B-ALERT X24

Hardware Manual

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Chapter 1.   Regulatory and Safety Information

1.   Indications for Use

The B-Alert System is not intended for the diagnosis or treatment of patients. It is 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.

2.   System Description

The X24 provides an integrated approach for wireless acquisition and recording of electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals. 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 X24 acquires twenty channels of monopolar EEG recordings with a linked mastoid reference and optional channel for ECG, EOG, or EMG. The 1-10th channels, as well as the 21st channel, are differential channels. The 22nd-24th channels are referential channels. The system consists of: X24 Headset with a Bluetooth (BT) Receiver for bi-directional transmission of digitized physiological signals, and a Sensor Strip with EEG sensors sites in the standard 10-20 format + POz (Fz, Cz, Pz, F3, F4, C3, C4, P3, P4, O1, O2, T5, T3, F7, Fp1, Fp2, F8, T4, and T6).

The Headset collects signals from the sensors placed on the subject 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. The Receiver provides bi-directional transmission of digitized physiological signals. Acquisition utilizes the bi-directional capabilities of the system to initiate scalp-electrode impedance monitoring and monitors the battery capacity in the Headset. The Receiver is used as the base unit affixed to the PC workstation.

⚠ **CAUTION! Read this manual carefully before using the X24**

3.   Meaning of symbols

Refer to instruction manual/booklet	Caution, consult accompanying documents	Dispose properly	Keep Dry	Non-ionizing electromagnetic radiation	Temperature limitation	Humidity limitation
Atmospheric pressure limitation	IP22 Limit objects, water ingress	Charge between uses	GITEKI (MIC) Mark	European conformity	UK Conformity	Do not re-use
REF Catalogue/Model Number	SN Serial number	Manufactured by				

4.   Safety

The X24 is designed to be applied and operated by a trained technician. **Read the warnings and cautions throughout this manual carefully, they are important for the effective and safe 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.

⚠ CONTRAINDICATIONS:

- Do not use device as a substitute for clinical electrocardiography.
- Device is NOT intended to be used:
  - as a cardiac monitor
  - for life supporting equipment which requires alarms
- Do not use the device:
  - with high frequency (HF) surgical equipment
  - in proximity to a Magnetic Resonance Imaging system

⚠ WARNING:

- Do not wear the device while it is connected to an AC Power Supply.
- To avoid applying current to a subject with a pacemaker, use 2-pin cable only when set to ECG mode.
- Device is not defibrillator proof. EEG leads, Strips, and sensor interfaces are not protected against the effects of defibrillation. Damage to the device is possible if worn during defibrillation.
- Explosion Hazards:
  - The Headset includes an internal battery and allows for an optional external battery. Do not use the Headset in any way that could cause an explosion (e.g., near open flame or high heat device).
  - The Headset internal rechargeable battery should only be replaced by an authorized distributor or the manufacturer.
  - Local ordinances must be followed for disposal of all electronic equipment.
  - Do not use the device in the presence of flammable anesthetics or gases.
- Electrical Shock Hazard:
  - Avoid touching the ExG (EEG/EOG/ECG/EMG) sensors/leads when the USB cable is connected to the X24 Headset and an AC powered source (i.e., PC workstation, USB hub, or USB wall charger).
  - Only use a medical 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 device must comply with IEC 60601-1, or be placed outside the subject environment (more than 3 meters or 10 feet).

⚠️ CAUTIONS – General

- This device has been tested and found to comply with the limits for medical devices to the IEC 60601 standards. These safety standards are designed to provide reasonable protection against harmful interference in a typical medical installation.

- This device has been tested and found to comply with the limits for commercial devices to the applicable CE/UK directives. These safety standards are designed to provide reasonable protection against harmful interference in a typical facility.

- The operating temperature of the device may increase:

  - when connected to a computer.

  - when data is being transferred from the Headset memory to the host computer.

  - when the internal battery is being charged.

- Device may not charge properly if in direct sunlight or if room temerature is above 30°C (86°F). Charging will automatically terminate when an unsafe operating temperature is detected.

- If device is stored or transported at temperatures < 5°C or > 40°C, the device must be kept in a room with an ambient temperature of 20°C for 6 hours, or until the device is within safe operating temperatures (5°C to 40°C), prior to use.

- Limitations of Use:

  - Sensors are intended for single use only.

  - Universal (Single-Use) Strips:

    - The Universal strip, Headstrap, and Doorstrap are intended for single use only.

    - Clean/disinfect the strip adapter enclosure according to recommended guidelines.

  - Reusable Strips:

    - The reusable strip and Headstrap should be replaced after 25 uses, or earlier if an inspection shows damage.

    - Clean/disinfect the strip, Headstrap, and Doorstrap after each use according to the recommended guidelines.

  - Inspect and clean/disinfect the headset and cables after each use according to recommended guidelines.

  - The device is not waterproof. Do not spray, pour, or spill any liquid on the device, its connectors, switches, or openings as such application of liquids may cause permanent damage and will void the Warranty.

  - 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.

- Do not use caustic or abrasive cleaning agents, or any cleaning agents other than those listed in the cleaning section below, on the device as such use of cleaning agents may cause permanent damage and will void the Warranty.

- Advanced Brain Monitoring's Warranty does not cover damage caused to the device for replacement of replaceable components (i.e., battery, flash card) by unauthorized entities.

⚠️ CAUTIONS – Subject Use

- Do not use the device if it appears to be damaged in any way, or if the LED does not properly illuminate during startup.

- Discontinue use of the device in case of any significant pain.

- Possible allergic reaction or skin irritation from device components (e.g., silicone and adhesive sensors, and neoprene/Velcro strap) may occur. Wearing the device may result in a mark on the subject's forehead that usually disappears in a few hours; on extremely rare occasions the mark may remain for 2-5 days.

⚠️ CAUTIONS – Limitations Affecting Use

- The device is not recommended for use by subjects with the following conditions:
    o Sensitivity of skin or scalp and/or open wounds on the forehead or scalp.
    o Allergic reactions to extended exposure to synthetic fabrics (e.g., polyester, rayon).

  Use of the device by subjects with any of these conditions may result in poor signal quality.

- Device use under any of the following conditions may result in poor signal quality.
    o Headstrap not adjusted properly (i.e., too loose or too tight).
    o Application sites (i.e., head, forehead, mastoid sites, collar bones) not prepared according to instructions (e.g., makeup, lotion, or hair under the sensor).
    o Not using conductive cream provided by ABM.

⚠️ CAUTIONS – Batteries

- For optimal performance, use a fully recharged battery.

- Only use approved Lithium Polymer rechargeable battery replacements.

- The device internal rechargeable battery should only be replaced by an authorized distributor and/or the manufacturer.

- When charging is completed, remove the device from the power supply to extend the life of the battery.

⚠️ CAUTIONS – Disposal

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

5.   Minimum PC System Requirements

- Personal computer (PC) with minimum Pentium™ 2.4 GHz processor
- Minimum of 4 GB of installed RAM memory
- Windows 10 or 11 operating system
- .NET framework version 3.5 installed (will be installed through B-Alert Live installation routine)
- VGA or higher resolution video adapter (for video feed)

- Two available USB ports (three for validation)
- Monitor size between 15" and 21" required for Baseline acquisition.

Chapter 2.   Getting Started

1.   B-Alert System Components

A.   B-Alert System and Optional Accessories

Components	LE System	Classic System	Component Image
B-Alert X24 Device			
X24 Headset (Headset)	✓	--	
	--	✓	
Enclosure Door with Transparent Loop (Enclosure Door)	✓	✓	
Small Neoprene Strap (Doorstrap)	✓	✓	
Micro B-to-USB Charging Cable (Charging Cable)	✓	✓	

Components	LE System	Classic System	Component Image
USB Charger	✔	✔	
Bluetooth Dongle (Dongle)	✔	--	
	--	✔	
Tape Measure	✔	✔	
3-pin Cable (EEG)	--	✔	

Components	LE System	Classic System	Component Image
3-pin Cable (EEG)	✓	--	
2-pin Cable (EEG/ECG/EMG)	✓	✓	
ESU Kit (optional)			
Multi-channel External Synching Unit (ESU)	N/A	✓	
Micro B-to-USB Charging cable	N/A	✓	
Serial cable	N/A	✓	

Components	LE System	Classic System	Component Image
Universal (Single-Use) Sensor Strip Kits			
10-20 Universal Strip* Kit • 10-20 Universal Strip (Strip) • Large Neoprene Strap (Headstrap) • Small Neoprene Strap (Doorstrap) *Medium, Small, and X-Small sizes*	✔	✔	
Single Use Strip Sensor Kit • Synapse <u>or</u> EEG Connect Conductive Cream (Cream) • Syringe <u>or</u> curved tip attachment • 4 AgCl Sensors (Adhesive Electrodes)	✔	✔	Synapse EEG Connect
Universal Strip Adapter Kit	✔	✔	
Reusable Sensor Strip Kits			
10-20 Reusable Strip* Kit (Strip) Large Neoprene Strap (Headstrap) *Medium, Small, and X-Small sizes*	N/A	✔	

Components	LE System	Classic System	Component Image
Disposable Kit: • Foam Sensors (Donuts) • Conductive Cream • Syringe with curved tip • Tweezer • AgCl Sensors (Adhesive Electrodes)	N/A	✓	

B.   Required Items not Included with the B-Alert System

- Scissors

- 70% Isopropyl Alcohol wipes (large, sturdy alcohol wipes provide the best results)

2.   Configuration Options

The B-Alert system consists of 1) Headset, 2) Bluetooth (BT) Receiver, 3) EEG Sensor Strip, and 4) acquisition software. Options for configuration of the system are as follows:

Headset Type	X24 LE	X24 Classic
BT Receiver Type Supported	LE Dongle	Dongle or ESU
Sensor Strip Type Supported	10-20, 10-20 Reduced	10-20, 10-20 Reduced
Internal Battery – expected hours of continuous use on a single charge	12	8

The term "X24" or "Headset" is used when the X24 LE Headset (X24 LE) and X24 Classic Headset (X24 Classic) operate in the same fashion; when they differ, the specific Headset type will be identified.

The term "Receiver" is used when the LE Dongle, Dongle, and ESU operate in the same fashion; when they differ, the specific Receiver type will be identified.

The supported Sensor Strip types include the following:

Strip Montages	Sensor Sites/Channels	Reference	Optional Channels	Universal (Single-Use) Strip	Reusable Strip
10-20	Fz, Cz, Pz, F3, F4, C3, C4, P3, P4, O1, O2, T5, T3, F7, Fp1, Fp2, F8, T4, T6, POz	Linked Mastoids	2-pin ECG	✓	✓
10-20 Reduced	Fz, Cz, F3, F4, C3, C4, P3, P4, POz	Linked Mastoids	2-pin ECG	✓	✓

The B-Alert System supports acquisition through the B-Alert Live software. Refer to the B-Alert Live Software User Manual for more information.

Chapter 3.   Headset/Receiver

1.   Headset Components

1	On/Off Switch	4	Micro-B to USB Charging Input	7	Speaker
2	LED Indicator	5	2-Pin EEG/EOG/ECG/EMG Input	8	Sliding Locks
3	3-Pin EEG Input	6	Door with Plastic Loop	9	Adapter Input
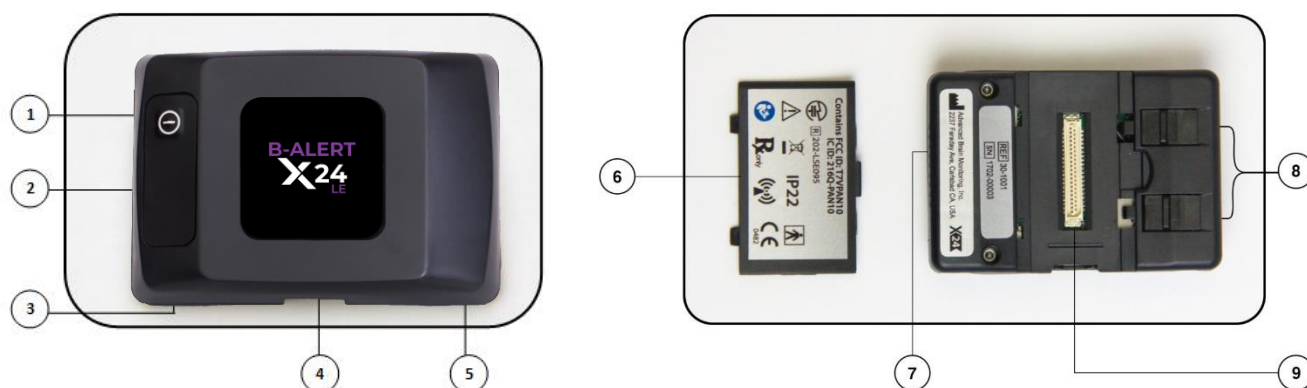
2.   Device Feedback

The Headset uses green and amber LED light indicators and may use sound to indicate operational status. These indicators do not indicate hazardous situations or alert conditions and should not be taken as alarm indicators.

Headset Mode	Green LED	Amber LED	Audio Message	LE	Classic
Powered on	Blinking 3x/sec	Off	"Device has been powered on"	✔	✔
Headset searching for Receiver/ Connection Lost	On	On	N/A	✔	✔
Headset connected to Receiver	On	Off	"Wireless communication established"	--	✔
			N/A	✔	--
Start of Acquisition	On	Off	"Acquisition started"	--	✔
	Dimmed	Off	N/A	✔	--
Acquiring data with good BT connection	On	Off	N/A	✔	✔
Low battery on startup	Off	Blinking 1x/sec	"The battery is too low to continue without recharging"	✔	✔
Connected to USB power supply	Blinking 2x/sec	Off	"Caution, the device is charging"	✔	✔
Charging completed	Blinking 1x/ every 2sec	Off	"Charging complete"	✔	✔
Turning off	Off	Off	"Device has been powered off"	✔	✔

The Receivers use LED light indicators for common operational events.

BT Receiver Event	LE Dongle	Classic Dongle	Classic ESU
Not connected to Headset	Blue blinking	Green & Amber on	Blue blinking
Connected to Headset	Blue on	Green on	Blue on
Hardware Error	--	Amber on	Blue / Green fast blinking

3.   Charging

Fully charge the Headset battery before first use. For ongoing use, charge the night before using. ***Do not attempt to charge during EEG acquisition.*** The following methods can be used to charge the device:

1. (Recommended method). Connect the Headset to an AC power outlet using the Micro B-to-USB Charging cable and provided USB Charger.

2. Connect the Headset to a PC using the Micro B-to-USB Charging cable. ***Do not charge via your PC if you use Anti-Virus/Anti-Malware that is invasive to USB devices.***

Refer to Device Feedback (Section 2) for operational status indicators.

4.   Syncing to Bluetooth Receiver

The Headset and Receiver are paired prior to shipping. Plug the BT Receiver into a PC running the B-Alert acquisition software.

1. **Dongle:** Plug the Dongle into the PC USB port. (LE Dongle on left; Classic Dongle on right)

2. **ESU:** Connect the ESU to the PC USB port using the Micro B-to-USB Charging cable. If using the ESU for 3rd party events, refer to the Software User Manual for additional connections.

Turn the Headset on. The Headset and Receiver on Classic Systems should pair within 10-30 seconds and 2-10 seconds on LE Systems. Refer to Device Feedback (Section 2) for operational status and event indicators. If the devices do not sync as expected, they may require "re-pairing." Refer to the Software User Manual for pairing instructions.
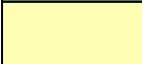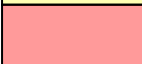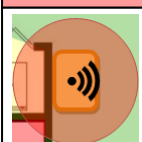
5.   Maintaining BT Signal Quality

A.   Guidance for Technicians

- Make sure the Headset and Receiver are within 30ft (10m) of each other. Transmission may work over 15m, but 10m is recommended to minimize data loss in transfer.

- Place the receiving unit and laptop at least 3 feet away from the subject and Headset.

- Reduce obstacles and avoid metal objects in the line-of sight of the Headset and Receiver.

- Provide guidance to subject on limitation of wireless coverage in the home environment.

- Visually confirm via software that data is being transmitted to PC.

- Adjust placement of Laptop with Receiver if necessary to optimize signal quality

B.   Sample Guidance for mobile placement in a 3 bedroom home

Dependent on the primary location of the subject in a mobile environment three optional Receiver 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

C.   Sample Guidance for subject with placement near a bed

While the above options provide guidance for a mobile environment, see below sample of Receiver placements in relation to a subject 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 Receiver.
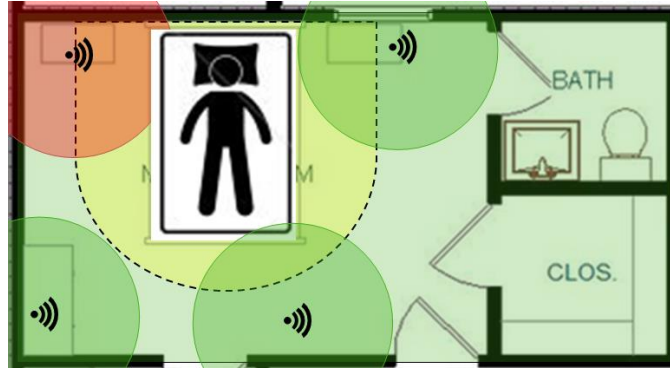
Chapter 4.   Sensor Strip

For a visual demonstration of Sensor Strip preparation and application, refer to ABM's EEG Training videos. ABM's 10-20 Sensor Strip adheres to the international standard 10-20 montage.
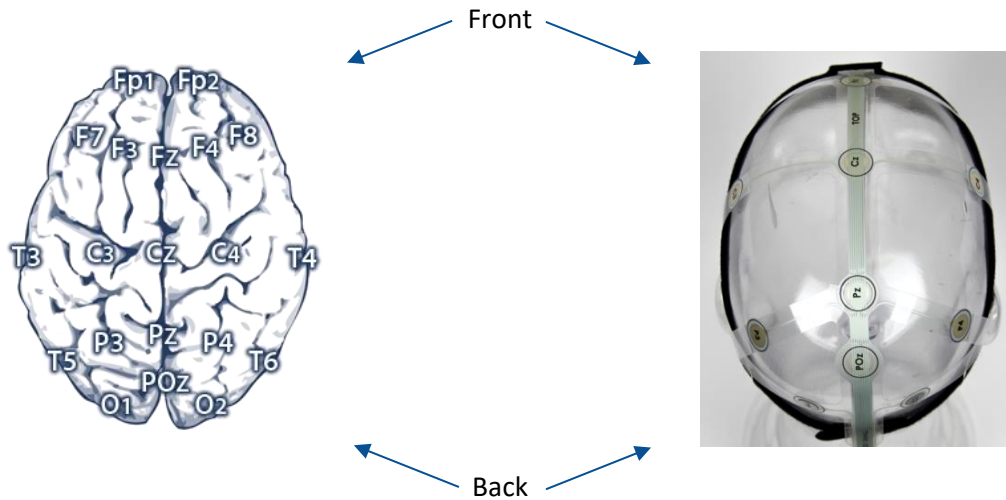
1.   Preparation

A.   Selecting a Strip Size

To select the appropriate Strip size for a subject, you will need to take three measurements, then identify the strip based on ABM's Strip Sizing Chart.

1. To locate the **Inion,** ask the subject to look up slightly and, starting at the nape of the neck, slowly walk your fingers from the bottom of the subject's head upwards until you reach the slight bump at the back of the skull.
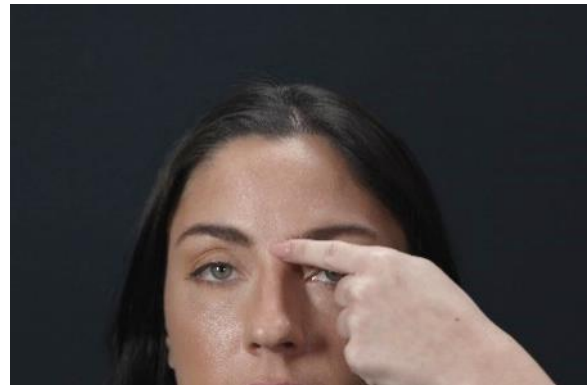
2. The **Nasion** is the depressed area directly between the eyes and just above the bridge of the nose.

3. Measure the distance (cm) from the **Nasion** to the bottom of the **Inion**, record the value. Pull the measuring tape tautly, especially if the subject has a lot of hair. Failure to do so will you give you a false measurement.

4. Measure the distance (cm) from the **Ear Attachment** on one side of the head (the topmost place where the ear attaches to the head) laterally to the **Ear Attachment** on the other side of the head, record the value.

5. When measuring Ear Attachment to Ear Attachment, run the measuring tape over the center point from the Nasion to Inion measurement. The center of both measurements should intersect.

6. Measure the head **Circumference** a finger width above the Nasion and Inion. It may be helpful to ask the subject to place their finger on the tape to prevent it from moving. Record the value.

Use the **Strip Sizing Chart** below to determine what strip size is appropriate based on the three measurements. This chart is provided in the Quick Start Guide that is included with your system for reference. Find the recorded Nasion-to-Inion value on the Y-axis and the Left/Right Ear Attachment value on the X-Axis. Locate the point where the two values intersect to identify the subject's appropriate Strip size.

Once the size is determined, refer to the Circumference. If the size is Small and the Circumference measures <52cm, downsize to an X-Small Strip. If the size is Medium and the Circumference measures <56cm, downsize to a Small Strip.

Strip Sizing Chart													XS	Extra Small Strip		M	Medium Strip	
													S	Small Strip		-	Outside ABM Range	

Nasion-to-Inion Measurement (cm)

Left/Right Ear Attachment Measurement (cm)																			
	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	S	M	M	M	M	M	M	M	M	M	M
36.5	-	S	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	S	M	M	M	M	M	M	M	M	M	M
37.5	-	-	-	S	S	S	S	S	S	S	M	M	M	M	M	M	M	M	M	M

Circumference Measurement (cm)
If measured a small and circumference measures < 52cm, downsize to X-Small Strip.
If measured a medium and circumference measures < 56cm, downsize Small Strip.

B.   Preparing 10-20 LM UNIVERSAL (SINGLE-USE) Strips
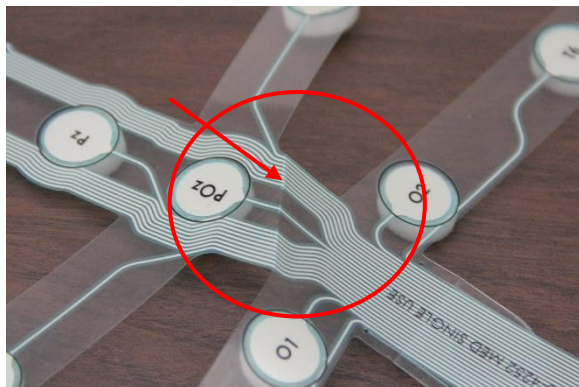
1. Lay the strip on a flat surface label side up. Confirm the Strip size and check the Strip for damage such as creases or tears.
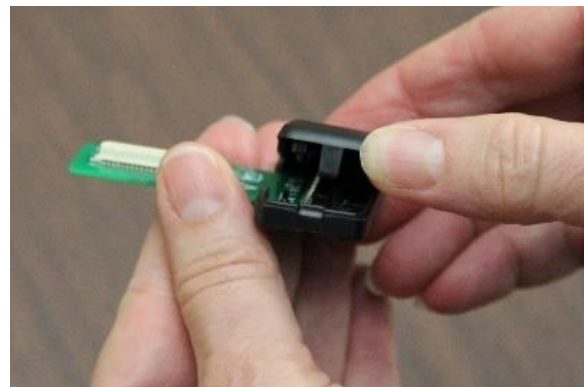
2. Remove the Adapter cover. It may be easier to detach the cover clips one side at a time.

3. Confirm that the Adapter type matches your required Strip montage. Note: ABM has different Adapters for different montages.

4. Insert the Strip tail into the connector until you feel a slight snap.
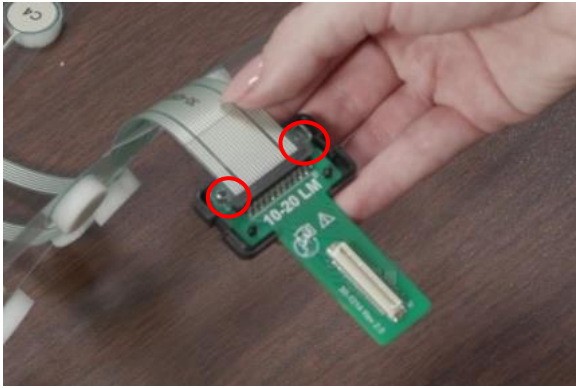
5. The Strip is fully seated if the holes on the Strip tail line up with the Adapter posts.
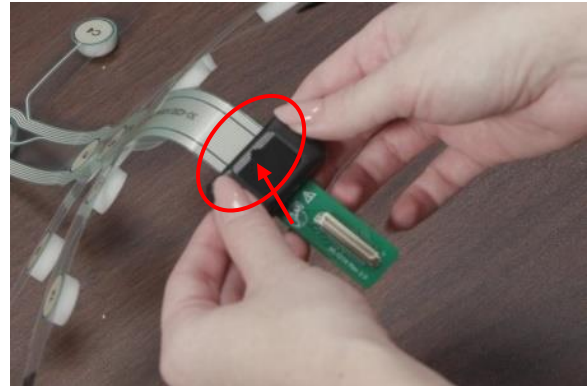
6. Once the Strip is seated, place the cover back on the Adapter. Align the label markings on the adapter cover with the strip. Press firmly to snap into place. ***The Adapter cover should seat fully on the bottom – if the cover does not seat fully, check to see if you have inserted the strip correctly.***
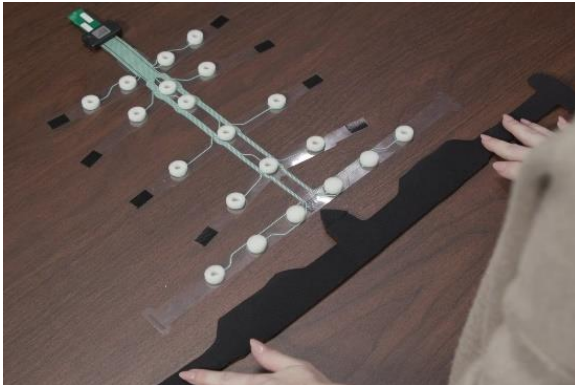
7. Flip the adapter and strip over (donuts up). Place the Headstrap with the looped, or fuzzy, side facing down.

8. Attach the Headstrap to the Strip by feeding the triangular tip of the Strap through the hole in the Strip (adjacent to site Fz), making sure that the tip is coming through from the bottom.

9. Center the Strip in the middle of the Headstrap and firmly press the Velcro down as straight as possible to set its position.

10. Unfold the Velcro side of the Headstrap and feed it through the slot on each end of the Strip. Insert one side of the barbell end of the Headstrap before pulling it through. ***Caution: passing a folded Strap through the Strip slot may cause damage.***

C.   Preparing 10-20 REUSEABLE Strips
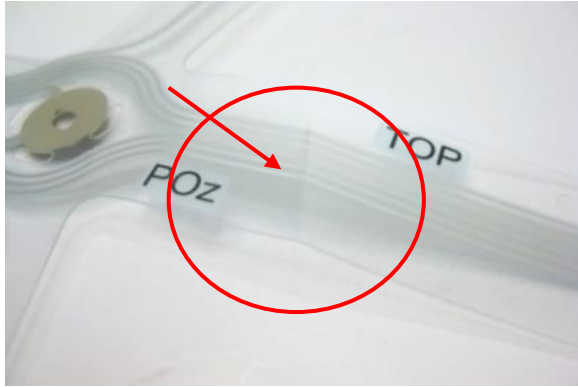
1. After selecting the appropriately sized Strip, inspect the entire Strip and verify there are no rips or hard creases.

2. Place the Headstrap with the looped, or fuzzy, side facing down and lay the Strip on the Headstrap with the sensor site labels facing down.

3. Attach the Headstrap to the Strip by feeding the triangular tip of the Strap through the hole in the Strip (adjacent to site Fz), making sure that the tip is coming through from the bottom.

4. Center the Strip in the middle of the Headstrap and firmly press the Velcro down as straight as possible to set its position.

5. Unfold the Velcro tabs of the Headstrap and thread them through the slots on each end of the Strip.
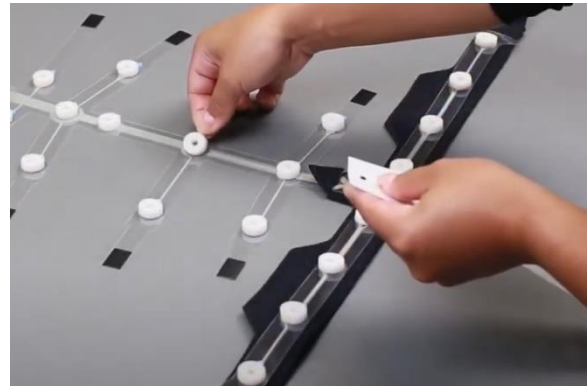
6. Affix one Foam Sensor to each of the 20 sensor sites on the Strip. Use the black circle around each site as a placement guide.

D.   Preparing the Foam Sensors

1. Fill each foam donut to the top with Conductive Cream. ***Note: for subject comfort, do not remove the donut inserts from the four sensor sites at the center of the Headstrap.***

2. Saturate the foam by using the end of the cream tube to gently press and swipe each foam donut. Allow the foam to absorb as much cream as possible.

3. Refill each donut and repeat one or two more times until the foam is completely saturated and the hole is full.

4. ***Caution: Do not overfill the donuts and cause the cream to squish outside the foam.***

E.   Preparing the Subject

We recommend the subject have clean hair without any hair products. Hair products are a major cause of high impedances. A thorough cleaning of the subject's head is key to good impedances. We recommend using large, sturdy 70% isopropyl alcohol wipes.

1. Wipe down the subject's head scrubbing with pressure similar to shampooing your hair and getting all the way down to the scalp.

2. Wipe the forehead and mastoid bones behind the ears with pressure similar to washing your face.

3. If using ECG leads, wipe the subject's clavicle, or collarbone, on their left and right side with an alcohol wipe.

4. When cleaning, get a fresh wipe as often as needed. Clean until no residue comes off on the wipe.

2.   Application

Application consists of applying the adhesive electrodes to the mastoid sites and, if ECG is used, collarbone, the prepared Sensor Strip, and the Headset.

A.   Applying the Mastoid Electrodes

For the 10-20 LM, linked mastoids are used as the reference. Impedance values will typically decrease over time, so it is best to place the mastoid electrodes first.
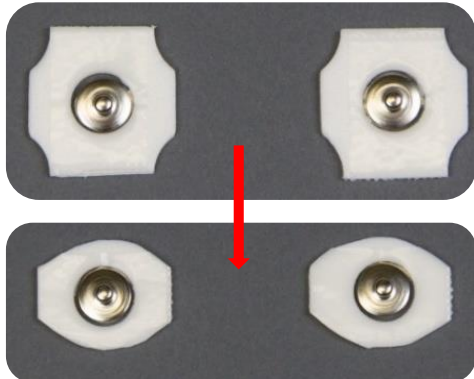
1. For easier placement and improved subject comfort, use scissors to cut down the size of the 2 adhesive electrodes (e.g., "football" or circular shape)

2. Apply a small dab of cream on the center of the electrode and spread it out evenly.

Note: proper and secure placement is critical.
- Feel for the bony area behind the ear.
- Be careful not to place the electrodes too close to where the Headstrap will sit or right up against the ear.
- Avoid the hair and muscle for optimal data quality and comfort.
- Avoid getting any of the cream on the adhesive area.

3. Peel the paper backing off the electrode to expose the adhesive and apply to both mastoid sites.

B.   Applying the ECG Electrodes (optional)
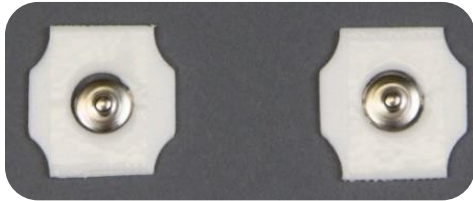
1. The adhesive electrodes do not need to be cut down for ECG.

2. Apply a small dab of cream on the center of the electrode and spread it out evenly.
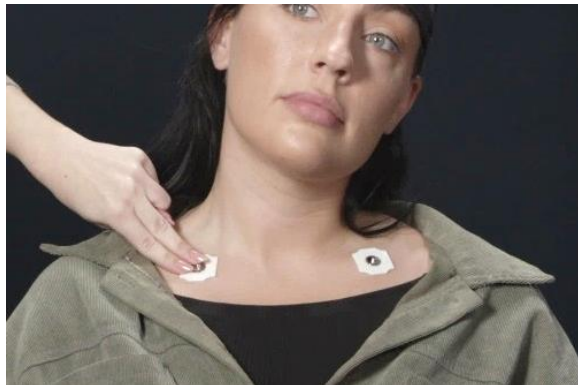
3. Peel the paper backing off the electrode to expose the adhesive and apply to the right and left sides of the subject's collarbone.

C.   Applying the Prepared Sensor Strip

1. To pick up the Strip, hold both arms of the Headstrap in one hand and the Adapter in the other.

2. Hand the Adapter to the subject and instruct them to look up slightly and hold the adapter at eye level away from their face.
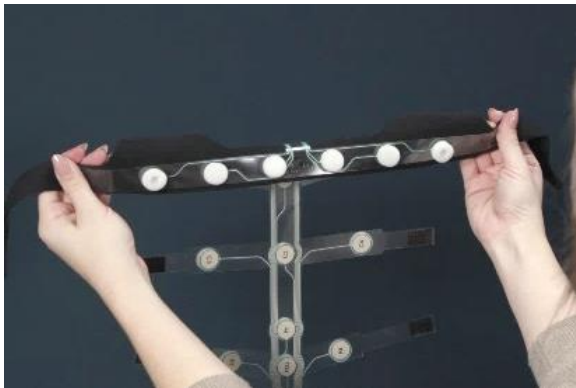
3. Using both hands, hold both sides of the Headstrap being sure to hold the plastic ends of the Strip at the same time.

4. Stand behind the subject, place the Headstrap/Strip on the subject's head just above the eyebrows. Align the triangular piece of the Headstrap between the subject's eyes.

5. Fasten the Headstrap/Strip around the circumference of the subject's head. Fit should be snug, but not too tight – similar to the fit of a bicycle helmet.

6. Check that both sides of the Headstrap sit just above the top of the subject's ears and the triangular tab is centered between the subject's eyes.

7. Tuck a finger in between the Headstrap and the Strip next to the ear. The Headstrap should feel snug on your finger. *Caution: Excessive pressure can have negative effects on both signal quality and subject comfort, including the cause for headaches.*
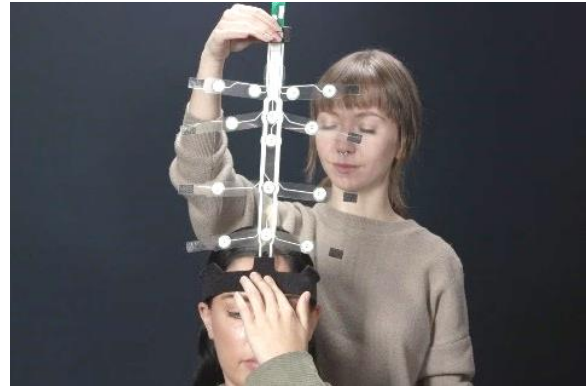
8. Take the Adapter from the subject and bring it up and over the top of their head. Ask the subject to hold their fingers on the Headstrap near their forehead to keep it from moving.

9. Walk your fingers down the Strip on the center line of the head keeping the Strip taut to prevent buckling or bunching. Make sure <u>not</u> to pull on the Strip too hard or it will move up on the subject's forehead.

10. Fasten the two furthest-back Strip arms down onto the Headstrap at the same time. This will keep the Strip centered and in place while you check the temporal sensor sites.

11. Gently pull back the top of the Headstrap to view the frontal sensors along the forehead and temples where there is hair. Use the curved tip of the cream tube to part any hair and expose the scalp to the foam sensors.

12. Refill the foam donuts with cream for the sensors that are not directly on the forehead.
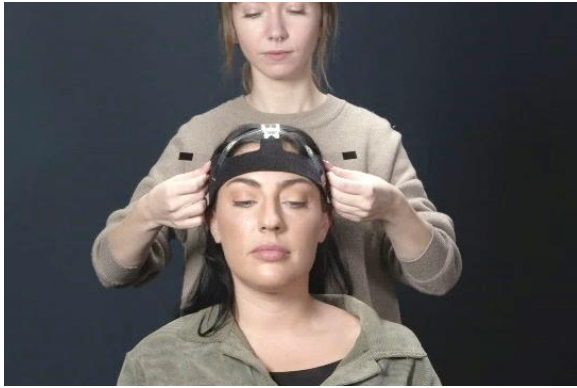
13. Starting at the front and moving to the back, fasten the remaining Strip arms in pairs to the Headstrap using the same amount of pressure to keep the center line straight.

14. While troubleshooting, be careful to maintain the correct alignment of the Strip on the scalp, ensure that the Strip is lying flat without any creases, and that the foam donuts are slightly compressed.
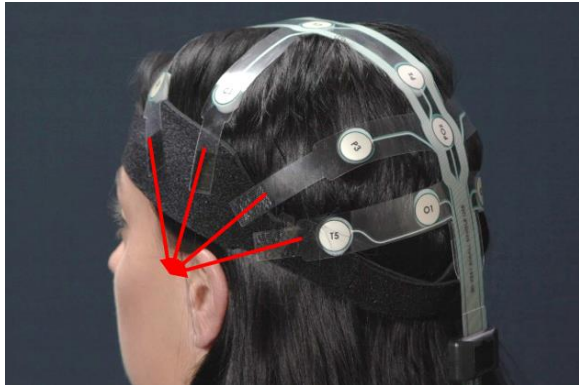
15. The ideal fit of the Strip is achieved when all arms converge at the same point and the Strip is pulled back taut so that there is no buckle on any part of the midline.
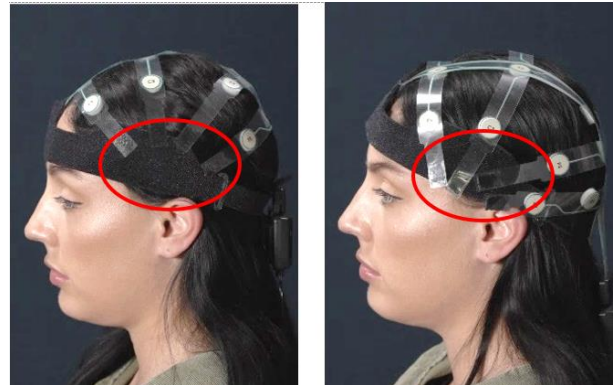
16. If the Strip arms do not reach the Headstrap, it is possible that the Strip is too small (left image). If the Strip arms fall below the Headstrap, it may be that the Strip is too big for the subject (right image).

17. The buckling shown in the red circles can be caused by not keeping the Strip taut from front to back, or an incorrect strip size.

18. Riding up of the Headstrap where the Strip is revealed may be caused by too small of a Strip, or aggressive tugging during troubleshooting.

19. Working front to back, lift each Strip arm one at a time. Hold the bottom of the Headstrap and peel the Strip arm off the neoprene to help the Velcro release and keep the Strip from moving out of place.

20. For best connectivity ensure sensor to scalp connection. Part the hair with the curved tip of the cream.

21. Refill each donut hole with cream.

22. Ensure strips lay flat. 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.

D.   Applying the Headset

1. If the 3-pin cable and 2-pin cable (optional) are not already connected to the Headset, connect them. Be sure to press the cable connector firmly into the Headset

2. With the Headset label side down, press down in the center of the Back Enclosure Door and slide the locks away from the center of the Headset. Make sure the slide locks are fully open before removing the door or it may cause damage to the locks.

3. **UNIVERSAL (SINGLE-USE) STRIP:** Hold the headset with the B-Alert X24 label facing **toward** you. Align the Adapter with the underside of the Headset. Carefully and firmly connect the two pieces. Flip the Headset over.

REUSEABLE STRIP: Hold the headset with the B-Alert X24 label facing **away** from you and the USB connector on the Headset facing up. Flip the Adapter upwards and align it with the underside of the Headset. Carefully and firmly connect the two pieces. *Caution: incorrect alignment of the two connectors can cause permanent damage to the Headset and Strip.*

4. Replace the Back Enclosure Door, press down on the center of the door and slide the locks toward the center of the Headset.

5. Slip the Doorstrap through the transparent plastic loop on the door with the fuzzy, or Velcro, side facing away from the Headset.

6. Holding the two ends of the Doorstrap, flip the Headset downward so it is right side up and attach the Velcro to the Headstrap/Strip on the subject's head.

7. **REUSEABLE STRIP ONLY:** Slide the Headset to the right on the Doorstrap so that it sits off-center in order to minimize bending the Strip.

E.   Connecting the Leads

1. Connect the **RED** EEG lead snap to the Adhesive Electrode on the **RIGHT** mastoid/A2. **R**ed = **R**ight

2. Connect the **BLACK** or **BLUE** EEG lead snap to the Adhesive Electrode on the **LEFT** mastoid/A1. b**L**ack or b**L**ue = **L**eft

3. Connect the **GREY** ECG lead snap to the Adhesive Electrode on the **RIGHT** collar bone. g**R**ey = **R**ight

4. Connect the **BLUE** ECG lead snap to the Adhesive Electrode on the **LEFT** collar bone. b**L**ue = **L**eft

3.   Troubleshooting Impedances

Turn the Headset on and establish connection with the Receiver (refer to Chapter 3 Section 4).

Refer for the B-Alert Live Software User Manual for how to obtain impedances using the acquisition software. In order to reduce impedances, additional troubleshooting may be necessary. ABM's acquisition software is designed to provide color-coded guidance for sensor connectivity: Red signifies values above 80 kOhms, yellow if between 40 and 80 kOhms, and green if less than 40 kOhms.

For quality data, ABM recommends that impedance values for ALL sensor sites are lower than 40 kOhms, or green, before proceeding with the data acquisition.

High Impedance Issues	Troubleshooting Recommendations
High Reference Value	✓ If the reference impedance is high, it will negatively impact ALL channels. If the reference is higher than 20 kOhms, reapply. *References less than 10 kOhms are ideal.* ✓ Unsnap the leads, remove the adhesive electrodes, use a paper towel to wipe away any residual cream, re-wipe the mastoid area with an alcohol swab, and allow the skin to dry. ✓ Reapply new electrodes. Make sure that the electrodes have a small dab of cream in the center and that the site is clear of any hair before reapplying to the mastoid.
High Impedance Values for All Channels	✓ If the reference and all channels are "out of range," check to make sure the 3-pin cable is pushed all the way into the Headset and the snaps are attached to the mastoid adhesive electrodes. ✓ If high impedances persist for all channels, it may be more efficient to remove the strip and start over again, paying close attention to thorough cleaning of the head, forehead, and mastoid sites with alcohol wipes. ✓ *Not cleaning the head thoroughly enough is the most common reason for poor impedances.*
High Impedance Values for Some Channels	✓ To address high impedances for only some sensors that persist, locate the specific channels that appear red, or yellow if on the high side of the range, on the impedance check. ✓ Lift the strip arms, if necessary, to access the sensor and use the tip to part the hair and expose the scalp where the sensor rests. Add more cream to the foam sensor. Ensure strip arms are lying flat and the foam is compressed. ✓ If after multiple failed attempts the impedances still are not within range, wipe the site thoroughly with an alcohol wipe and reapply cream to the foam donut.

Please remember the following:

- Ill-fitted equipment could cause the strip to ride up on the subject's head causing the foam connectors to disconnect from the scalp.

- If you observe that the strip arms are too tight, or that it is difficult to get sensors to lie flat, you may need to check the strip size measurements or troubleshoot other steps of the setup.

- Remember that impedances will decrease over time, so re-running an impedance check without troubleshooting may result in lower values. Troubleshooting may disrupt good impedances, so only troubleshoot when necessary.

- If no amount of troubleshooting changes impedance values, the sensor strip may be damaged.

Chapter 5.   Post-Acquisition Procedures

1.   Removal from the Subject's Head

1. When acquisition testing is complete, turn the Headset off.

2. Carefully remove the EEG and ECG adhesive sensors. Stick them to each other so that they don't stick to the subject.

3. Unfasten the Velcro tabs on the Doorstrap that attach the Headset to the Headstrap and tuck the tabs in so that they stick to itself.

4. Detach all strip arms tabs from the Headstrap, starting from the back and working to the front.

5. Unfasten the Velcro on the Headstrap and lift the strip away from the subject being careful to not let the Headset or cables hit the participant.

6. Using a damp paper towel, wipe away any residual cream from the subject's head, mastoids, and collarbone. *Caution: do not use alcohol wipes with EEG Connect for cleaning up the subject as it will cause the cream to become stickier and more difficult to remove.*

2.   Cleanup – UNIVERSAL (SINGLE-USE) Strips

1. With the Headset label side up on a flat surface, remove the adapter board cover.

2. Lift the strip slightly so that it clears the posts on the adapter board and pull the strip out of the connector.

3. Replace the adapter cover.
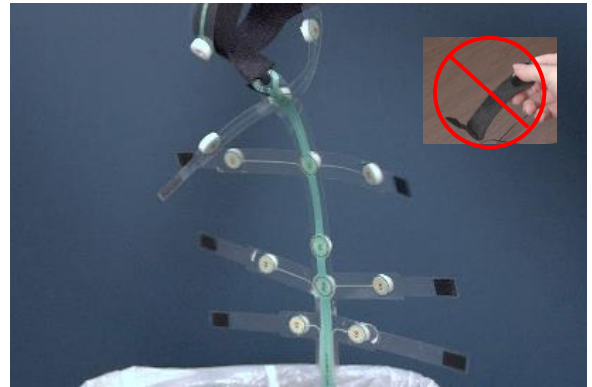
4. Discard the entire strip including the neoprene Headstrap. *Do not discard the Doorstrap.*

5. Unsnap electrodes from the cables and dispose.

6. To clean the Headset, remove the Doorstrap from the Enclosure Door.

7. Wipe down the Headset, strip adapter cover, and cables with an alcohol wipe (70% IPA). All areas should remain wet for a minimum of 15 seconds. If any visible soil remains, repeat cleaning as needed. *Allow to air dry. Do not attempt to charge or turn on the Headset until it is completely dry.*

8. Wipe the Doorstrap with an alcohol wipe and slip it back through the transparent plastic loop with the fuzzy –or—Velcro--- side facing away from the Headset.

9. Gently wind the attached cables and place them on <u>top</u> of the Headset in the system case.

10. *Do NOT wind the cables <u>around</u> the Headset or put tension on them as it may damage the cables.*

3.   Cleanup – REUSEABLE Strips

The Strip should be replaced after twenty-five (25) uses, or if there is a consistent pattern of poor signal quality or damage to the strip. Cleaning the Strip is only required if the Strip will be reused. If the Strip has exceeded its recommended life, signal quality is poor, or there is damage to the Strip, dispose of it.

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.

c. Clean the 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.

d. Clean the 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.

e. Clean the Enclosure:

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 6.   Product Information

1.   Technical Specifications

System Specifications				
Brand name	B-Alert			

Operating Modes	Mode	Description		
	Monitoring	Transmits via Bluetooth (BT)		
	Hibernation	Device turned off		
	Disconnect	Long term storage		

Signals acquired	Signal	Number of channels	Default dynamic range	Default samples per sec	Interfaced to PCB/electronics
	EEG	23	$\pm$ 1000 µV	256	PET strip
	EEG/EOG/ECG/EMG	1	$\pm$ 1000 µV	256	Touch-proof two-lead cable
	Actigraphy	3	-180 to 180º	10	On device

Signal Processing	Signal	Resolution for full dynamic range	Processing/Filtering	
	EEG	16 bit	0.1 Hz High Pass, firmware 67 Hz Low Pass, hardware	
	2-pin connector	16 bit	0.1 Hz High Pass, firmware 67 Hz Low Pass, hardware	
	Actigraphy	12 bit	Down sampled from 100 Hz to 10 Hz	

Typical Signal Accuracy and Resolution	Signal	Accuracy (typical)	
	EEG	Resolution 0.03 µV, typical noise 3.7 µVpp (EEG circuit 3.0 µVpp)	
	Optional 2-pin connector	ECG	Resolution 0.06 µV, typical noise 4.0 µVpp
		EOG/EEG/EMG	Resolution 0.03 µV, typical noise 3.7 µVpp
	Actigraphy	+/- 3 degrees in +/-60 degrees range	

EEG Impedance Monitoring	Performed in monitoring mode when initiated by software. Impedance monitoring is performed on ExG 2-pin channels if optional channel configured for EEG, EOG, or EMG, but not for ECG. High Impedance indicates poor connection between scalp and EEG electrode, but might be also caused by disconnected electrodes, leads, or strips.
EEG Offset Voltage	± 600mV
EEG Input Impedance	500MΩ, typical
EEG Common Mode Rejection	-115dB Common Mode Rejection Ratio, typical
Calibration	The X24 device does not require calibration for use.

Battery				
Battery Charging	Via USB cable connected to: • Computer USB port, 5V/0.5 A • USB wall charger IEC 60601-1 approved, Output 5V/1.0A • External battery IEC 62133 compliant			
Power Supply	650mAh 3.7V Lithium Polymer Battery			

Typical Power Consumption and Operating Time by Mode	Mode	Consumption (typical)	Hrs of Use (range) 0-4 days after charge	Hrs of Use (range) 5-10 days after charge
	Monitoring (LE System)	27 mAh	16 to 18	14 to 16
	Monitoring (Classic)	40 mAh	8 to 10	6 to 8
	Hibernation	< 0.5 mAh	N/A	N/A

User Interface	
User Control	ON/OFF tactile switch
Acoustic audio feedback	Internal speaker
Visual feedback	Green, Amber LED
Dimensions	2.8" long x 1.9" wide x 0.8" deep
Weight	0.071kg (Device with battery)

Materials of Data Acquisition Device	
Device Enclosure	ABS
Strap	Neoprene with loop fastener
EEG Sensors	Foam Sensor (100 PPI Natural Color Filter Foam)
ECG/Mastoid Sensors	MBS (3BF3) disposable Ag/AgCl sensors with adhesive
EEG Sensor Strip	Polyester film
Conductive Cream	Kustomer Kinetics, Synapse Conductive Cream Advanced Brain Monitoring, EEG Connect Conductive Cream
Cables	PVC

Cleaning	
Cleaning	Cleaned and disinfected by rubbing with 70% isopropyl alcohol (IPA); water and dish soap for strap

USB Specification	
USB Standard	USB 2.0
USB Data Transfer	USB Flash Disk

Wireless Specification	
Wireless Module	X24 Classic – Bluetooth v2.1+EDR compliant to IEEE 802.15.1 X24 LE – Bluetooth 5.0 compliant to IEEE 802.15.1
Operating Frequency	2.4 to 2.48 GHz (ISM Band)
Antenna	On-board
Output Power	Maximum 4 dBm
Limitations of Operation	Maximum range 10 meters line of sight
Data Throughput	Typical 10KB/sec, maximum 30 KB/sec
Latency	Typical 20-30 ms, maximum 300 ms from data sample acquisition until received by PC.
Data Integrity	Bluetooth protocol ensures data integrity by retransmitting corrupted data packets Communication Protocol recognizes and inserts zeros for missed samples
Quality of Service	Average transmitted data loss <0.1%
Security Characteristics	Communication Protocol establishes and Bluetooth protocol maintains secure transmission between the Headset and Receiver.

Environmental Conditions*	Operation	Transportation	Storage
Temperature / Relative Humidity	5°C to 40°C (41°F to 104°F), relative humidity 15% to 90%, non-condensing and water vapor pressure up to 5kPa	-25°C to 5°C (-13°F to 41°F), 5°C to 35°C (41°F to 95°F) with relative humidity up to 90%, non-condensing, >35°C to 70°C (95°F to 158°F) at water vapor pressure up to 5kPa	-25°C to 5°C (-13°F to 41°F), 5°C to 35°C (41°F to 95°F) with relative humidity up to 90%, non-condensing, >35°C to 70°C (95°F to 158°F) at water vapor pressure up to 5kPa
Synapse Cream Temperature	7°C to 20°C 45°F to 68°F	7°C to 20°C 45°F to 68°F	7°C to 20°C 45°F to 68°F
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

*Note that these environmental conditions only apply to the X24 device. For environmental conditions of third-party components, see the third-party labels and/or user manuals.

Device Safety Limits	
Max external surface temperature during charging at ambient temperature of 22.8 °C	Less than 57 °C (120°F)
Max temperature of accessible parts during recording at ambient temperature of 22.2°C	Less than 45 °C (104°F)
Max temperature of applied parts during recording at ambient temperature of 22.2°C	Less than 41 °C (104°F)

General Compliance	
Item	**Compliant With**
Equipment classification	Class B, EN 55011:2009+A1:2010

Degree of protection against electrical shock	Low Voltage Directive, Electrical Equipment Regulations
Mode of operation	Continuous
Degree of protection against ingress of water/liquids	IP22
Electromagnetic compatibility	Electromagnetic Compatibility Directive/Regulations EN 301 489-1, EN 301 489-17
Electrostatic Discharge	EN 61000-4-2
Radio Frequency Electromagnetic Field Amplitude Modulated	Radio Equipment Directive/Regulations EN 61000-4-3
Proximity Field from Wireless Transmitters	EN 61000-4-3
Power Frequency Magnetic Field	EN 61000-4-8

Essential Performance
The X24 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 X24 device has an expected service life of five years. The sensor strip, battery, straps, and sensors are considered replaceable components and are expected to be replaced during the service life of the device. The universal (single-use) sensor strip is for single use only. The reusable sensor strip has an expected service life of 25 uses. The device internal 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 Headstrap does not have an expected service life but is recommended to be replaced after 25 uses when used with a reusable sensor strip. 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).

2.   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 X24 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X24 System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The X24 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 X24 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 X24 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X24 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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X24 System requires continued operation during power mains interruptions, it is recommended that the X24 System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (Both 50Hz and 60Hz field)	30 A/m (Both 50Hz and 60Hz field)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity			
The X24 System is intended for use in the electromagnetic environment specified below. The customer or the user of the X24 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	Not Applicable 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the X24, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *Not Applicable* $d = 0.4 \sqrt{P}$ 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: $((\cdot))$
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 X24 System is used exceeds the applicable RF compliance level above, the X24 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 X24 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 X24 System

The X24 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X24 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X24 System is recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz *Not Applicable*	80 MHz to 800 MHz $d = 0.4\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$
0.01	*Not Applicable*	0.04	0.07
0.1	*Not Applicable*	0.1	0.22
1	*Not Applicable*	0.35	0.70
10	*Not Applicable*	1.11	2.21
100	*Not Applicable*	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

3.   Customer Support, Warranty, and Terms of Use

A.   Customer Support

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

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

B.   Warranty and Terms of Use

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

For information on warranty, terms and conditions, and limitations of use, please refer to this link and the sections below: www.advancedbrainmonitoring.com/warranty.

4.   Additional Information

A.   Trademark Acknowledgements

- Windows is a trademark of Microsoft Corporation.
- 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.