



Quick-20m

This manual includes operating instructions, maintenance instructions, and general information for use of the CGX Quick-20m.

Carefully read this manual to familiarize yourself with the headset, software, and accessories before use.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Description

The Quick-20m is a wireless, battery-operated 10-20 montage EEG headset utilizing dry sensor technology. The headset provides an integrated approach to the wireless acquisition of EEG signals. A seated patient is free to exhibit natural movements while real-time data is collected.

The Quick-20m includes advanced amplification and shielding to reject ambient electrical noise.

The headset obtains high-quality EEG with minimal scalp preparation. Patented mechanisms and a range of replaceable dry sensors align to various head shapes and sizes, maintaining sensor positions in a standard 10-20 layout. EEG channels are digitized with 24 bits of resolution at 500 Hz. The Quick-20m is suitable for general-purpose EEG.

The Quick-20m is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.

The Quick-20m headset is not a diagnostic tool. Any medical diagnosis related to the EEG should be derived by a certified physician.

This Device Is Not Intended For The Following Uses:

- monitoring of patients in a clinical environment
- on patients undergoing surgery
- on patients on life support systems
- use in sterile environments
- use with sleeping patients

Do Not Use This Product In These Situations:

- near high-frequency surgical equipment
- if exposed to radio-band, ionizing, microwave, infrared, ultraviolet, or gamma radiation
- in oxygen-rich environments (concentration > 25% at 1 atm)
- in wet environments (i.e., steam rooms)
- in the presence of flammable anesthetics or gases
- in the presence of heavy machinery
- in dusty environments

Precautions For The Practitioner

- Check if your patient has a sensitive dermatological condition causing sensor intolerance.
- To avoid cross-patient contamination, do not use with patients having open wounds or scalp infections.

Patient Considerations

- This device is intended for human use only.
- Patient should have a healthy scalp.
- This device fits teens and adults with a head circumference from 52 to 62 cm.
- Do not use with infants or neonates.
- Patients may or may not have hair.
- All sensors must be able to contact the patient's scalp.
- The entire headset may come into contact with the patient's skin.

Disposable Sensors

- Store clean sensors in the provided jars.
- Clean sensors after each session following instructions on Page 16.
- Replace sensors at or before their stated lifecycle limits (Specifications, Page 18), or if they appear worn.

Always Use Supplied Accessories

Using accessories other than those supplied with your Quick-20m system may result in damage or diminished efficacy of the system.

The Quick-20m uses two AAA Alkaline or NiMH batteries. Follow care and handling instructions provided by the battery manufacturer.

Avoid Cross-Patient Contamination

Always inspect patient head to ensure skin surface is clean and free of open wounds prior to use of EEG.

Clean the device and clean or replace sensors after use following the cleaning instructions on Page 15 to avoid cross-patient contamination.

Care Instructions

The Quick-20m is constructed of flexible materials to improve comfort and fit. These materials are prone to breakage under extreme conditions. Do not drop, sit on, step on, fold, push, pull or stretch the product.

Patient Will Be In Direct Contact With:

- Sensors
- Headset

Safety Warnings

Do not:

- Sterilize the product.
- Immerse the product in any liquid.
- Expose the product to excessive: vibration, moisture or humidity, mechanical shock, or dust.
- Disassemble or modify the product. This will void the warranty.
- Use caustic or abrasive cleaners on the headset or sensors.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Cybersecurity

The Quick-20m does not pose an inherent cybersecurity risk. The wireless bluetooth system relies on a built-in security encryption method utilizing 128-bit AES encryption.

The Quick-20m is MR Unsafe.

Keep it outside the MRI scanner room.

Performance Warnings







The Quick-20m is designed for use in a professional healthcare facility by a trained healthcare professional.

- Use in environments near HF surgical equipment, magnetic resonance imaging equipment, or other equipment which produces a high level of EM disturbances will affect the performance of the device.
- In case of EM disturbances, the recorded bio-potential waveforms may have environmental artifacts including unanticipated high frequency components.
- No harm to the patient or operator may occur when using the device in an unsupported environment.

Performance Degradation

The Quick-20m presents no additional risk to the operator or patient should the performance or efficacy of the system be diminished.

Warnings

Symbol	Title Of Symbol	Standard	Title Of Standard	Description Of Symbol
	Prescription Only	21 CFR 801.15(c)(1)(i)(F) 21 CFR 801.109	Labeling - Medical device; prominence of required label statements. Labeling - Prescription devices.	Requires a prescription in the United States of America. Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.
	Serial Number	ISO 15223-1:2016	Medical devices: Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Manufacturer	ISO 15223-1:2016	Medical devices: Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Keep Dry	ISO 15223-1:2016	Medical devices: Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements	Indicates a medical device that needs to be protected from moisture.
	Consult Instructions For Use	ISO 15223-1:2016	Medical devices: Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements	Indicates the need for the user to consult the instructions for use.
	Caution	ISO 15223-1:2016	Medical devices: Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General Requirements	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Quick-20m Overview

EEG is the measurement — through the use of sensors and amplifiers — of scalp surface electrical potentials arising from activity in the cortex.

The Quick-20m follows the international 10-20 system standardizing electrode placements across the scalp. The 10-20 system derives its name from measurements of 10% and 20% of the distance between landmarks on the head, specifically, the depression above the bridge of the nose (nasion), the bump at the back of the head (inion), and the depressions in front of each ear (preauricular points).

Sensors are labeled with a combination of letters and numbers indicating their respective locations, with even numbers on the right and odd numbers on the left side of the head. Midline locations are marked with a “z” for “zero.” For instance, Fz sits on the frontal midline, while F3 sits left of and F4 sits right of Fz.

The Quick-20m is sized to fit heads with a circumference between 52 and 62 cm as measured about the thickest part of the skull.

The Quick-20m meets the mechanical, electrical, and sensor needs required to make an effective dry EEG system.

Conventional wet systems rely on electrolytic gels to penetrate hair, contact the skin, and provide a conductive path. The gel serves as a buffer filling in gaps between the sensor and skin.

No conductive gel is used in a dry system. The benefits are obvious: faster set-up, and no after-use clean-up required.

Yet, dry systems are prone to several challenges. First, the sensor must be designed to directly touch the scalp or skin, even through thick hair. Second, the sensor must remain securely in place to minimize artifacts and noise. Finally, the electronics must tolerate impedances up to 200 times higher than wet systems — while rejecting noise and interference. A high-end dry solution — like the Quick-20m — balances sensors, mechanics and electronics achieving virtually the same signal quality as a traditional wet cap for most EEG applications.

Device Overview

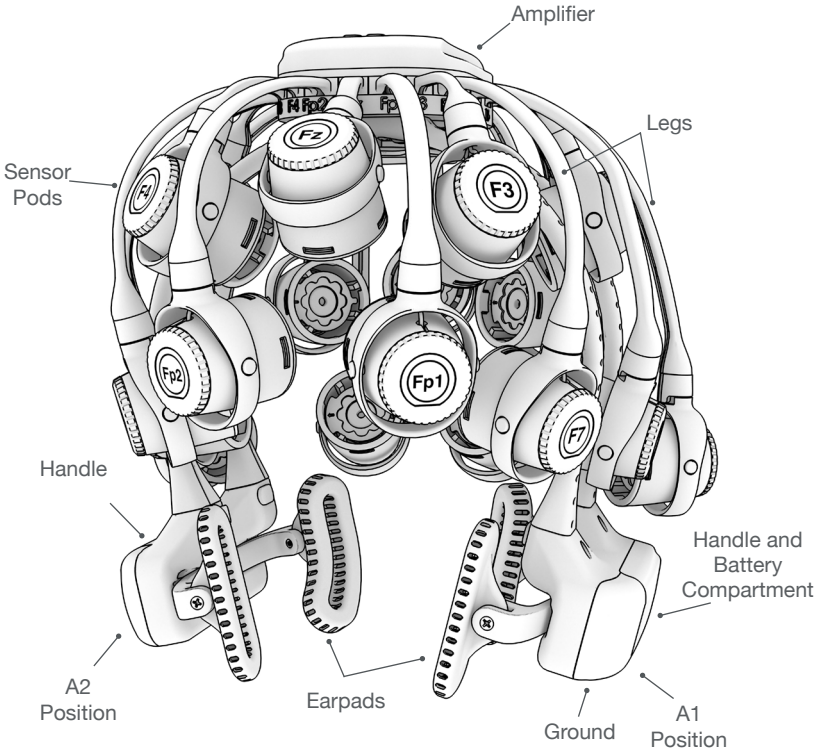
The Package Contains The Following Items

Quick-20m Headset
Bluetooth Dongle
20 Drypad Sensors
40 Flex Sensors

10 Drypad Ear Sensors
A1 Earclip
A2 Earclip
3 Active Lead Wires
2 Passive Lead Wires
30 Skintact Sensors
5 Alcohol Wipes

4 Rechargeable AAA Batteries
Battery Charger
Carrying Case
Manual

Quick-20m Headset



Device Overview

Amplifier



Wireless amplifier collects signals and transmits to Bluetooth Dongle.

Bluetooth Dongle



High-speed receiver dongle plugs into your computer's USB port.

Drypad Sensor



Drypad sensors make direct skin contact for ECG and EEG recordings.

Flex Sensor



Flex sensors slide through hair for high-quality scalp contact.

A1 Earclip



A1 earclip has two sensor locations: Reference and Ground.

A2 Earclip



A2 earclip is used in linked-ears configurations.

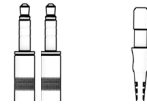
Drypad Ear Sensor



Dedicated Drypad sensors for use with Earclips.

Lead Wires

Active Passive



Active lead wire (3.5mm audio jack) for Reference/A1 and A2.

Passive lead wire (touchproof) for Ground and EEG.

Preparation

1. Select Sensors

Choose the appropriate sensor for your application.

Drypad Sensors

Use Drypad sensors in positions where the patient has no hair (forehead and bald areas).

Flex Sensors

Use Flex sensors to penetrate hair. On most patients, these are all the positions except Fp1, Fp2, F7 and F8.

2. Attach Sensors

Push at the center of the sensor when installing. For Flex sensors, do not apply pressure to, or bend the sensor tips.

When removing sensors, pry between the sensor and the connector.

3. Assemble The A1 Earclip

Ground and Reference contacts are required for proper use of the headset. Be sure Ground and Reference cables are properly attached to the Earclip and the headset.

1. Pinch the earclip.
2. Insert Drypad Ear Sensors into the grooved holes in the earclip.
3. Attach the passive and active lead wires to either Drypad Ear Sensor.
4. Attach the passive lead to the touchproof connector on the A1 handle.
5. Attach the active lead to the 3.5mm audio jack on the A1 handle.

4. (Optional) Assemble The A2 Earclip

Use the A2 Earclip for recordings requiring both ears.

1. Pinch the earclip.
2. Insert Drypad Ear Sensor into the grooved hole in the earclip.
3. Attach the active lead wire (3.5mm) to the Drypad Ear Sensor.
4. Attach the active lead to the 3.5mm audio jack on the A2 handle.



Drypad Ear Sensor



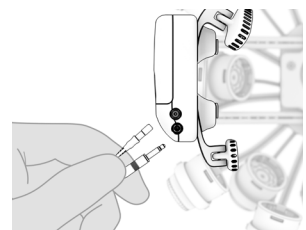
A1 Earclip



Insert the Drypad Ear Sensor into the Earclip with snap facing out. Attach lead wire to snap as shown.



A1 uses a touchproof lead wire for Ground and the 3.5mm audio jack lead wire for Reference



Plug touchproof and audio jack wires into headset, matching orientation as shown

5. Charge And Insert The Batteries

Use fresh alkaline batteries, or if using NIMH batteries, fully charge before using.

- Open the battery door on the A1 handle.
- Place the batteries in the correct configuration following the markings inside the battery housing.

6. Check Power Status and Trigger Status Lights On Top Of Amplifier

Power Light	Status
Off	Headset Off
Green	Headset On
Yellow	Low Battery
Red	Critically Low Battery (replace immediately)

Trigger Light	Status
Off	Trigger Out Of Range
Blue	Trigger In Range

7. Insert Bluetooth Dongle

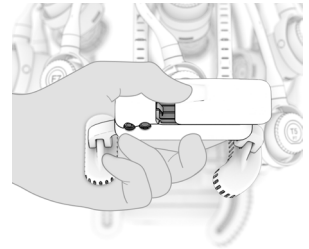
Plug the dongle into your computer and Windows should automatically install the correct drivers. Verify driver installation by checking the Device Manager for problems, marked by a yellow exclamation mark.

- The dongle is specific to each headset.
- For best performance, ensure a clear line of sight between the dongle and the front of the headset.

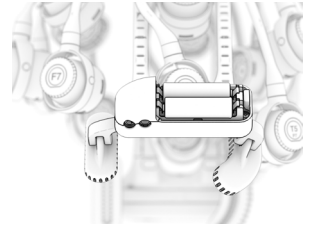
Each Quick-20m is permanently paired to a receiver dongle. The pair automatically discover and initiate a connection when both are powered on and within a 10m range.

The light on the dongle indicates its current state:

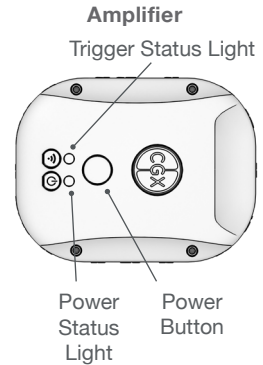
Dongle Light	Status
Green	Power On, Not Paired
Purple	Searching For Device
Blue	Device Found
Flashing Blue	Data Transmitting



Slide to open battery door



Insert 2 AAA batteries as shown



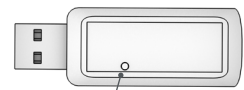
Amplifier

Trigger Status Light

Power Status Light

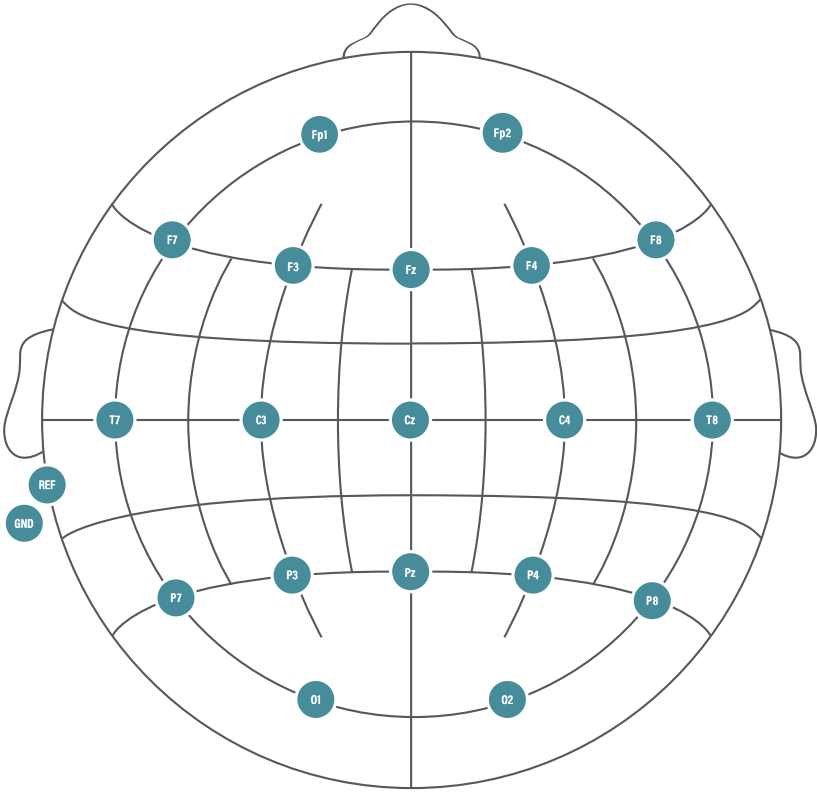
Power Button

Dongle

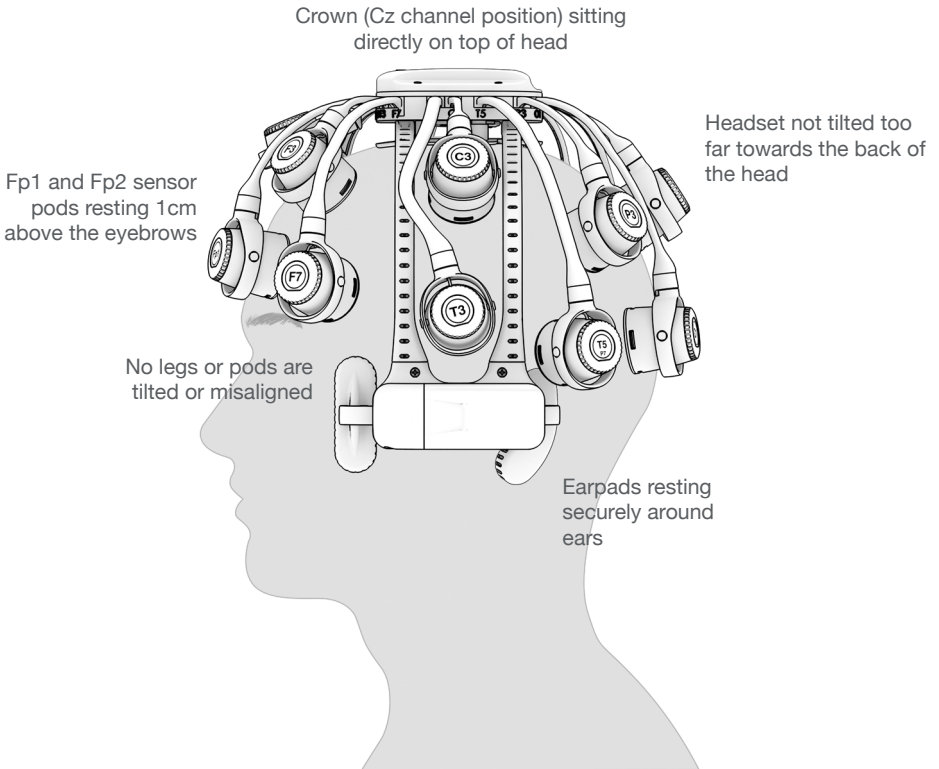


Status indicator light

Sensor names and positions

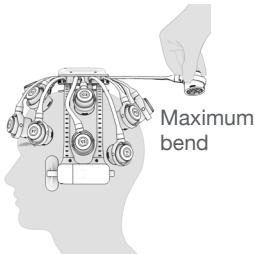


Headset Placement For Accurate 10-20 Recordings



Do Not Extend Legs Past 90°

Legs may break or deform if bent more than 90° from their resting position.



Position Of The Patient During EEG

Use the Quick-20m headset for patients in an upright position. Do not let the patient lie or sleep on the headset. It may damage the headset.

8. Place The Quick-20m On The Patient's Head

Positioning The Headset

- Grasp both handles and gently pull them apart to open the headset.
- Slide the headset over the patient's head.
- Adjust the position of the headset so the earpads fit around the patient's ears.
- Pull down firmly on the headset until Cz makes good contact with the top of the head.
- Position headset back-to-front with Fp1 and Fp2 sensors resting 1 cm above the eyebrows.
- Check that headset is level and not tilting to one side.

Adjustments

- Brush aside excess hair near and underneath the earpads.
- Reorient misaligned legs and pods.
- Grasp and rotate each pod so the sensor is perpendicular to the patient's head.
- Push the headset downward again so the sensor at the crown (Cz) makes firm contact with the patient's head.
- Ensure pods lie flat on the patient's head.
- Brush aside excess hair on the forehead and any other positions where Drypad sensors are installed.

Earclips

- Lift the earpad to access the ear lobe and clean with supplied alcohol wipe.
- Place the A1 earclip on the earlobe of the patient, and clip onto the back of the ear.
- Attach the A1 earclip on the A1 handle.

Optional Setup

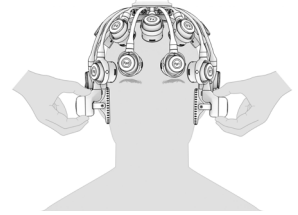
- Option: Attach the A2 earclip on the A2 handle for configurations requiring both ears.
- Option: Attach EEG passive lead wire on the A2 handle for additional biometric measurements.

Before Starting A Session

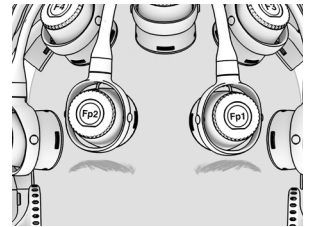
- Verify headset is properly positioned on the patient's head.
- Ask the patient for any areas of discomfort and, if necessary, reposition sensors to lay flat on the head.



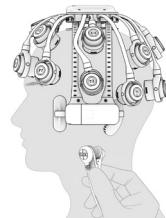
Don headset front-to-back



Pull down on handles until the top sensor (Cz) makes firm contact with the head, and the headset is level from side-to-side



Position two front channels (Fp1 and Fp2) so the bottom of the pod rests 1 cm above the eyebrows



Apply earclip to earlobe

9. Optimize Sensor Contact

After properly positioning the headset on the patient, obtain direct contact on all sensors before recording.

The range of impedances with dry sensors may be higher than what you are accustomed to when working with conventional wet sensor amplifiers. CGX devices utilize a combination of advanced electronics, shielding, and mechanics to obtain EEG signals even when contact is poor, and can tolerate sensor impedance up to 5,000 k Ω .

10. Start Third-Party EEG Analysis Software

Start third-party software. Connect Quick-20m to software according to third-party EEG Analysis software manufacturer's directions.

11. Adjust Pods, If Required, To Improve Impedance Measurements

Start the impedance check function on third-party software. Check for acceptable impedance measurements on each channel.

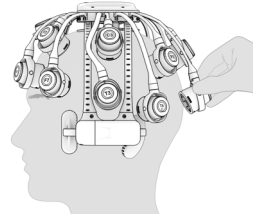
A1 Reference and Ground earclip must be applied for impedance check to operate.

To ensure good impedance measurements:

- Gently pull down on the handles until the Cz position reports adequate contact.

It is important the headset is seated properly in the correct position and all legs and pods are aligned with the patient's head before pulling down. Failure to do so may result in poor contact at the Cz position.

- Lift the pod slightly to move hair aside.
- Lower the pod back in place, keeping the sensor aligned to the patient's head.
- Gently twist the sensor adjustment back and forth to help move the sensor through the patient's hair.
- Lightly press down on the pod, holding for 5 seconds, then gently release the pod.



Grasp pod on sides to reposition



Gently twist swivel mechanism without displacing pod

Third-Party EEG Analysis Software

Only use authorized FDA-cleared third-party EEG analysis software with the Quick-20m. Contact CGX for a list of authorized software providers.

Use of non-authorized software may lead to system malfunction, data loss, and data corruption.

Follow third-party analysis software instructions for installation and refer to software manufacturer for information on cybersecurity/malware controls and ongoing software support.

12. Record An EEG

After you have acceptable impedance levels, record the EEG on the third-party EEG analysis software.

13. End The Session

Remove the batteries from the headset. The headset should be placed either upside down, with the top of the headset resting on a table top, or on its side resting on a handle.

Preventative Care To Maintain Safety And Effectiveness

To avoid cross-patient contamination, follow the cleaning instructions to clean sensors and headset after each use.

This device is not intended to be sterilized in an autoclave.

Cleaners listed below have been evaluated based on their chemical compatibility with the device materials. The cleaners and disinfectants tested and listed below may not be available in all countries.

Sensor Performance

While sensors do not have a set expiration date, the conductive coating will degrade with repeated uses. Regularly check the sensor surface for coating degradation and replace as needed. Contact CGX for replacement sensors.

Recommended Cleaning Agent

The recommended cleaning agents for all parts of the Quick-20m headset, including sensors and accessories is a germicidal wipe, such as Super Sani-Cloth Germicidal Wipe, or 70% isopropyl-based alcohol.

- Do not use water to clean the headset or accessories.
- Do not use 90% or 99% alcohol. These solutions will dry out and damage the sensors.
- Do not use detergents, enzymatic cleaners, or UV cleaners. These may damage the system and accessories.

Use the supplied carrying case when transporting the headset.

It is not recommended to leave the Quick-20m in the carrying case for long term storage since the legs may become compressed. This will not affect functionality, but may cause the headset to be excessively tight on larger heads.

To restore the shape of your headset, place on a mannequin head for several hours until the legs relax.

Super Sani-Cloth Germicidal Disposable Wipe

SDS Number/Formula SDS:
0020-00/4FQ51801

Mfg: PDI, Inc.

Follow manufacturer's directions for cleaning and disinfecting.

Cleaning Sensors

Use either of these two methods to clean sensors.

Immersion Method

1. Remove sensors from headset.
2. Immerse sensors in 70% isopropyl-based alcohol for 1 minute.
3. Remove from alcohol and let fully dry before re-installing in headset.

In Situ Method

1. Keep sensors in headset.
2. Clean sensors with Super Sani-Cloth Germicidal Disposable Wipes or 70% isopropyl-based alcohol wipes.
3. Be sure to thoroughly wipe all surfaces.
4. Let dry before reusing headset.

Cleaning The Sensor Pods, Legs, and Lead Wires

Use Super Sani-Cloth Germicidal Disposable Wipes or 70% isopropyl-based alcohol wipes to clean sensor pods, legs, and lead wires.

Cleaning The Amplifier

1. Turn amplifier Off.
2. Clean amplifier with Super Sani-Cloth Germicidal Disposable Wipes, or 70% isopropyl-based alcohol wipes.
3. Let amplifier dry fully before restarting system.

Do Not Let The Headset Come Into Contact With Liquid

In the event headset comes into contact with liquid, immediately take the batteries out and let the headset dry before resuming use.

Storage

- Transport headset in the case.
- Store headset in a temperature and humidity controlled room without the batteries.
- Remove and charge batteries when headset is not in use.

Disposal Instructions

To protect the environment, always follow local law, rules, and policies regarding electronic and battery disposal. You may also return the headset to CGX for proper disposal.

Clean Sensors Between Patients

The Quick-20m system includes 2 full sets of sensors.

Remove sensors after use with a patient, and replace with cleaned sensors for the next patient.

Clean one set while the other is in use.

Contact CGX for replacement sensors.

Follow These Advisories To Keep Your Quick-20m In Good Working Order

- Do not immerse the headset in liquid.
- Do not expose headset to direct sunlight or heat source, moisture, vibration, mechanical shock, excessive dust, or humidity.
- Do not open, modify or disassemble the headset — this will void the warranty.
- Do not use if the headset is damaged.
- Do not use when wet. If moisture penetrates the headset, remove the batteries and let it thoroughly dry prior to use.
- Do not use caustic or abrasive cleaners on the headset or sensors.
- Avoid bending the legs greater than 90° from resting position.
- Only use 1.2 or 1.5 volt AAA batteries.
- Do not use concurrently with any subject electrical or magnetic stimulation.

Obtaining Clean EEG Data

The most important aspect of EEG recording is that output data is only as good as the recording input. While algorithms exist to remove artifacts, poorly recorded data cannot be fixed in post processing.

Recording good EEG data requires preparation of the participant for optimal sensor contact:


1. Participants should have their hair recently washed and fully dried before recording. Wet hair, hair gel, conditioners, and hair spray may cause interference and degrade signal quality.
2. Clean the head directly below the intended sensor location with a 70% isopropyl-based alcohol wipe.
3. In the event of difficulty establishing good contact, apply a small amount of water between the sensor and scalp to create an electrical bridge.
4. It is important for patients to reduce tension in the head, neck, and shoulders during readings.

Quick-20m sensor locations lie within 1.0 centimeter on the vast majority of hand-measured 10-20 placements on heads sized from 52-62 centimeters.

Quick-20m EEG data should only be read and interpreted by a qualified physician.

Specifications

System	
Number Of EEG Physiological Acquisition Channels	20
Number Of EEG Reference Signal Acquisition Channels	1
EEG Electrode Material	Ag/AgCl coated plastic
Wireless Amplifier	
Input Resistance	>100 MΩ
Input Capacitance	<5 pF
Frequency Response	Linear between 0.1 and 100 Hz
Input Impedance	>100 MΩ
Signal Input Range	+/- 300 mV
Signal Output Range	+/- 300 mV
Ground Type	Active DRL
CMRR	>90 dB at 60 Hz
Gain	3
A/D Resolution	24-Bit simultaneous sampling analog-to-digital converters
A/D Conversion	24-Bit Delta-Sigma
Sampling Rate	500 samples per second
Bandwidth	0-131 Hz with true DC coupling
Accelerometer	3-axis, measures head motion
Wireless Range	10 meters
Noise	<0.6 μV RMS from 1-30 Hz, shorted inputs
CGX Product Compatibility	Compatible with CGX Wireless StimTigger
Sensors	
Use Rating	Drypad: 200 uses Flex: 200 uses Drypad Ear Sensor: 200 uses
Wireless Transmitter	
Modulation Type	Bluetooth Low Energy GFSK
Frequency Band	2.4 GHz ISM

Effective Radiated Power	7 mW
RF Radiated Group 1 Class B Emissions, CISPR 11	
Device uses RF energy for internal functions. Low RF emissions are not likely to cause any interference in nearby electronic equipment.	
RF Conducted Group 1 Class B Emissions, CISPR 11	
Device can be used in all establishments, including domestic establishments.	
Electrostatic Discharge (ESD), IEC 60100-4-2	
±15 kV air ±8 kV contact	
<ol style="list-style-type: none"> Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Electrodes are sensitive to ESD events. In case of an ESD event, the device will automatically recover. In the unlikely event of unexpected malfunction, turn the device OFF, then ON again. 	
RF Immunity, IEC 60100-4-3	
Test level: 3V/m with 80% AM at 1 kHz modulation, 80 MHz – 2.7 GHz Compliance level: 3/m	
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
Recommended separation distance: $d = 1.2\sqrt{P}$ 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 according to the transmitter manufacturer and d is the recommended separation distance in meters.	
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:	
	

Quick-20m Headset

3 year warranty on manufacturing defects. 90 day warranty on accessories and disposable parts. Warranty is void if the device has been opened or tampered with.

Replacement Sensors And Parts

Contact CGX at Sales@CGXSystems.com for purchases.

System Support

System firmware can not be modified in the field. In the unlikely event firmware modification is required, CGX will inform the original purchaser, and will arrange for the device to be returned to CGX for modification.

Third-Party EEG Analysis Software Support

To ensure delivery of malware-free software, download software and updates from approved third-party sources. Third-party software updates should only be made according to that manufacturer's instructions. Refer to third-party software provider for cybersecurity considerations.

Returns

All units returned to CGX for repair and assessment must have an RA (return authorization) number issued by CGX.

CGX will pay outbound shipping costs only.

Ship all returns with an RA number to:

CGX

Attn: Service

8445 Camino Santa Fe, #213

San Diego, CA 92121



Covered by Patents issued and/or pending under license from Cognionics, Inc.

US9314183B2, US9615761B2, US9935726B2, US8798710B2, and International patents.

Quick is a trademark of CGX, LLC. NeuroGuide is a registered trademark of Applied Neuroscience, Inc.

CGX A Cognionics Company

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