CGX Patch™ EEG

This manual includes operating instructions, maintenance instructions, and general information for use of the CGX Patch EEG device. Carefully read this manual to familiarize yourself with the device, software, and accessories before use.

Description

The Patch EEG is a wireless, battery-operated EEG device utilizing a proprietary HydroFlex™ Electrode. The device provides an integrated approach to the wireless acquisition of EEG signals. A seated, supine, or sleeping patient is free to exhibit natural movements while real-time data is collected via Bluetooth.

The Patch EEG includes advanced amplification to reject ambient electrical noise. The Patch EEG can also record data to a MicroSD Card.

The device obtains high-quality EEG with minimal forehead preparation. Proprietary mechanisms and a disposable semi-solid gel electrode align to various head shapes and sizes. EEG channels are digitized with 24 bits of resolution at 500 Hz. The Patch EEG is suitable for general-purpose EEG.

The Patch EEG device can be used with the CGX Flowpoint desktop software running the Patch EEG Plug-In to display, record, and read EEG files.

Warnings

The Patch EEG is intended to be used to acquire the electroenchephalogram (EEG) and transmit it wirelessly to a computer running CGX Flowpoint Software with the Patch EEG Plug-In.

The Patch EEG device 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

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

Sizing Considerations

This device fits people aged 9 and above with a forehead box between 44 mm (height) and 116 mm (width) as shown.

Height is the distance from the top of the eyebrows to the center of forehead hairline.

Width is the distance between the left and right hairline above the eyebrow.

Forehead Box

Warnings

Precautions For The Practitioner

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

Patient Considerations

- This device is intended for human use only.
- Patient should have a healthy forehead.
- This device fits adults and children approximately 9 years and older with forehead height greater than 44 mm and forehead width greater than 116 mm.
- Do not use with infants or neonates.
- The entire Electrode must be able to contact the patient's forehead.
- The entire device may come into contact with the patient's skin.

Avoid Sweat

The Electrode may become loose if the patient's forehead is sweating. Keep the forehead as dry as possible during use.

Disposable HydroFlex Electrodes

- Keep HydroFlex Electrodes in their sealed pouch until ready to use.
- Discard HydroFlex Electrode after each session.

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.

Warnings

Always Use Supplied Accessories

Using accessories other than those supplied with your Patch EEG system may result in damage or diminished efficacy of the system.

The Patch EEG uses an internal rechargeable Li-Ion battery and can not be accessed by the user.

Avoid Cross-Patient Contamination

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

Clean the device and replace HydroFlex Electrode after use following the cleaning instructions on Page 24 to avoid cross-patient contamination.

Care Instructions

The Patch EEG is constructed of durable materials. 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:

- Patch HydroFlex Electrodes
- Carrier
- BPU

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.

The Patch EEG is MR Unsafe.

Keep it outside the MRI scanner room.

Warnings

- Breach the BPU. This will void the warranty.
- Use caustic or abrasive cleaners on the BPU or Carrier.

Cybersecurity

The Patch EEG does not pose an inherent cybersecurity risk. The wireless Bluetooth system relies on a built-in security encryption method utilizing 128-bit AES encryption.

Performance Warnings

The Patch EEG 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 biopotential waveforms may have environmental artifacts including unanticipated high frequency components.

Performance Degradation

The Patch EEG 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
	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 th 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.

Warnings

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

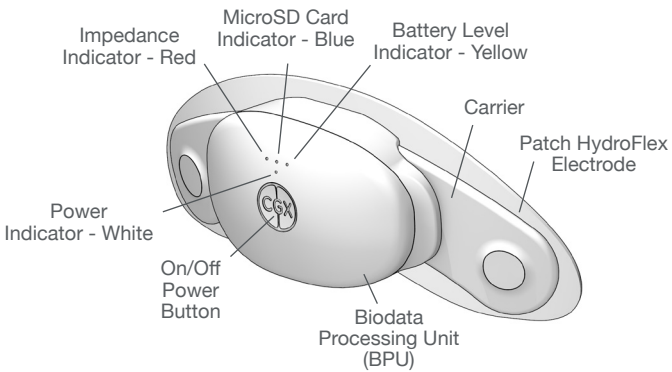
Portable RF communications equipment, including peripherals like antenna cables and external antennas, should be kept at least 30 cm (12 inches) away from any part of the Patch EEG, including the manufacturer-specified cables. Failure to maintain this distance may result in degraded equipment performance.

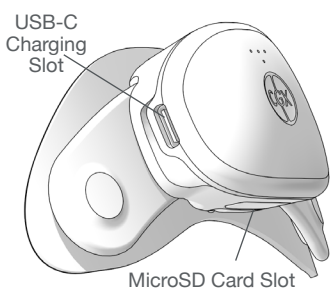
Device Overview

The Package Contains The Following Items

Biodata Processing Unit (BPU)
Bluetooth Dongle
Carrier
MicroSD Card and Adapter
USB-C Charging Cable
Charging Block
Carrying Case
Manual

Patch EEG Device





Device Overview

Biodata Processing Unit

Wireless amplifier collects signals, saving to removable MicroSD card or transmitting to Bluetooth Dongle.

Bluetooth Dongle

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

Carrier

Carrier interfaces and transfers EEG signals from the HydroFlex Electrode to the BPU.
Part # CAR-PEG-10

HyroFlex Electrode

Disposable HydroFlex Electrode affixes to the forehead. Can be used continuously for 14 hours.
Part # SEN-PEG-10

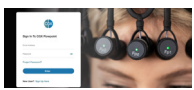
MicroSD Card

Commercially available MicroSD Card. See CGX website for replacement recommendations.

MicroSD Card Reader

Commercially available MicroSD Card reader. See CGX website for replacement recommendations.

Flowpoint Software + Patch EEG Plug-In



Windows-based desktop software to format the Patch EEG MicroSD Card, and display, record, and read Patch EEG data files.

Create A CrunchBox Account

CrunchBox is the CGX App portal where you download CGX software. You will need to register an account in order to proceed.

1. Go to CGXCrunchBox.com
2. Create an account

Download The CGX Flowpoint Software

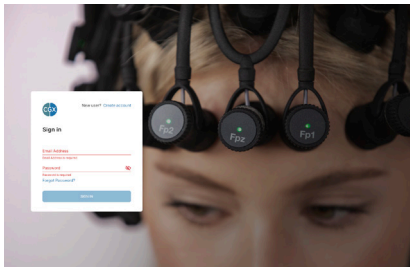
Flowpoint desktop software is a Windows-based program that displays, saves, and reads CGX device files. After creating a CrunchBox account, navigate back to CGXCrunchBox.com to download Flowpoint and the CGX Patch EEG Plug-In.

Please see the Flowpoint User Guide for complete instructions.

Using The CGX Patch EEG Plug-In

The Patch EEG Plug-In allows you to:

- Sync the date and time on the Patch EEG internal MicroSD Card with your computer
- Add patient metadata to a MicroSD card recording
- Monitor battery level of the device
- Stream the Patch EEG output live through a Bluetooth connection
- Save Patch EEG files in .CSV and .EDF format for further analysis
- View and convert .CGX files



Go to CGXCrunchBox.com to download Flowpoint and the CGX Patch EEG Plug-In

Auto-Sync Date And Time

Set the device date and time by setting the **Info & File Settings**. This syncs the Patch EEG device's internal clock with the computer's clock, ensuring files generated on the SD card have the correct start and end times.

Info & File Settings

Enter optional patient data to be appended to the file name of a Patch EEG recording, including Patient Code, First Name, Last Name, Gender, and Birth Date.

Streaming

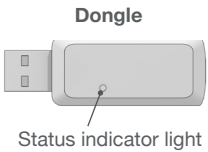
Stream live data from the Patch EEG device into Flowpoint.

Insert Bluetooth Dongle Into Windows-based Computer

Each Patch EEG 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.

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

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



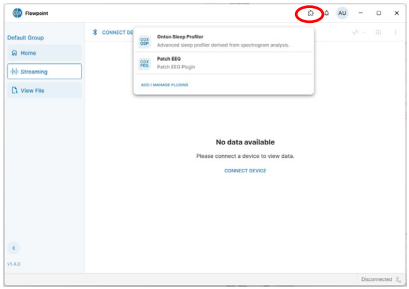
Dongle Status Light		
Color	**Status**	**Indication**
Green	Solid	Power **ON** Pairing **OFF**
Purple	Solid	Searching For Device
Blue	Solid	Device Found
Blue	Flashing	Data Transmitting

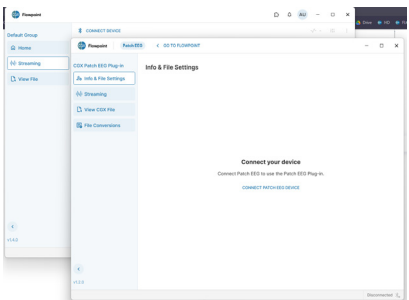
Navigate to Patch EEG Plug-In

1. Open Flowpoint.
2. Click the Plug-In icon on the top right corner.
3. Select Patch EEG Plug-in.

The Patch EEG Plug-in window will appear. Select the Pavch EEG Plug-in.

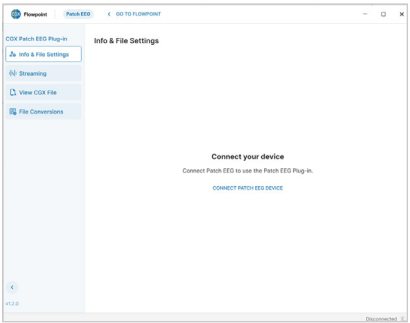
The Patch EEG Plug-in allows you to connect to the Patch EEG device.

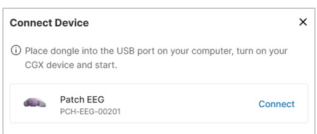




Connect Device

1. Insert the dongle into the USB port
2. Turn on the Patch EEG device
3. Select **Connect Patch EEG Device**





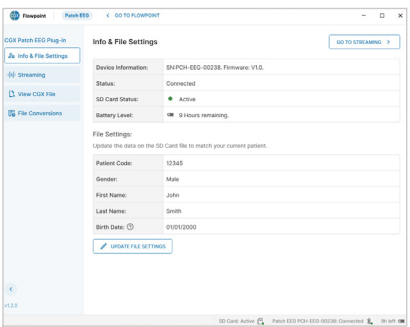
Info & File Settings

Enter optional patient meta data. All fields accept 32 alphanumeric characters. (The underscore character "_" is not permitted.)

- Patient Code
- First Name
- Last Name
- Gender
- Birth Date

This information will be used to create the file name on the MicroSD Card, using this rubric:

Patient ID_First name_Start day_ month_year_hour_minute_second_ to_End day_month_year_hour_ minute_second



The system uses a 24-hour time format.

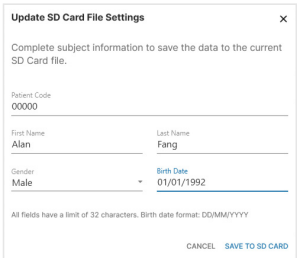
Example

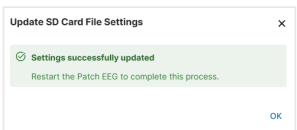
00000_Alan _5_4_24_13_25_20_ to_5_4_24_21_25_38.cgx

Explanation

April 5th 2024, 13:25:20 and ends April 5th 2024, 21:25:38.

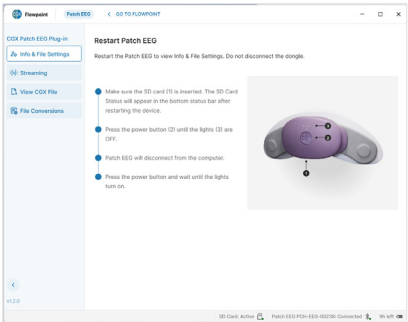
Patient metadata will also be included in the header of the recorded file.

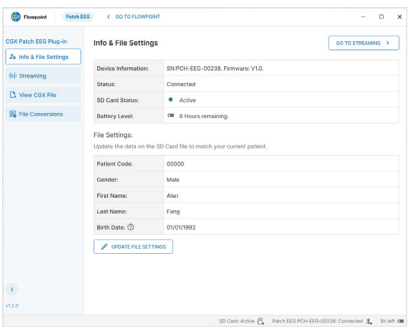




Turn Off and Turn On Patch EEG

After updating the Info & File Settings, follow the prompts and power cycle the Patch EEG device by turning it On and Off to register the changes.





Streaming

Click on Streaming to stream live data.

Display

You can adjust the default filter settings if desired. These settings control the display only and do not impact the recording of the signal.

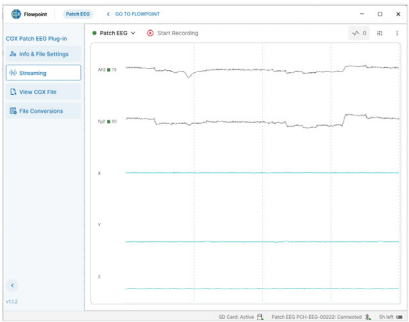
- Low Pass
- High Pass
- Time Scale
  This impacts the horizontal display
- EEG Scale
  This impacts the vertical display
- ACC Scale
  This impacts the vertical scale of the acceleromoter channels.

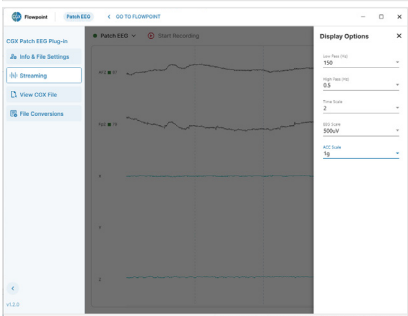
Impedance Measurements

When a channel is experience high impedance, the channel displays a red background.

Battery Display

Battery level is displayed on the bottom right corner of the window.

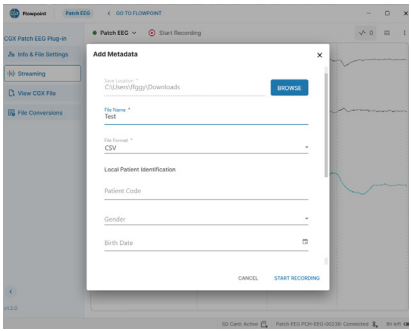




Live Recording

Click **Start Recording** to begin recording live data.

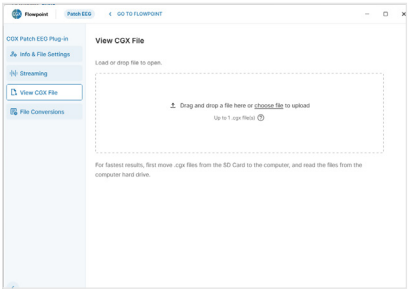
1. Enter the file name
2. Choose the file format (.CSV or .EDF)
3. Add optional patient information
4. Click **Start Recording**

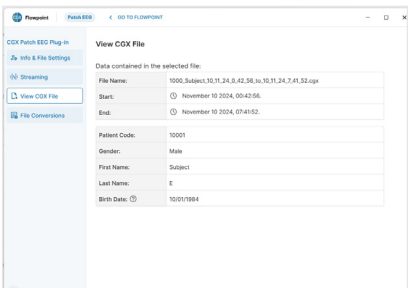


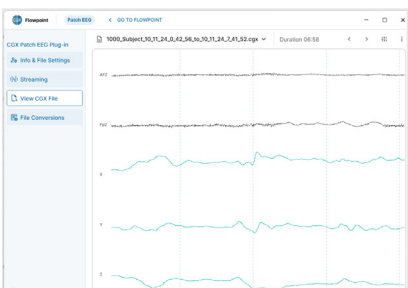
View CGX File

To view the raw data, select the desired .CGX file.

If you accidently change the .CGX file name, and try to view the file, it will show an error. Change it back to the required convention to view the .CGX file. See page 14 for example.



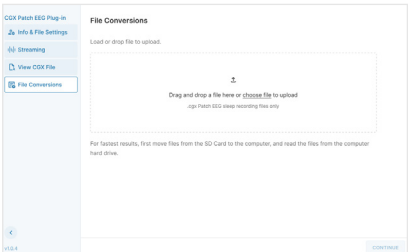


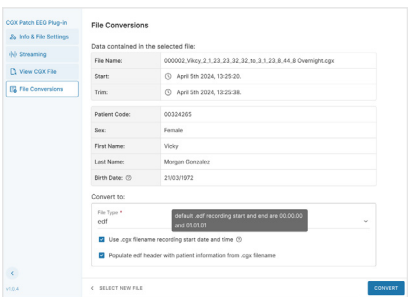


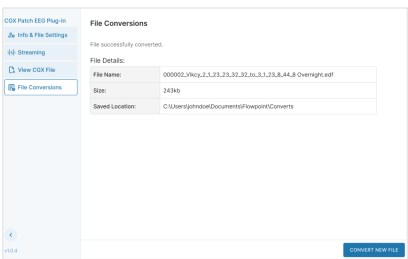
File Conversion

You can convert a .CGX file into an .EDF or .CSV file. The converted file will be stored in the **Saved Location**.

1. Drag a .CGX file into the File Conversion window
2. Choose export format: .EDF or .CSV







Streaming To Flowpoint

Data streaming to the CGX Flowpoint software is automatic when the Patch EEG is ON and paired with Flowpoint.

See Page 17 for more information.

Recording To A MicroSD Card

Data recording to a MicroSD Card is automatic when the Patch EEG is ON and a MicroSD Card with available storage space is inserted.

The supplied removable MicroSD Card will hold approximately 150 hours of session data, including EEG and accelerometer information.

Formatting the MicroSD card

- Download the MicroSD Card Formatter: https://www.sdcard.org/downloads/formatter/
- Insert the MicroSD card into the MicroSD card reader and connect reader to computer
- Open the MicroSD Card Formatter and select the appropriate card under **Select Card**
- Select **Quick Format** under Formatting Options and click **Format**

Reformat the SD card regularly for best performance

Installing the MicroSD card

Insert the supplied MicroSD card into the device by lifting the rubber door. Close the door after installing the card to keep out moisture and debris.

Use the supplied MicroSD Card (see the CGX website for recommended brand and model replacement cards).

Note: MicroSD Card brands and models are not interchangeable, and use of a non-recommended card may result in data loss.

Reading the MicroSD card in Flowpoint

- Remove the MicroSD card from the device and place into the supplied MicroSD card reader
- Insert the reader into a Windows computer running Flowpoint
- Choose Open Saved File
- Open the desired file to display in the Flowpoint run window

Insert MicroSD Card

Close MicroSD door after installation of MicroSD card

Preparing The Patch EEG Device For Use

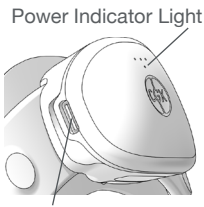
1. Charge The Battery

Fully charge the Patch Device before using

- Attach the USB-C cable to the charging block and to the port on the left side of the BPU, as shown
- Plug the charger into an electrical outlet
- Note the status of the white Power Indicator light on the face of the BPU

White Power Indicator Light	
Status	**Indication**
Flashing	Charging (while plugged into an electrical outlet)
Solid	Fully charged

Charging The Battery



Attach USB-C cable to charging port.

2. Check MicroSD Card

If recording a session, check MicroSD card is installed and functioning properly. See Page 10 for information on checking MicroSD status through the Patch EEG Plug-In.

3. Remove HydroFlex Electrode From Packaging

Take a HydroFlex Electrode from the pouch without peeling off the protective cover.

Note: Replacement Patch Electrodes can be purchased through the CGX website. See back page for more information.

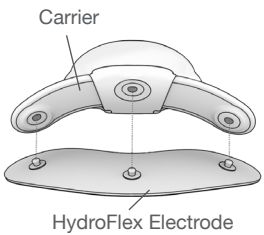
Preparing The Patch EEG Device For Use

4. Attach HydroFlex Electrode To Carrier

Keeping the protective cover on, attach the HydroFlex Electrode at the three snap locations to the Carrier. Try to keep the Carrier as flat as possible when securing the HydroFlex Electrode to prevent damage.

Be sure the HydroFlex Electrode is securely snapped to the Carrier before starting an EEG session.

Align the three snaps on the HydroFlex Electrode to the snaps on the Carrier and affix.



Donning

Preparing The Patient

Once you've completed the Patch EEG device setup, you can attach the device to a patient. The Patch EEG is simple to use, and most patients will have no problems self-donning. Keep the Patch EEG device OFF until you are ready to being a recording session.

1. Prepare The Forehead

- Clean the forehead with the 70% isopropyl alcohol wipe included in the Electrode pouch
- Let skin dry fully
- Brush aside any hair from the forehead before placing the Patch EEG device. Hair under the Electrode may impact performance.

2. Remove The Electrode's Protective Cover

Removing the cover reveals the sticky hydrogel layer. Hydrogel is a skin-safe material that adheres to the skin and detects the small electrical currents in the brain.

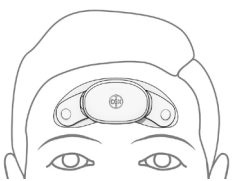
Remove the protective backing from the HydroFlex Electrode, revealing the sticky hydrogel layer

3. Place The Patch EEG On The Patient's Forehead

Once again, brush aside any hair that may be in the way of the Patch EEG Electrode.

- Adhere the Patch EEG device directly to the patient's forehead, with the Electrode:
  - > Below the hairline
  - > Above the eyebrows
  - > Centered side-to-side
- Push the device against the forehead, making good contact with the skin.
- Smooth out any wrinkles that may have formed under the Electrode

Note: Wrinkles in the Electrode will not degrade performance.



Place the Patch EEG below the hairline and above the eyebrows

4. Verify Placement

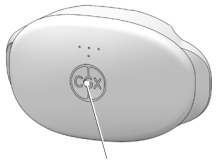
Before starting a recording session, verify device is properly positioned on the patient's head.

Ask the patient for any areas of discomfort and, if necessary, reposition the device.

Note: The electrode may need to be replaced if it is not sticking firmly to the forehead after repositioning.

5. Turn On Device

Turn on the device by pushing on the Power Button. The Patch EEG will begin a self-diagnostic start-up sequence once the device is turned ON.



Push Power Button (CGX logo) to turn the device ON.

6. Check the Patch EEG System Status Lights

Look at the System Status Lights on the face of the BPU. The White light stays lit while the device is powered ON. The Yellow, Blue, and Red indicator lights only appear when the self-diagnostic start-up sequence encounters a problem.

Note: The self-diagnostic start-up sequence runs for the first 30 seconds when the device is powered ON.

Patch EEG System Status Lights			
Color	**Function**	**Indication**	**Action**
Flashing Yellow	Battery level check	Battery has less than 8 hours of run-time	Recharge system prior to use
Flashing Blue	MicroSD Card Status	MicroSD Card not present or malfunctioning	• Check if MicroSD Card is inserted properly • Check if MicroSD Card has available memory • Check if MicroSD Card is correct brand and type • Ignore if no MicroSD Card is being used for the session
Flashing Red	Impedance	Electrode not making proper skin contact	Discard the electrode and repeat Step 3 *Place The Patch EEG On The Patient's Forehead* using a new electrode
White	Power	Device is ON	

To avoid cross-patient contamination, follow the cleaning instructions to clean the device 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.

Super Sani-Cloth Germicidal Disposable Wipe
SDS Number/Formula SDS: 0020-00/4FQ51801
Mfg: PDI, Inc.
Follow manufacturer's directions for cleaning and disinfecting.

Recommended Cleaning Agent

The recommended cleaning agents for the Patch EEG Carrier and BPU are a germicidal wipe, such as Super Sani-Cloth Germicidal Wipe, or 70% isopropyl-based alcohol.

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

Cleaning The BPU

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

Preventative Care To Maintain Safety And Effectiveness

Do Not Let The Device Come Into Contact With Liquid

In the event device comes into contact with liquid, Immediately turn the device OFF and let it dry before resuming use.

Storage

- Transport device in the case
- Store device in a temperature and humidity controlled room

Disposal Instructions

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

Follow These Advisories To Keep Your Patch EEG In Good Working Order

- Do not immerse the device in liquid.
- Do not expose device to direct sunlight or heat source, moisture, vibration, mechanical shock, excessive dust, or humidity.
- Do not open, modify or disassemble the device — this will void the warranty.
- Do not use if the device is damaged.
- Do not use when wet. If moisture penetrates the device, let it thoroughly dry prior to use.
- Do not use caustic or abrasive cleaners on the device.
- Do not use concurrently with any subject electrical or magnetic stimulation.

Replacing The Carrier

Replace the Carrier if it has degraded from use, is torn, or does not make firm contact with the Electrode.

The Carrier is rated to last for 500 uses before requiring replacement. See back page for ordering information.

To replace the Carrier:

1. Remove the Carrier clip from the BPU by sliding the pin as shown.
2. Gently clean the exposed area of the BPU and the new Carrier with a 70% alcohol wipe and let dry.
3. Place the Carrier into position and slide the clip back into position as shown.
4. Test with a new HydroFlex Electrode.

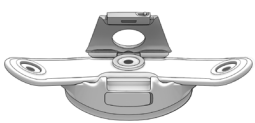
Remove Old Carrier

Slide pin left. Lift right side of the clip.

Slide pin right. Lift entire clip.

Remove old Carrier

Install New Carrier



Place the new Carrier into the housing, being certain to align the circular openings between the arrier and and the enclosre.

Slide pin right. Push clip down until pin snaps into place

Slide pin left. Push clip down until pin snaps into place

Specifications

System	
Number Of EEG Physiological Acquisition Channels	2
Number Of EEG Reference Signal Acquisition Channels	1
EEG Electrode Material	Hydrogel, Skin Safe PSA (Pressure Sensitive adhesive), Skin Safe Foam
Wireless Amplifier	
Input Resistance	>100 MΩ
Input Capacitance	<13.5 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	Passive
CMRR	>90 dB at 60 Hz
Gain	6
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

Specifications

Accelerometer	3-axis, measures head motion
Wireless Range	10 meters
Noise	<0.6 µV RMS from 1-30 Hz, shorted inputs
Electrodes	
Use Rating	Single use
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 1. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. 2. Electrodes are sensitive to ESD events. In case of an ESD event, the device will automatically recover. 3. 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:

Notes:
1. At 80 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations
3. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Specifications

Output Format	
Real-Time Streaming API	Full access to raw data
Continuous Impedance Check	Real-time monitoring of all channels simultaneous with EEG with CGX Flowpoint Software and Patch EEG Plug-In
Export Data To	CGX proprietary file format.
Resolution	24-Bit
Phase Jitter Between Channels	0
Power	
Power	Internal, rechargeable Li-Ion battery
Supply Voltage	3.7 V DC
Power Consumption	0.09 VA, 14 hour battery life
General	
Applied Part	Type BF
Ingress Protection	IP22
Temperature Range	40-104° F (5-40° C)
Humidity Range	65 Rh +/- 20%
Pressure	70 kPA to 106 kPA
Altitude	-390m to 3,012m
Weight	43g in use
Fitting	Age 9 and above with forehead box height larger than 44 mm and width larger than 116 cm
Dimensions (HWD)	44 x 116 x 24 mm

Specifications

Certifications	
Safety Standards	IEC 60601-1 / AAMI ANSI ES60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 80601-2-26 ISO 14971 IEC 62304 / AAMI ANSI IEC 62304 AAMI ANSI ISO 10993-1 AAMI ANSI IEC 62366 IEEE 2010-2012
SweynTooth Vulnerabilities	The Patch EEG has been evaluated for potential exposure to the SweynTooth family of vulnerabilities and is not susceptible.

Electro-Magnetic Compliance		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The Patch EEG 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 A	The Patch EEG 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.
Harmonics IEC 61000-3-2	PASS	
Flicker IEC 61000-3-3	PASS	

Specifications

Electro-Magnetic Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PATCH EEG requires continued operation during power mains interruptions, it is recommended that the PATCH EEG be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Specifications

Electro-Magnetic Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V1) in ISM between 0.15 MHz and 80 MHz2) 80 % AM at 1 kHz	3 V 0.15 MHz-80 MHz 6 V1) in ISM between 0.15 MHz – 80 MHz	HOME HEALTHCARE PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	HOME HEALTHCARE PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

1) r.m.s. before modulation is applied.
2) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

Specifications

Electro-Magnetic Compliance						
Test Frequency	**Band[1]**	**Service[1]**	**Modulation[2]**	**Max. Power**	**Distance**	**Immunity Test Level**
MHz	**MHz**			**W**	**Meters**	**(V/m)**
385	380-390	TETRA 400	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation[2] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[2] 18 Hz	2	0.3	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[2] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[2] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n		0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included. [2] The carrier shall be modulated using a 50 % duty cycle square wave signal. [3] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Warranty and Service

Patch EEG Device

90 day warranty on the BPU and Carrier. Warranty is void if the device has been opened or tampered with.

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.

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

Replacement Parts

HydroFlex Sensors (SEN-PEG-10-100)

Carrier (SUB-1004-A)

8445 Camino Santa Fe, #213 San Diego, CA 92121
858-864-9400 Sales@CGXSystems.com

MAN-0002-A