BrainScope EEG Capabilities

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Introduction

BrainScope is an FDA cleared, point-of-care device that facilitates the rapid acquisition of quality EEG recordings. The device uses sophisticated proprietary FDA cleared algorithms for artifact detection and marking for removal. The device also provides real time feedback to the operator during EEG acquisition as to the presence and type of artifact and progress. The instructions for use and design of the single-use electrode headset assures ease of use and proper placement by any health care professional. During electrode application, the device provides feedback to the operator on connectivity. During the assessment, the device provides real-time feedback on the presence of artifacts and the acquisition of artifact-free EEG signal. Continuous monitoring of impedance (maintaining electrode connection to the scalp), assures high reliability of the recording for the clinical assessment of EEG.

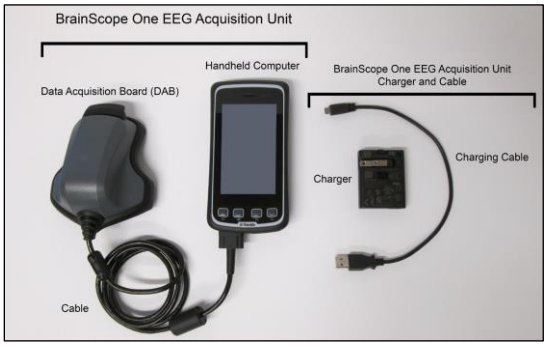


Figure 1: BrainScope data acquisition unit and charging peripherals.

Figure 2: Patient with headset in place on the forehead, being tested.

EEG Acquisition

The BrainScope handheld medical device is used to acquire eyes closed resting EEG data. The EEG data is recorded from 8 electrode locations of the standardized expanded International 10-20 Electrode Placement System, referenced to linked ears. The EEG data is acquired at a sampling rate of 1 kHz and all electrode impedances are below 10 kΩ. Amplifiers have a band pass filter from 0.3 to 250 Hz (3 dB points) and EEG data is down sampled to 100 Hz for feature extraction. **Figure 1,** shows the BrainScope EEG acquisition unit and peripherals and **Figure 2** shows the headset affixed to a patient's forehead.

Impedance checks

The device is equipped with impedance checking to confirm proper adherence of the electrode to each placement location (frontals, fronto-temporals and ear lobes). The user is provided with the actual impedance levels attained, and color coding for easy feedback, with green<5 kΩ, yellow=<10>5 kΩ, and red ≥10 kΩ. The device will not permit acquisition to begin until all leads are below 10 kΩ. Figure 3 shows an example of impedance measurements as shown on the device screen during preparation of the headset, prior to starting data acquisition. While all greens are

preferred, data can be collected with green and/or yellow levels.

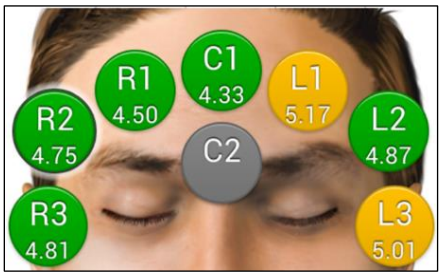


Figure 3: Image shown on device during placement of the headset with impedance for each electrode shown and color coded for level.

Continuous monitoring of impedance occurs throughout the recording and is displayed on the acquisition screen so that the operator is notified, and acquisition is stopped if any lead rises above 10 kΩ. Figure 4 shows an example of an acquisition screen, and shows the traces, a gray area marking identification of an artifact (marked for removal prior to post-hoc statistical analyses), and the color-coded indicator of real-time impedance status. Under normal acquisition conditions the user observes the patient throughout data acquisition for vigilance, and alerts the patient if necessary, for example, if they appear drowsy.

Artifact identification

On-line artifact rejection algorithms are used to identify signals which are not of brain origin and mark them for later removal prior to quantitative analyses. The artifact algorithms identify EEG data contaminated by any of the following: vertical eye movement (blinks), horizontal/lateral eye movements, muscle activity (EMG), head movement, high frequency impulse signals, significantly low amplitude, and atypical electrical activity (e.g., spike-wave complexes).[1]

Importantly, these algorithms were validated in comparison to visual editing by an EEG experienced expert and shown to have a high percentage of data overlap (87.6%) which is significantly higher than the average inter-rater agreement reported in the literature between experienced visual editors.[2] The artifact algorithms were FDA cleared in 2009 as part of the BrainScope device.

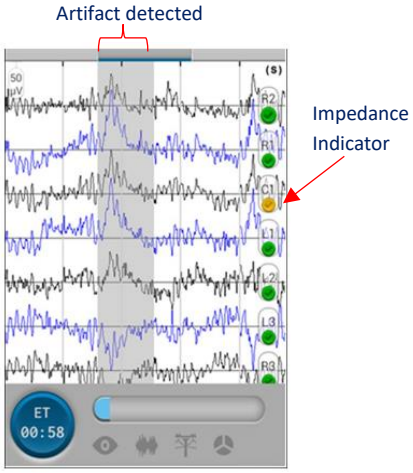


Figure 4: Device screen showing the EEG traces during acquisition. The colored circle on the far right provides real-time information about impedance on each lead. The grey area in the center of the screen indicates the identification of an "artifact" (see below).

The operator is guided during data acquisition by feedback about the presence of artifacts throughout the recording on a dashboard screen, see Figure 5. The dashboard indicates the collection progress of artifact-free data, as well as "flashing" artifact symbols when specific artifacts are present. The dashboard indicates the type of artifact detected in 4 main categories (eye movement, muscle activity, electrical interference, and other) and the operator is

[1] Prichep LS, Jacquin A, Filipenko J, Dastidar SG, Zabele S, Vodencarevic A, Rothman N. Classification of traumatic brain injury severity using informed data reduction in a series of binary classifier algorithms. *IEEE Trans Neural Systems Rehab. Engin.* 2012;20(6):806-822.

[2] Norman RG, Pal I, Stewart C, Walsleben JA, Rapoport. Interobserver agreement among sleep scorers from different centers in a large dataset. *Sleep*. 2000;23(7);901–908.

provided through periodic on-screen messages regarding information on possible mitigation strategies to aid in instructing the patient toward the aim of collection of artifact-free data more rapidly**.**

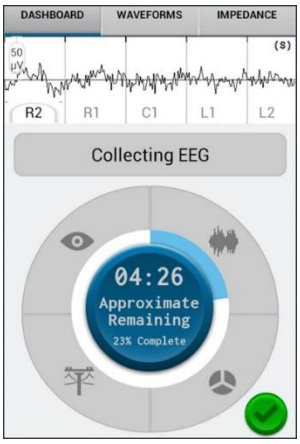
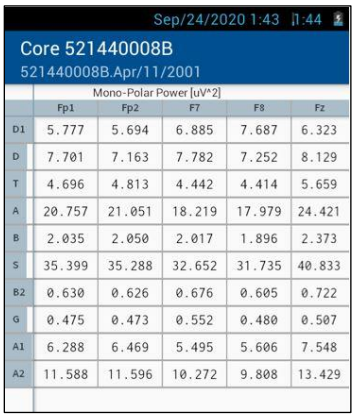


Figure 5. The dashboard provides a blue ring showing progress in data collection of artifact-free data (center ring), and the type of artifact when present is seen by the symbols around the outer ring.

BrainScope EEG acquisition is programmed to identify two minutes of artifact-free (clean data with no artifacts) from 10 minutes of continuous recording. This artifact-free data is used to power the FDA cleared machine learning algorithms for likelihood of structural and functional brain injury assessment. In the case of BrainScope, the *stationary* background state of the EEG is of primary interest.

EEG data replay and tabular results

The BrainScope device provides the ability to replay the continuous EEG recording on the device (including artifacts), export the EEG record (.edf), and a set of tabular data of extracted features. These features include: absolute power, relative power, mean frequency, power asymmetry and coherence for each monopolar and bipolar lead derivation, for each frequency band (delta, theta, alpha, beta, total, beta2, gamma1, alpha 1 and alpha2) and fractal dimension (total power). Figure 6 shows the table for monopolar absolute power for 5 scalp locations, for all frequency bands.



	Fp1	Fp2	F7	F8	Fz
D1	5.777	5.694	6.885	7.687	6.323
D	7.701	7.163	7.782	7.252	8.129
T	4.696	4.813	4.442	4.414	5.659
A	20.757	21.051	18.219	17.979	24.421
B	2.035	2.050	2.017	1.896	2.373
S	35.399	35.288	32.652	31.735	40.833
B2	0.630	0.626	0.676	0.605	0.722
G	0.475	0.473	0.552	0.480	0.507
A1	6.288	6.469	5.495	5.606	7.548
A2	11.588	11.596	10.272	9.808	13.429

Figure 6: Monopolar Absolute Power tabular values for FP1, FP2, F7, F8 and aFz scalp locations for all

What is the difference between EEG and qEEG?

EEG (electroencephalogram) is a recording of electrical activity of the brain (brainwaves), using small sensors (electrodes) attached to the head. An EEG detects very small electrical charges that reflect neuronal activity of the brain. These signals are then amplified and can be graphed for visual inspection. In current time, conventional electroencephalographers take advantage of programs that allow them to extract standard features describing most typically the amplitude and frequency composition of the EEG. This begins to cross over to qEEG (quantitative electroencephalogram) as the waveforms are submitted to further analysis.

qEEG processes the EEG data to allow quantitative characterization of the signal into features that can be used to describe brain activity. qEEG enables use of statistical analyses for further exploration of features of brainwaves, often not able to be detected by visual inspection (e.g., phase synchrony). It has also been demonstrated that changes in the EEG with age can be described mathematically and that deviations from the age expected normal values can be used to statistically describe abnormal

signals in an individual, removing the effect of age. Also, importantly, EEG has very high time resolution (milliseconds) and can capture physiological changes much better than other brain imaging tools (e.g., MRI or PET), making it uniquely suited to reflect the types of changes in brain activity that occur in mTBI.

BrainScope uses qEEG features (with age regression) as inputs to AI/machine learning algorithms that describe distinctive profiles of brain electrical activity used to determine the likelihood of structural and functional brain injury with high accuracy[3]. The algorithms provide a multivariate interpretation of the EEG data, which can be thought of as a composite of abnormal features which are found in the individual's EEG and the likelihood that an individual with that pattern will be CT+ or CT-, or if they have brain function impairment such as that seen in concussion. This capability does not require a neurologist or electroencephalographer to "read" the brain waves and allows comparison to large populations of patients with closed head injury.

Conclusion

The BrainScope FDA cleared medical device provides EEG data acquisition and review capabilities. During recording, real-time online feedback is provided to the operator to aid in minimizing artifact and maintaining high quality. Further, BrainScope's validated, machine learning, FDA cleared algorithms provide objective markers of the likelihood of structural and functional brain injury, to aid in the clinical evaluation of the patient. The integration of the BrainScope output with the clinical assessment of the patient, patient history, and other evaluations performed, provides an objective marker of mTBI to assist in the clinician in making his/her diagnosis.

[3] Hanley D, Prichep LS, Bazarian J, et al. Emergency Department Triage of Traumatic Head Injury Using Brain Electrical Activity Biomarkers: A multisite Prospective Observational Validation Trial, *Acad Emerg Med.* 2017;24(5):617-627.