BrainScope®

REVOLUTIONIZING HEAD INJURY AND CONCUSSION ASSESSMENT

4.8 MILLION
brain injury-related ER visits every year[1]

84%
OF ER VISITS
result in a head CT[2]

47%
INCREASE
in brain injury-related ER visits between 2007 and 2013[1]

91%
OF CT SCANS
are negative[2]

95%
of head injuries are mild[2]

A GROUNDBREAKING SOLUTION FOR A LARGE AND GROWING NEED.

Sustaining a head injury is common and widespread, from home to workplace to athletic field to military environments. Awareness and concern around the dangers of brain injury have increased sharply. Head injury-related visits to the emergency room have grown almost 50% in the last 10 years.

And yet, assessing these injuries has been problematic. Clinical diagnosis of potential brain injury in the ER relies largely on CT scan findings—effective in screening for bleeding and intracranial brain injury, but not for functional injury such as concussion, where physicians have relied on subjective report and response tests, with no clear accepted clinical diagnostic criteria.

SUBJECTIVITY   **CT SCAN**

The **BrainScope One** system fills the gap.

It answers the need for an objective, quantitative, comprehensive assessmentfor mildly presenting head injury, that can be performed quickly, reducing unnecessary exposure to radiation.
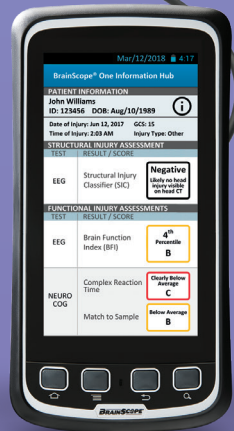
BRAINSCOPE® ONE

Forehead-only disposable EEG headset for proper and rapid application

Electrode solid gel eliminates need for wet conductive gels, allowing fast, user-friendly placement and removal

Electrodes are labeled for accurate placement

Ruggedized handheld device for durability and ease of use in any environment

Handheld serves as a centralized hub for display and use by provider and patient

Quick, Easy 3-Step Process

STEP 1
EEG Measurement:
5 min prep, 5 min for test

STEP 2
Cognitive Performance Tests:
8 minutes

STEP 3
Digitized Concussion Assessments:
Variable by selected assessments

RAPID, ACCURATE ASSESSMENT AT THE POINT OF CARE.

Combining state-of-the-art handheld technology with a user-friendly disposable headset, the BrainScope One system, leveraging advanced algorithms and machine learning technologies, identifies and evaluates physiological biomarkers of brain injury. The system is engineered for fast, confident decision-making— even in challenging settings—integrating easily in acute assessment without impinging on the patient care path.

The BrainScope One system provides objective data that helps clinicians answer two key questions in mildly presenting head-injured patients:

1. Is it likely that there is a structural brain injury that would be visible on a CT scan?

2. Is there evidence of functional brain impairment that could indicate a concussion?

BrainScope One addresses these questions using a panel of multi-parameter capabilities that help physicians make confident decisions based on objective, physiologically-based information. The system provides four primary capabilities, which can be configured to meet users' needs:

- EEG-Based Capabilities
  – Structural Injury Classifier (SIC)
  – Brain Function Index (BFI)
- Neurocognitive tests
- Digitized concussion assessments

Intended patient population: 18-85 years of age, GCS of 13 – 15, and for use within 3 days of mild head injury. BrainScope One is not intended as a stand-alone diagnostic or to be used as a replacement for a CT scan. For a list of complete indications please visit **www.brainscope.com/products.**

Potential to Significantly Reduce Unnecessary Scans.

Visible on CT

BRAIN INJURY SPECTRUM OF PATHOLOGY

The BrainScope One assessment covers the full spectrum of brain injury, including brain abnormalities not visible on CT scans.

The vast majority of mild brain injury cases do not show structural damage on CT scans. **Result:**

91%

of patients receiving CT scans for brain injury are unnecessarily exposed to radiation.[2]

In an FDA validation trial, the BrainScope One system demonstrated

99%

sensitivity to even the smallest amount of detectable blood (≥1cc), with negative predictive value (NPV) of 98%.[3]

Based on its ability to accurately predict which patients are likely CT-positive, using the BrainScope One system has the potential to reduce false positives by

33.3%[4]

compared with standard clinical practice—adding up to a reduction in unnecessary scans of more than

1 MILLION PER YEAR
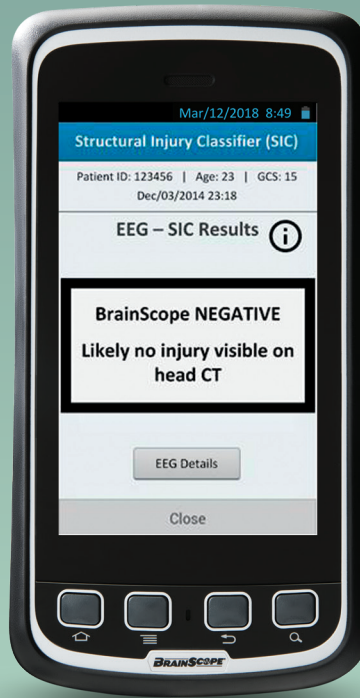
STRUCTURAL INJURY CLASSIFIER (SIC)

The BrainScope One system uses EEG data from a disposable headset, integrating real-time information with noise removed from the signal to ensure quality. Characteristics of the EEG signal are then extracted from the clean data, age-regressed and entered into the BrainScope Structural Injury Classification algorithm (the SIC). The SIC algorithm also includes specific patient-related clinical signs/symptoms.

The SIC predicts whether the patient would likely be positive or negative for brain injury on a CT scan. An "equivocal zone" classification alerts physicians that a patient is close to the decision border, possibly needing further evaluation or observation.
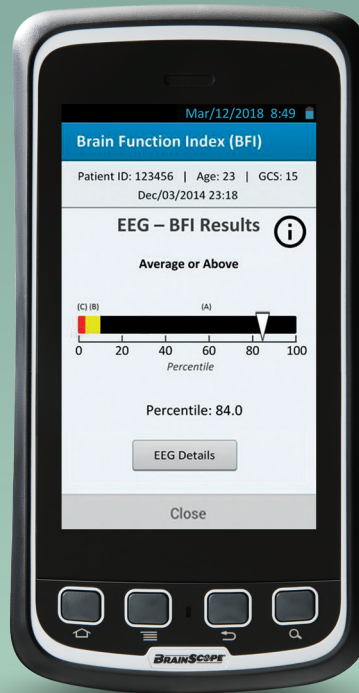
BRAIN FUNCTION INDEX (BFI)

Using the same rapidly-acquired EEG data, the BrainScope One system informs the clinical assessment of concussion by comparing a patient's brain electrical activity to the age-regressed non-head-injured population.

The system provides objective assessment of a head injured patient's brain electrical activity signature related to concussive brain injury, including signals that reflect changes in connectivity between brain regions. The BFI is expressed as a percentile, with a lower score showing higher levels of impairment. This enables physicians to make more confident clinical diagnoses including objective physiological data.

In an FDA clinical trial, the Brain Function Index was validated and demonstrated to scale with severity of functional impairment: as the BFI goes down, the level of impairment increases.[6]

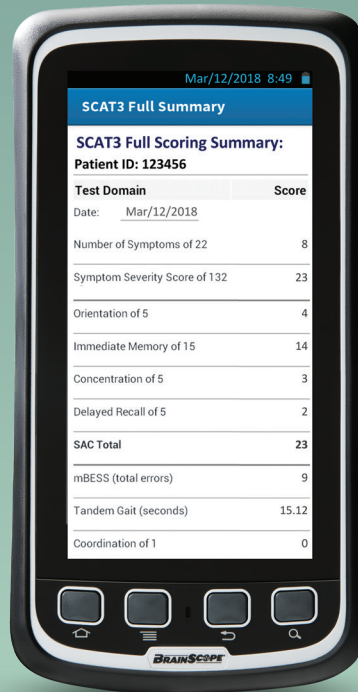# COMPREHENSIVE ASSESSMENT METRICS, CONFIGURED TO YOUR NEEDS.
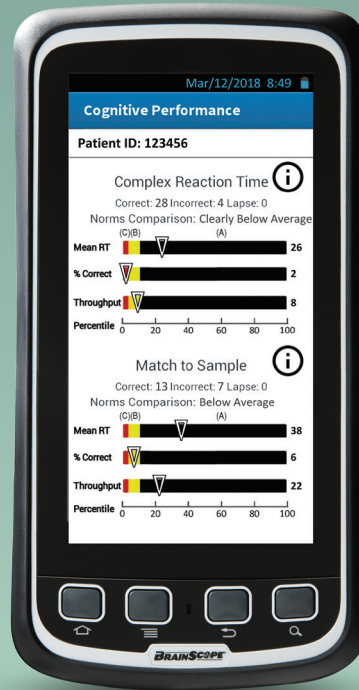
NEUROCOGNITIVE TESTS

The BrainScope One system can be configured to include two rapid neurocognitive performance tests, performed by the patient on the system's handheld device. These tests, which complement data obtained from the BrainScope EEG, include:

• **Complex Reaction Time**, which measures information processing speed, visuomotor reaction time, simple decision-making and attention.

• **Match-to-Sample**, which measures visual-spatial processing, working memory and visual short-term recognition memory.

Results are displayed as a percentile of the performance of the non-head-injured population of the same age.

BrainScope conducted a large normative study of subjects from 18-85 years old performing the two tests on the BrainScope One device, and demonstrated the results to be in line with previously published normative data.[6]

Mar/12/2018 8:49

SCAT3 Full Summary

SCAT3 Full Scoring Summary:
Patient ID: 123456

| Test Domain	Score
Date: Mar/12/2018	
Number of Symptoms of 22	8
Symptom Severity Score of 132	23
Orientation of 5	4
Immediate Memory of 15	14
Concentration of 5	3
Delayed Recall of 5	2
SAC Total	23
mBESS (total errors)	9
Tandem Gait (seconds)	15.12
Coordination of 1	0

DIGITIZED ASSESSMENTS

To supplement the EEG and objective neurocognitive assessments, BrainScope has digitized and made available as part of the BrainScope One assessment, more than a dozen standard neurocognitive tests that clinicians may use to support clinical diagnostic decisions on concussions. Print-outs of these digitized assessments appear in the format normally seen by users.

These tests can be configured and administered as desired as part of the concussion assessment process, but are not required or part of the BrainScope One assessment.

Digitized Assessments include:

- Military Acute Concussion Evaluation (MACE)
- Concussion Symptom Inventory (CSI)
- Grade Symptom Checklist

- ACE–Emergency Department
- ACE–Physician Office
- ACE–Sports

- SAC
- SCAT3, SCAT5
- NFL SCAT
- VOMS and others
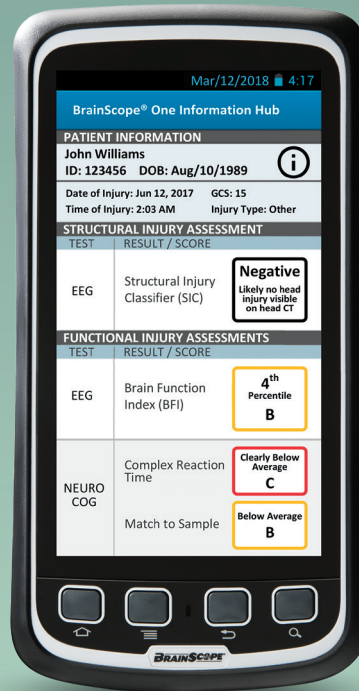
MULTIMODAL PANEL SUMMARY

The results of the BrainScope One assessment—the EEG-based Structural Injury Classifier and Brain Function Index, as well as neurocognitive tests and selected digitized assessments—are displayed in a multi-parameter panel, which can be viewed on the device, or printed and shared with providers and patients.

The BrainScope One assessment typically takes between 10 to 30 minutes. Actual assessment time may vary based on number of tests chosen.

By the Numbers

The BrainScope System represents over

10 YEARS

of research, funded in part by

8 DEPARTMENT OF DEFENSE CONTRACTS,

with substantial private investment.

BrainScope has obtained

5 FDA CLEARANCES,

With the fifth received in May, 2018 for additional BrainScope One* device capabilities w.r.t. concussion / mTBI.

* BrainScope One was originally cleared as Ahead® 300 in 2016. Subsequent clarification in the IFU regarding concussion/mTBI was cleared in 2018.

To date

>20

CLINICAL INVESTIGATOR-INITIATED PEER-REVIEWED PUBLICATIONS

appeared in scientific literature based on data using BrainScope technology.

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BrainScope holds over

100

ISSUED AND PENDING PATENTS

around BrainScope's technology for neurological diagnostics, including brain injury.

Continuing Advancement in Brain Injury Assessment

With the BrainScope One medical device, BrainScope Company, Inc. has taken an important step in overcoming the complex and subjective nature of brain injury assessment. And the company is continually working to advance the science. The BrainScope One platform was developed by applying advanced machine learning algorithms to extensive patient data, including symptoms, personal history, EEG data, CT scan and neurological test results. As the database grows, the BrainScope One system's machine learning capabilities can identify additional data patterns, enhancing future technology, and advancing the potential clinical application of brain injury assessment.

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