

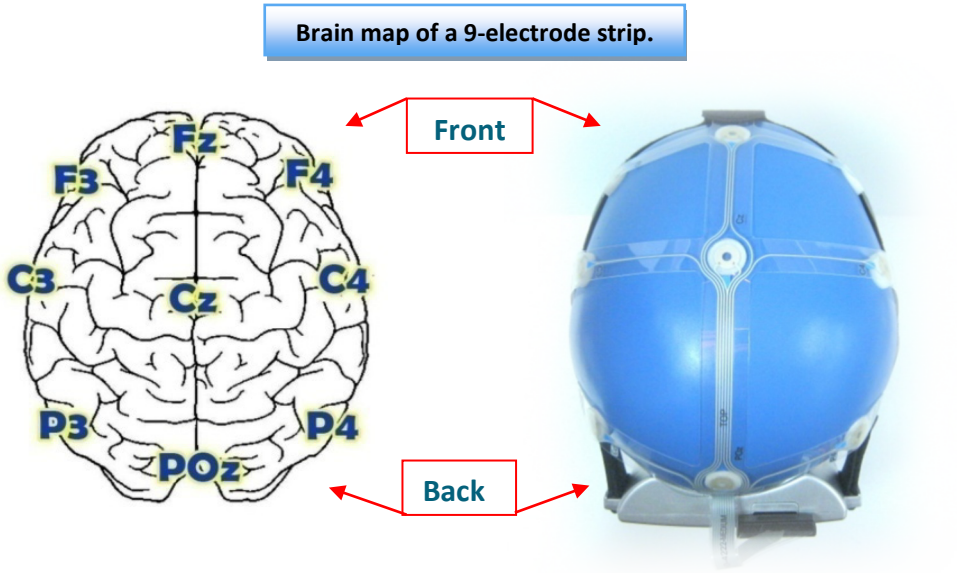
✓ Wall Charger, USB Cable & Charging Adapter

✓ Neoprene Strap

✓ Tape Measure

Chapter 2: Sensor Headset Use

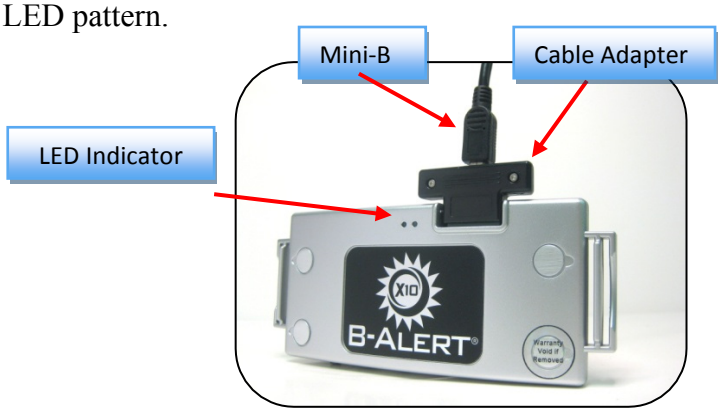
Note: This chapter presents a detailed, written process of a standard participant setup. For an additional demonstration, refer to the instructional videos provided with the included software.



A. Charging

The X10 Sensor Headset will arrive fully charged and ready for use. For ongoing usage, it is recommended that you charge the headset the night before using. Fully charged headsets should record for a minimum of 12hrs. It takes 2-3hrs to fully charge a headset. To recharge the Headset follow the steps below.

1. Verify the Headset is in the off position. Insert the X10 cable adapter into the sensor headset.
2. Plug the Mini-B connector into the X10 cable adapter and the USB-A connector into your computer's USB port.
3. Once power is recognized, the sensor headset will automatically begin charging, confirmed by a double blinking green LED pattern on the front of the headset.
4. Charging will automatically terminate once the batteries are fully charged, confirmed by a single blinking green LED pattern.



B. Preparation


Fuzzy side of neoprene


Triangle Strip Connector

1. Preparing Sensor Headset

a. Ensure that the fuzzy side of the Neoprene is facing out and the strip connector triangle is pointing up.

b. Using a clean Neoprene Strap, feed the Strap ends through each side of the Sensor Headset strap holders and fasten the Velcro. Do this equally to both sides, but leave loose for easy application to participant later.

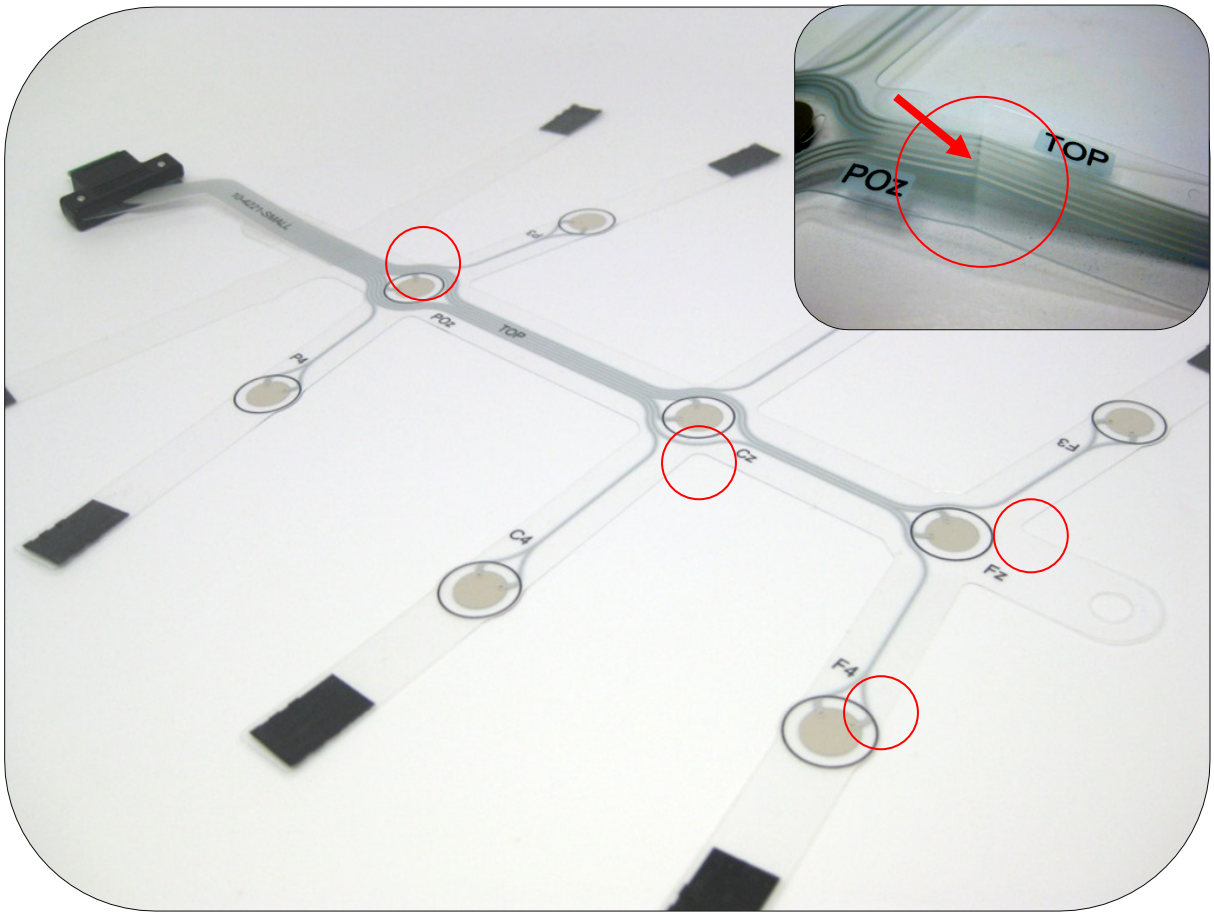
c. Verify that the Mastoid Leads are plugged into the system.

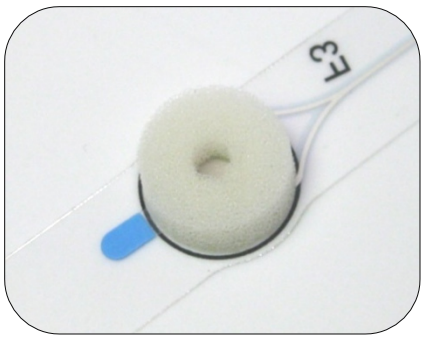
Mastoid Leads

2. Preparing the Strip

a. Inspect the Strip and verify there are no rips or hard creases on the Strip itself. Check the entire strip, paying special attention to spots (circled in **red**) prone to rips and creases.

CAUTION!
Use of damaged or broken Strips may result in inaccurate EEG recordings.



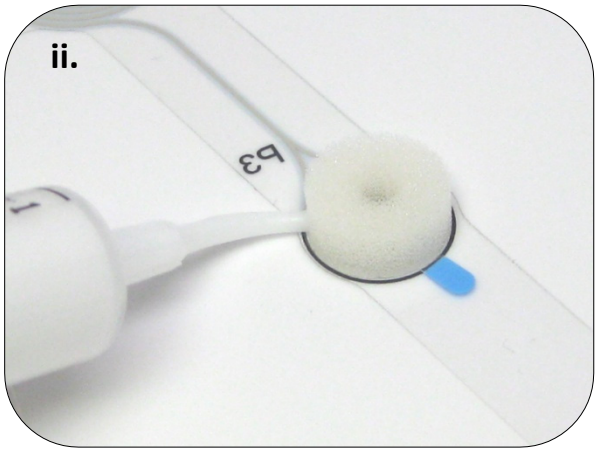


b. Attach the foam pieces to the sensor sites. Ensure the foam is centered within the black circle to maximize the contact surface between the sensor site and the foam.

c. Using the provided syringes with curved tip applied, fill each foam piece with synapse gel in one of two ways:

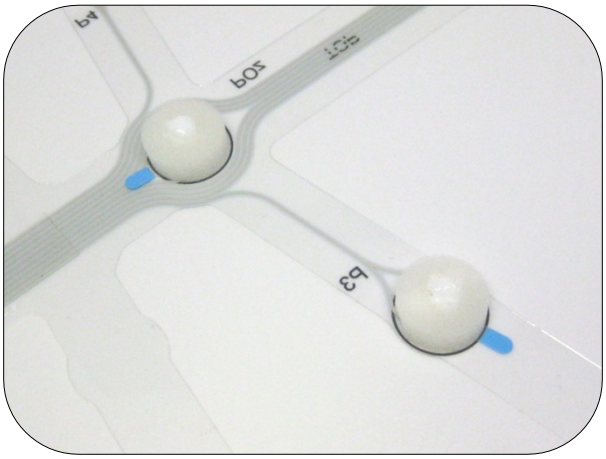
i. Place the syringe in the hole of the foam and dispense gel. You should see the gel begin filling the center of the foam.

ii. The gel can also be dispensed into the foam from the sides by pushing the tip into either side of the foam until it begins to fill the center.



d. Make sure to completely fill foam piece. Each sensor will hold 0.4-0.6 cc of synapse gel.

e. The foam should be saturated with gel and the center hole should be filled to the top.



CAUTION!

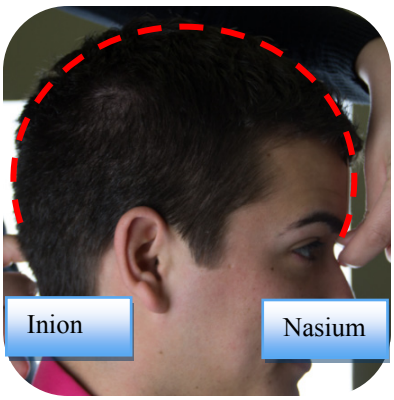
Synapse gel should be used with all sensors and electrodes to avoid signal quality problems.

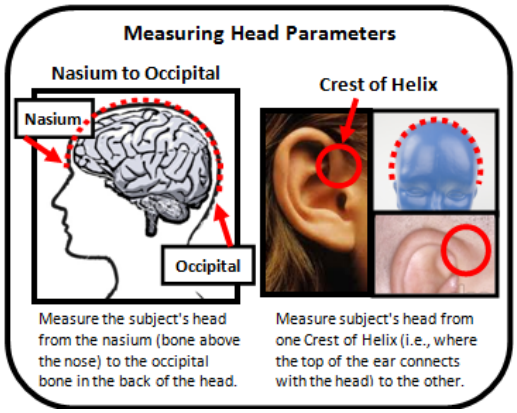
C. Application

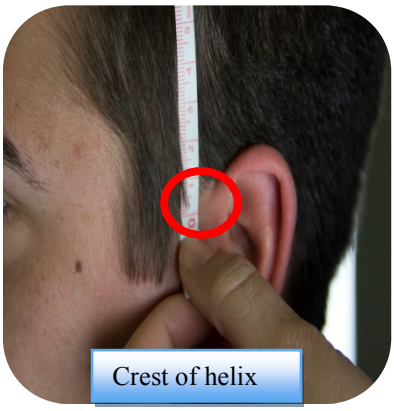
1. Sensor Headset and Neoprene Strap

*The nasium-inion (occipital bone) and crest of helix to crest of helix are the driving measurements for the X10 Standard strip. The circumference should be checked to determine size-down.

a. Measure the distance from the nasium (bone above the nose) to the inion (occipital bone in the back of the head), and the crest of helix (i.e., where the top of the ear connects with the head) to the other to determine the strip size according to sizing chart.





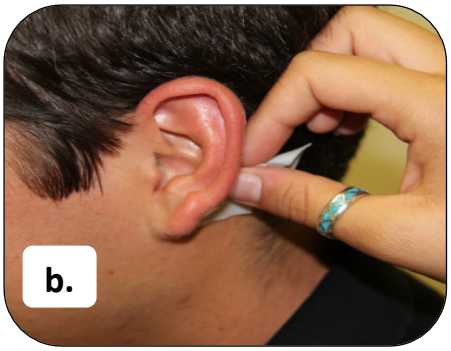


Strip Sizing Chart

Nasium to Occipital \ Crest of Helix to Crest of Helix	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

Where **XS** = extra small strip, **S** = small strip, **M** = medium strip, and - indicates head dimensions outside the suitable range for ABM strips.

b. Use an alcohol swab to wipe down areas where the sensors will be placed, ensuring broad and vigorous strokes across the scalp and temporal sites. Also wipe down the Mastoid and ECG locations with an alcohol swab.

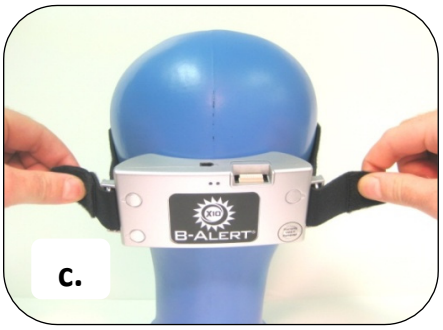


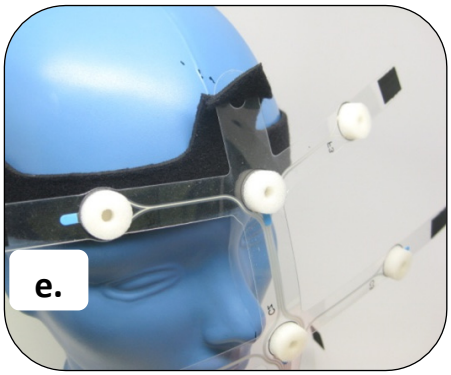
c. Place the Sensor Headset onto the participant's head and tighten the Neoprene Strap to provide a snug fit.

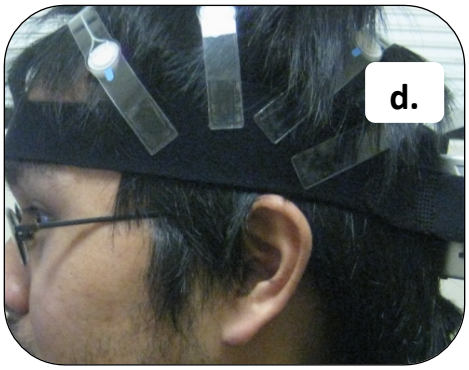
d. Verify that the Neoprene Strap is centered on the participant and that it is not resting on the ears.

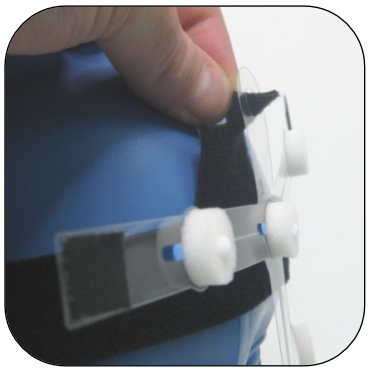
e. While holding the strip in front of the participant, with the foam pieces facing away from the face, attach the Strip to the front of the Neoprene Strap by feeding triangular tip through the hole adjacent to site Fz.

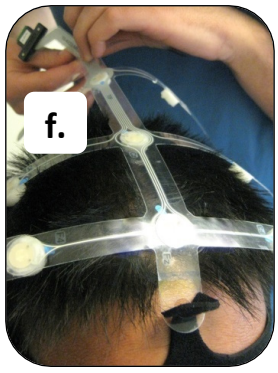
f. Carefully bring the Strip over the top of the participant's head from front to back, verifying that the Strip is centered. Pull the strip back so it is taut and snug against the scalp to prevent buckling/bunching of the strip.





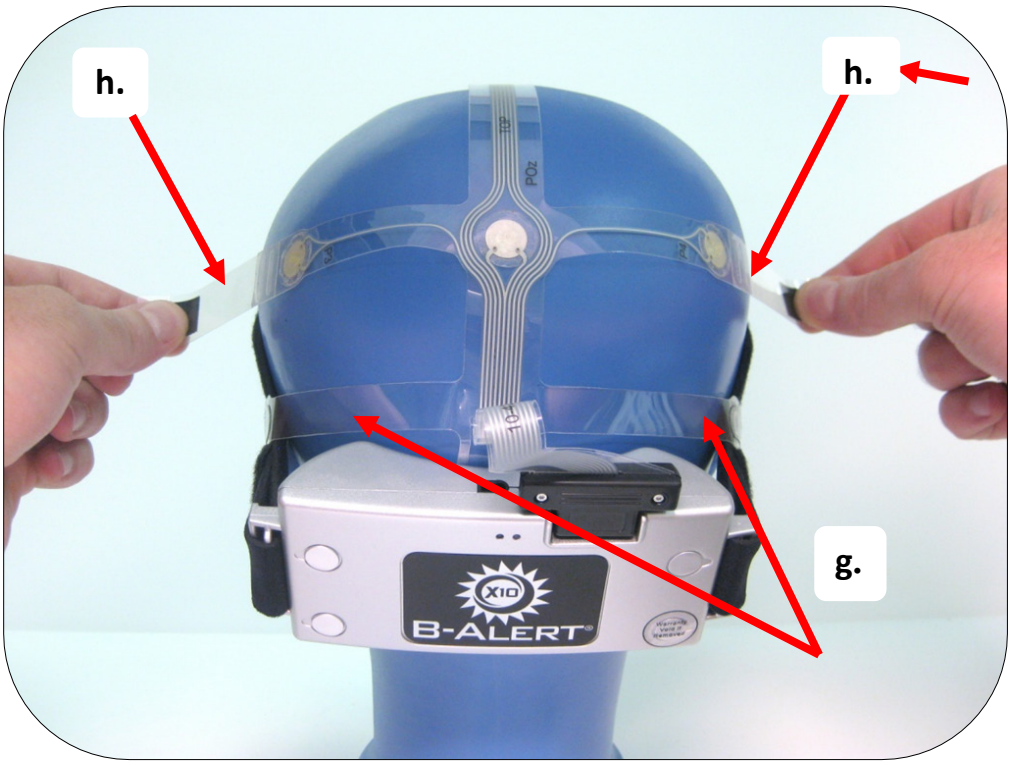






g. While holding the Strip in place over the inion, take the two Strip Arms closest to the inion and attach them to the Neoprene Strap.

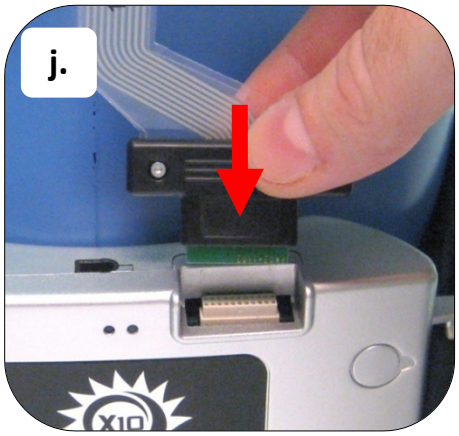
h. Tighten the remaining Strip Arms in pairs, from the back of the head to the front, so that the Strip sits flat against the participant's head, while maintaining the correct alignment on the scalp.



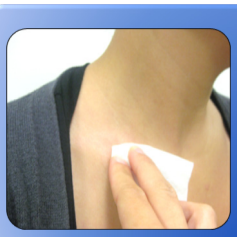
i. Verify that all sensor sites are contacting the head and adjust straps if necessary.

j. Gently plug connector on the back of the Strip into the Sensor Headset. The connection between headset and strip is snug; be gentle when plugging/unplugging.

k. If the participant complains about discomfort from any electrode, loosen individual Strip Arms.



2. Mastoids and ECG Leads



ECG LEADS

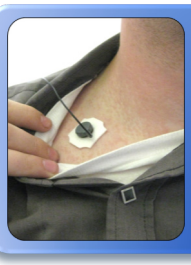
Be sure the right collar bone and left lower rib area have been wiped with an alcohol swab.

The ECG Leads are color coordinated to distinguish between the left and right leads. The gRey is the **R**ight side lead and the bLue is the **L**eft side lead.

Obtain two disposable adhesive EEG Sensors, one for each ECG lead.

Snap EEG Sensors onto ECG Leads.

Apply a small amount of synapse gel to the center of each EEG Sensor. Peel off paper.

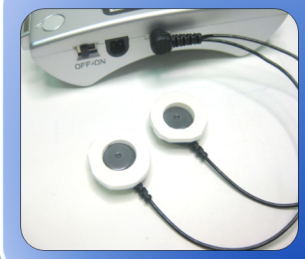


Position the gRey ECG Lead on the participant's **R**ight collar bone and the bLue ECG Lead on the **L**eft lower rib bone.

Insert the ECG Lead plug into the 2-pin receptacle on the top of the Headset.

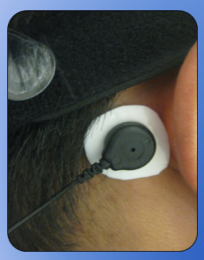
MASTOID LEADS

Be sure that the mastoid bones have been wiped with an alcohol swab.

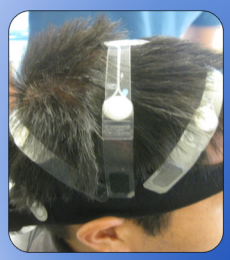


Verify the Mastoid Lead plug is plugged into the 3-pin receptacle on the bottom of the Sensor Headset. Cut two disposable EEG Sensors into circles and snap onto Mastoid Leads.

Apply a small amount of synapse gel to the center of each EEG Sensor. Peel off paper to expose adhesive and apply the Sensors to the participant one at a time.



Position the Mastoid Lead directly on the mastoid bone. It is imperative to avoid applying the Mastoid Lead over any hair or on muscles. Data can be compromised if not properly placed on mastoid bone.



Before proceeding, ensure that hair is not pulling on the leads, all leads are correctly positioned, and the participant is comfortable.

D. Additional ECG Placements

The ECG signal is robust and the sensor placement is somewhat flexible. ABM's recommended placement is to have the Left (**bLue**) ECG Lead on the lower most rib and the Right (**gRey**) lead on the right collarbone. Alternative ECG placements however can be used if the recommended configuration is not ideal for a given application. For alternative ECG placement, the appropriate leads must be placed across the heart (**bLue** lead ALWAYS on the Left side of participant and **gRey** lead always on the right side). The adhesive electrodes should be placed on boney parts of the participant, where there is little potential for movement (from breathing or muscles) which can compromise signal integrity. Contact ABM for additional information on alternative ECG placement.

E. Ready to Collect

1. Plug in X-Series BT Receiving Unit (i.e. ESU-MC or B-Alert Dongle) to an available USB port on the computer running the ABM Acquisition Software.

2. Verify the Sensor Headset is synced to the BT Receiving Unit by switching on the Sensor Headset and viewing the indicator lights on the front of the Sensor Headset. The Sensor Headset has established connection when the green indicator light turns solid after 5-seconds. If the amber indicator light stays on while the green indicator light is blinking, the headset is not properly connecting and the headset must be re-synced to the BT Receiving Unit.

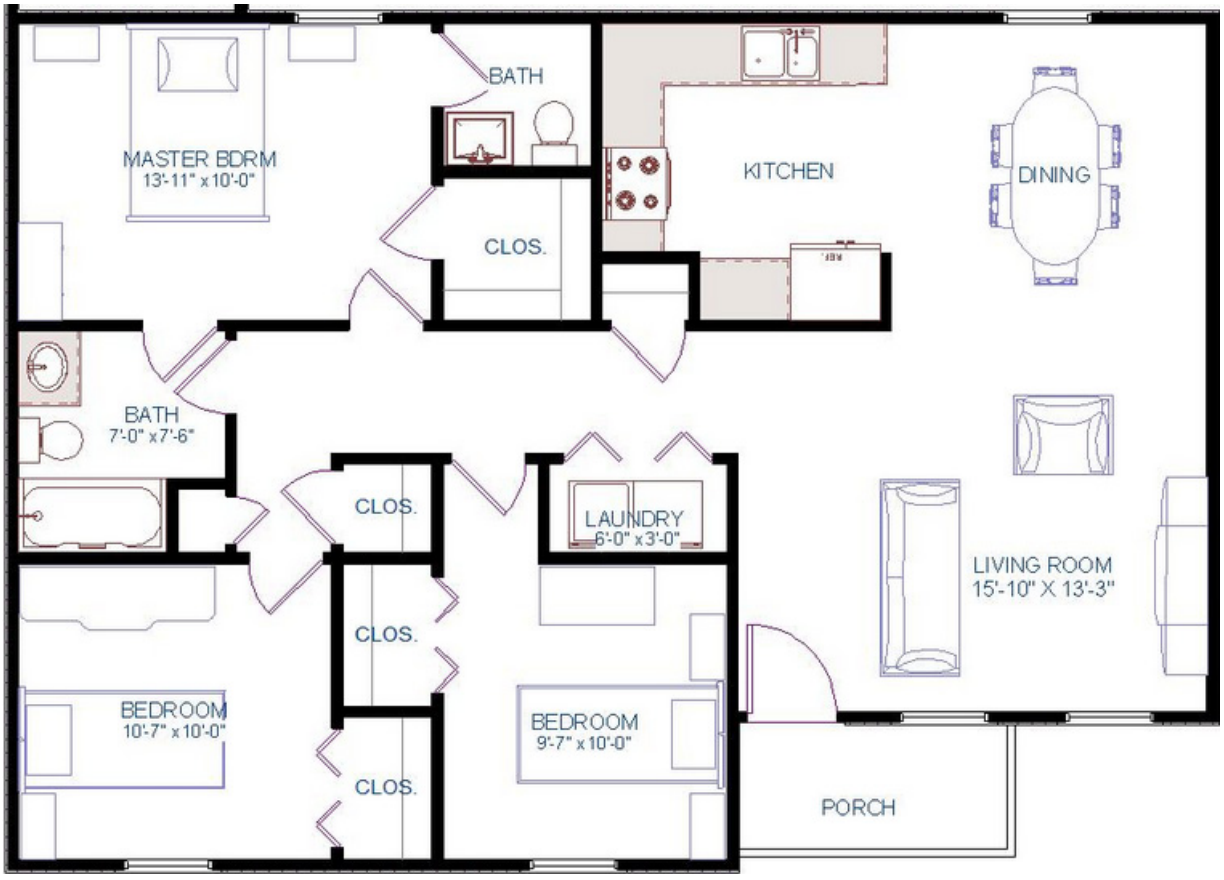
F. Maintaining BT Signal Quality:

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

2. Guidance for Technicians

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

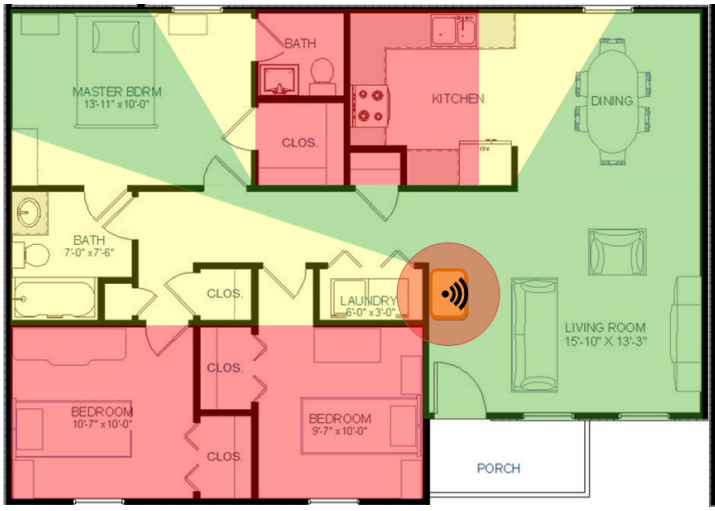
See sample guidance for mobile placement in a 3 Bedroom Home.



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.

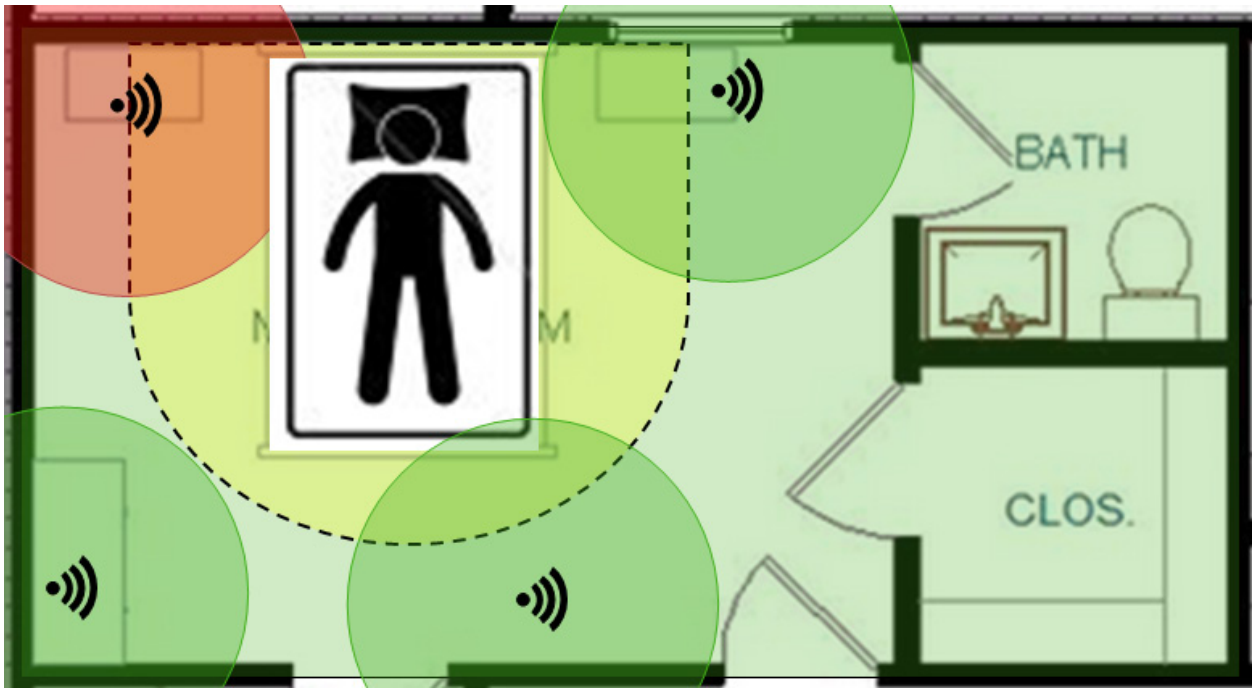
Option 1



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.

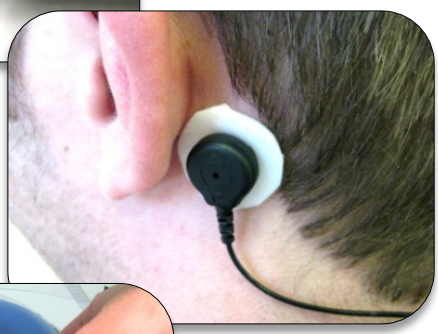


G. Post-session Clean-up

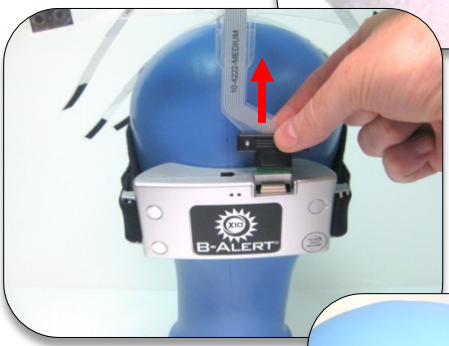
1. Removal of Sensor Headset and Electrodes

After testing is complete, turn off the sensor headset by sliding the switch to the off position.

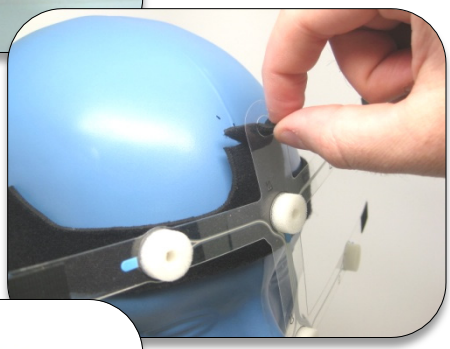
Carefully remove the EKG and mastoid leads from the Participant.



Gently unplug the strip from the headset and detach all strip arms from the Neoprene Strap.

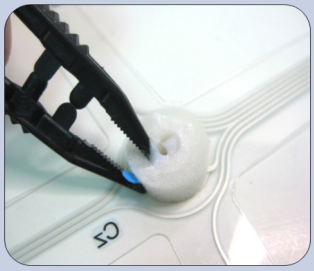


Lift strip away from participant and detach the front of the strip from the Neoprene Strap.

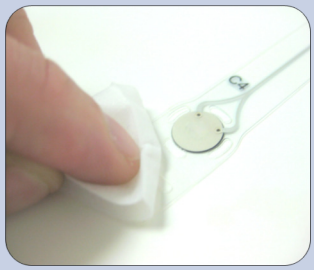


Remove the headset and strap by lifting up, off the head.

2. Cleaning the Sensor Strip and Neoprene Strap



1. 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.



2. Remove any remaining gel with a tissue. Wipe down the entire strip with an alcohol swab, ensuring that all gel is removed from sensor sites.

3. Hand-wash the neoprene strap with hot water and antibacterial soap. Thoroughly rinse strap and allow to air dry.

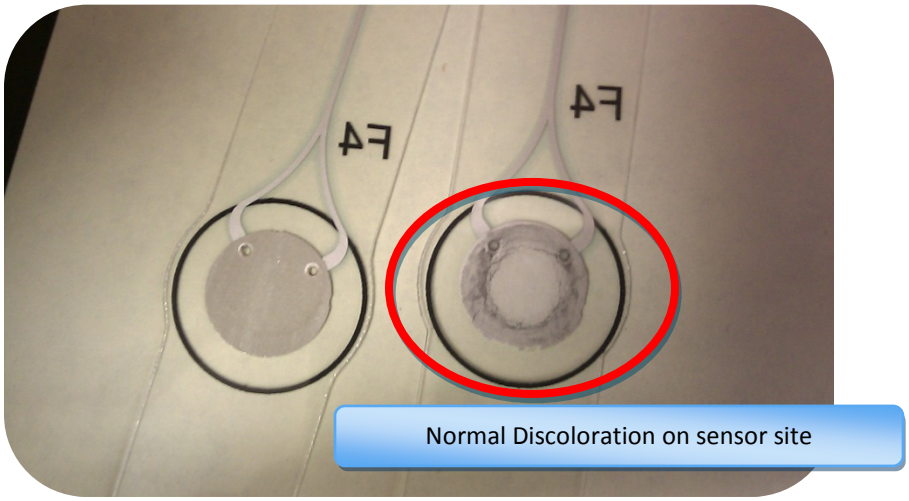
4. After the neoprene strap is dry, wipe down with an alcohol wipe prior to next use.

CLEANING CAUTIONS:

*********Strips are recommended for 25 uses**********

- **Clean the strip immediately after use to minimize deterioration.**
- Do not reuse foam sensors.
- Do not aggressively scrub the Sensor pads when cleaning.
- If Sensor pad is removed from strip discontinue use of strip.
- When removing the sensor strip from the headset, DO NOT pull or jerk the connector.

1. Strip Discoloration



It is normal for the electrode sites to have some minor discoloration. **ABM recommends replacing the strip after 25 uses**. The strip life can be extended if cared for carefully as well as taking note of the cleaning cautions above. Leaving the wet foam sensors (post application) and adhesive rings on the strip for extended time will cause the sensor pads on the strip to deteriorate more quickly.

Chapter 3: Acquisition Troubleshooting

A. Common Headset and Sensor Issues

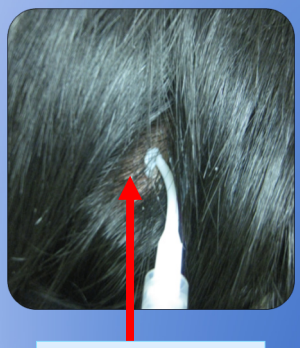
The following topics describe critical troubleshooting methods to undertake when encountering problems during the setup session of a participant.

Excessive EMG

Hands should be away from Face!

- **Is participant 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 participant 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 participant is not resting their head on their hand.
  - Adjust the temperature of the room, especially if the participant is drowsy.

High Sensor Impedances



Part thick hair and add cream.

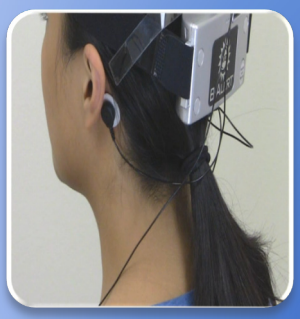
Try the steps below, in order:

- Ensure the sensors are seated evenly and properly on the strip.
- Check sesnors to confirm they are secured to the participant's scalp-- re-seure velcro strip arms to Neoprene strap if necessary.
- Remove strip arms individually and part hair underneath the sensor using the tip of the syringe--exposing the scalp. Dispense additional synapse gel to the site. Re-secure strip arms to neoprene strap when finished.
- If the Ref channel's impedance is high, remove the mastoid sensors, reclean the mastoid area and reapply the sensors.
- Refer to Training Video 5: Starting Data Collection for additional tips.

Sensor Placement and Comfort

- **Alignment hole does not mach up with the inion?** Pull the strap anterior so the strap sits closer to the eye brows.
- **Participant 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.
- Remove the strip from head **BEFORE** removing the Neoprene strap to east clean up and minimize mess for participant

Troubleshooting for subjects with long hair



- Participants with long hair can let their hair down before cleaning the head and applying the strap.
- Have the participant keep their bangs or hair off the forehead when applying the strap.
- Do not part the hair along the midline as this will make applying the system more difficult.
- The participant may put their hair in a low ponytail after checking to see if the headset is secured.

- **Long hair may require more attention to parting and application of gel when troubleshooting high impedances.**
- Make sure the sensors are seated properly on the head.
- Lift the strip arms individually and part the hair underneath the sensor.
- Add an appropriate amount of conductive gel to each site that has high impedance.
- Reattach the strip arms back onto the strip making sure the sensors are not sitting at an angle and are making contact with the scalp.

Chapter 4: Specifications

A. X10

<table>
<tr><th colspan="2">System Specifications of the X10 – subject to change</th></tr>
<tr><td>Model</td><td>Nine channels of EEG. One optional dual-lead for ECG/EEG/EOG/EMG with no impedance test.
Sensor Site montage for nine EEG Channels.</td></tr>
<tr><td>Working Modes</td><td>
<table>
<tr><td>Mode</td><td>Consumption</td></tr>
<tr><td>Monitoring mode</td><td>Transmits via Bluetooth</td></tr>
<tr><td>Hibernation</td><td>Device turned off</td></tr>
</table>
</td></tr>
<tr><td>Signals acquired</td><td>
<table>
<tr><td>Signal</td><td>Number of channels</td><td>Dynamic range</td><td>Samples per sec</td><td>Interfaced to PCB/electronics</td></tr>
<tr><td>EEG</td><td>9</td><td>± 1000 µV</td><td>256</td><td>PET strip</td></tr>
<tr><td rowspan="3">Optional channel</td><td>ECG</td><td>± 1000 µV</td><td rowspan="3">256</td><td rowspan="3">Dual lead cable</td></tr>
<tr><td>EOG</td><td>± 1000 µV</td></tr>
<tr><td>EEG/EMG</td><td>± 1000 µV</td></tr>
<tr><td>Actigraphy</td><td>3</td><td>-180 – 180°</td><td>10</td><td>PCB mounted</td></tr>
</table>
</td></tr>
<tr><td>Signal Processing</td><td>
<table>
<tr><td>Signal</td><td>Resolution for full dynamic range</td><td>Processing/Filtering</td></tr>
<tr><td>EEG</td><td>16 bit</td><td>0.1 Hz High Pass, hardware
100 Hz Low Pass, hardware</td></tr>
<tr><td>Actigraphy</td><td>12 bit</td><td>Down sampled from 100:10 Hz</td></tr>
</table>
</td></tr>
<tr><td>Typical Signal Accuracy and Resolution</td><td>
<table>
<tr><td>Signal</td><td colspan="2">Accuracy (typical)</td></tr>
<tr><td>EEG</td><td colspan="2">+/- 3.7 µV peak-to-peak, resolution 0.03 µV</td></tr>
<tr><td rowspan="3">Optional Channel</td><td>ECG</td><td>+/- 4.0 µV peak-to-peak, resolution 0.06 µV</td></tr>
<tr><td>EOG</td><td>+/- 4.0 µV peak-to-peak, resolution 0.06 µV</td></tr>
<tr><td>EEG/EMG</td><td>+/- 4.0 µV peak-to-peak, resolution 0.03 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>Impedance monitored on EEG channels only, when initiated by host computer</td></tr>
<tr><td>EEG Input Impedance</td><td>100GOhm</td></tr>
<tr><td>EEG Common Mode Rejection</td><td>110dB Common Mode Rejection Ratio (typically)</td></tr>
<tr><th colspan="2">Battery</th></tr>
<tr><td>Battery Charging</td><td>Via JED Connector and USB cable connected to
• USB port, 5V/0.5 A, or
• USB wall charger Model FY-0501000, Input 110/220V, Output 5V/0.5A up to 5V/1.0A</td></tr>
<tr><td>Power Supply</td><td>One 600mAh 3.7V Lithium Ion Battery</td></tr>
<tr><td>Typical Operating Time</td><td>14 - 15 hours following charging for the first four days.</td></tr>
<tr><td>Operating Time</td><td>Recording Days after Charge Hours of Use (range)
• 0-4 Days 14.0 to 15.0 hours
• 5-10 Days 10.5 to 14.0 hours</td></tr>
<tr><td>Typical Power Consumption</td><td>~ 40 mA @ 3.7 V</td></tr>
<tr><th colspan="2">User Interface</th></tr>
<tr><td>User Control</td><td>ON/OFF switch</td></tr>
<tr><td>Visual feedback</td><td>Green, Amber</td></tr>
<tr><td>Dimensions</td><td>5.0” long x 2.25” wide x 1.0” deep</td></tr>
</table>

Weight	3.9 ounces 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 70% isopropyl alcohol
Wireless Specification	
Wireless Module	Bluetooth v2.1+EDR compliant to IEEE 820.15.1
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 20 meters line of sight
	Recommended 10 meters to minimize data loss due to blue tooth transmission
	Maximum 7 in-band Bluetooth transmitters in vicinity using Bluetooth spectrum management
Data Throughput	Typical 34Kbit/sec, maximum 100 Kbit/sec
Latency	Depends on PC Bluetooth, up to 200ms from data sample acquisition until received by PC.
Data Integrity	Bluetooth protocol ensures data integrity by retransmitting corrupted data packets, X4 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 Headset and BT Receiving Unit.
Software Performance	
Compatibility for client workstation	Personal computer with Pentium 4, 2GB RAM or higher processor (or equivalent) with Windows 7 Operating System
Estimated File Size	1 MB/min
File Size per 8 hr of recording	480 Mb

B. Environmental Conditions

Environmental Conditions	Operation	Transportation	Storage
Temperature	5°C to 40°C 41°F to 104°F	-20°C to 70°C -4°F to 140°F	-20°C to 70°C -4°F to 140°F
Altitude	-390m to 3,012 m -1,254 ft. to 9,882 ft.	-390m to 3,012 m -1,254 ft. to 9,882 ft.	-390m 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 14.7 in. Hg to 31.3 in. Hg	70 kPa to 106 kPa 14.7 in. Hg to 31.3 in. Hg
Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5	15% to 95% non-condensing	15% to 95% non-condensing

Note: Specifications, subject to change.

Chapter 5: Compliance

A. FCC/IC

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 26lase 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 201

Guidance and manufacturer's declaration – electromagnetic emissions		
The X10 is intended for use in the electromagnetic environment specified below. The customer or the user of the X10 should assure that they are used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions **CISPR 11**	Group 1	The X10 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 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**	N/A	
Voltage fluctuations/ flicker emissions **IEC 61000-3-3**	N/A	

Table 204

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The X10 is intended for use in the electromagnetic environment specified below. The customer or the user of the X10 should assure that they are used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiated RF IEC 61000-4-3</td><td>3 Vrms 150 kHz to 80 MHz

3 V/m 80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>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

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[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 is used exceeds the applicable RF compliance level above, the X10 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.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the Model X Devices			
The X10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X10; recommended distances are below, according to the max 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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.**			

B. General Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1, CSA 601.1, EN865, EN/IEC 60601-1-2 2nd edition
Type of protection	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-class 44.6 IPXO
Degree of Safety in presence of flammable mixtures	IEC 60601-1, sub-clause 5.5, Not suitable
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
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(b)
Case mechanically strong	IEC 60601-1
Transmitting Power below SAR testing requirements*	4474981 D01 Mobile Portable RF Exposure v04 – Device power output below U.S. limit of 24.979mW and EU limit of 20mW

* Transmitting power of our BT module (worst case) – 5.85 dBm = 10^[(5.85-30)/10]*1000 mW = 3.8459mW

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

1. **Parties.** This Warranty Agreement is between Advanced Brain Monitoring, Inc. (ABM) and purchaser (the "Customer," "You," or "Your") for the X10 B-Alert System covered by this Agreement ("Product").

2. **Product Coverage.** ABM warranties its Products to be free from defects in workmanship and to 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 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 due to misuse, abuse, use outside of the specifications, or improper installation or maintenance. Non-normal Product failures explicitly excluded from warranty coverage include:
        i. Detachment of the connector(s) inside the enclosure – damage typically occurs when the cable connector is improperly forced into place;
        ii. 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;
        iii. Items attached to the enclosure (i.e., strips, straps and sensors).
    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 Coverage:** ABM will provide up to ten (10) hours of telephone technical support to assist with technical problems not covered by the Technical Manual or Training Video(s) as well as software upgrades free-of-charge for a period of 12-months after the date of shipment.

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

5. **Return of Product.** To return a Product to ABM under a warranty claim, 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 contact 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.

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

7. **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. The foregoing remedies shall be Purchaser's sole and exclusive remedies under this warranty.

8. **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 Agreement, You agree to pay ABM its usual and customary fees for such work.

9. **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 LICENSE, PRODUCTS ARE PROVIDED "AS IS" WITHOUT WARRANTY. ABM DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, THAT ARE NOT EXPRESSLY PROVIDED IN THIS WARRANTY INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

10. **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 AGREEMENT) AND REGARDLESS OF THE FORM OF ACTION OR LEGAL THEORY SHALL BE THE AMOUNT YOU ACTUALLY PAID FOR THE SOFTWARE 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.

11. **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 AGREEMENT.

12. **DISPUTE RESOLUTION**. Any dispute, controversy, or claim against ABM or its parent or affiliate companies arising out of or relating to this Agreement, 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 Agreement may be brought by either party more than one (1) year after the cause of action arose.

13. **ENTIRE AGREEMENT**. This 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.

D. Authorized European Representative

European Representative
MPS Medical Product Service GmbH
Borngasse 20

E. Trademark Acknowledgements

B-Alert is a registered trademark; B-Alert Sensor Headset is a trademark of Advanced Brain Monitoring, Inc., Carlsbad, CA. Synapse® is a registered trademark of Med-Tek/Synapse®, Arcadia, CA. All other products or brand names are trademarks or registered trademarks of their respective companies.