BrainScope®

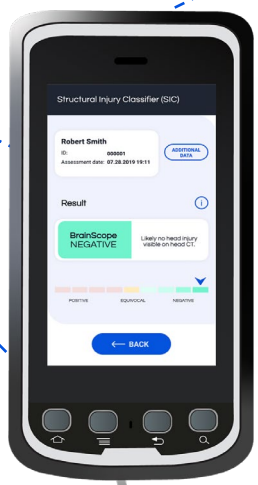
The first and only FDA cleared device to assess mild traumatic brain injuries (bleed and concussion) at point-of-care.

FDA CLEARED

BrainScope is an FDA cleared, A.I-powered, mild TBI decision support triage tool

3 FDA cleared algorithms provide objective biomarkers of brain injury

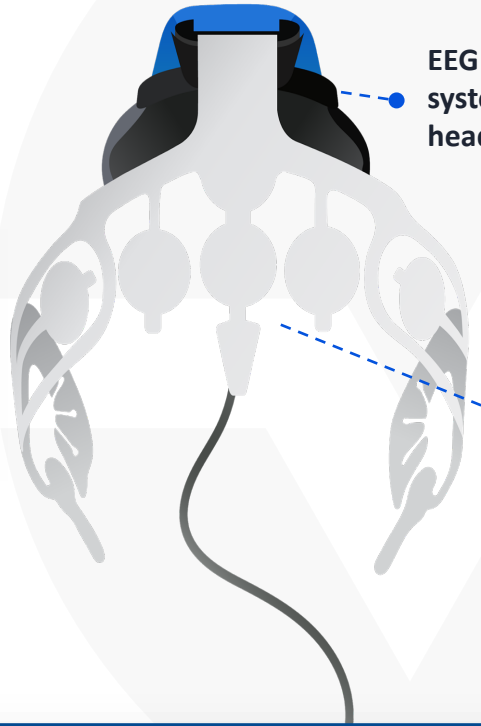
EEG signal processing with no connectivity required



Hand-held, device that uses objective markers of brain bleed and concussion to rapidly assess patient status at point-of-care

FDA cleared, ruggedized handheld device

EEG acquisition system connects headset to device



FDA cleared disposable EEG headset

Algorithms identify “noise” to assure high quality EEG data
No physician EEG interpretation necessary

Physician ordered, technician operated assessments provide actionable results instantly available at point-of-care

Issues with current mTBI diagnostic tools

Structural – Brain Bleed

Head CT is the Standard of Care

Issues with Head CT

- **91% of results are negative**
- Exposes patients to unnecessary radiation
- 3 to 6+ hour average wait-time
- Average net reimbursement $153
- Cannot detect concussion

4.0M
head CTs are performed

3.6M
head CTs are negative

Functional - Concussion

No Standard of Care

Issues with Concussion Tests[1,2]

- Single test can lead to misclassification
- Multiple tests
- Inconsistent usage of tests
- Subjective, easily cheated

up to 50%
wrong result[1]

Current Options:

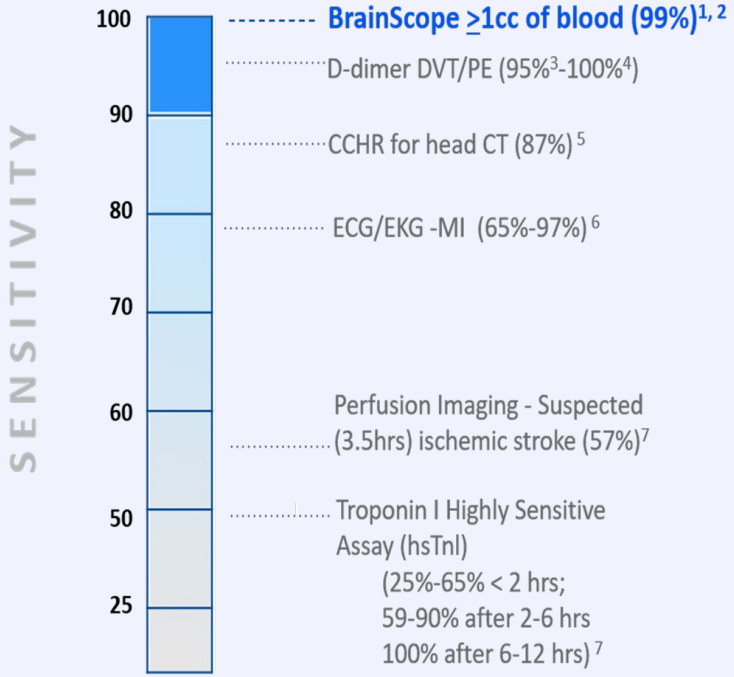
- ImPACT/other neurocognitive tests
- Eye tracking/ blinking
- Balance
- Reading a list of numbers
- Phone apps with questionnaires

1. Raab et al. (2020) *Arch Clin Neuropsychol*.
2. Resch et al (2016) *BMJ Open Sport & Exercise Medicine.*

BrainScope®

Outstanding clinical performance
A future new gold standard for mTBI triage

Clinical sensitivity as high or higher than other trusted technologies



- Sensitivity is 99% to ≥1 cc of blood
- Similar to D-dimer - high confidence in ruling out unnecessary imaging
- **Outstanding negative predictive value of 98%**

Performance you can trust

In the FDA validation study, false negative patients were considered **"not clinically important,"** did not require neurosurgery, and did not return to the hospital within 96 hours. All were Glasgow Coma Score (GCS) 15.

Clinical Outcomes Study findings reported 100% sensitivity to head CT[2]

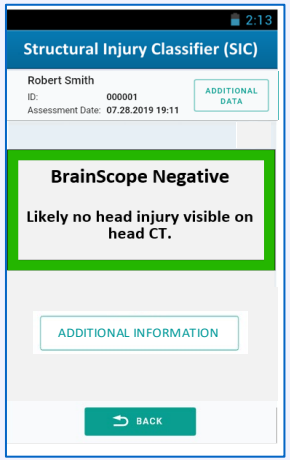
References

1. Hanley, et al. (2017) *Acad Emer Med.*
2. Naunheim, et al. (2019) *Amer J Emerg Med.*
3. Segal, et al. (2007) *Annals Family Medicine.*
4. Anoop, et al. (2009) *Hematology.*
5. Yiadom, et al. (2017) *J American Heart Association.*
6. Smits, et al. (2010) *Radiology.*
7. Daubert & Jeremias. (2010) *Vascular Health and Risk Management* (Review).

BrainScope®

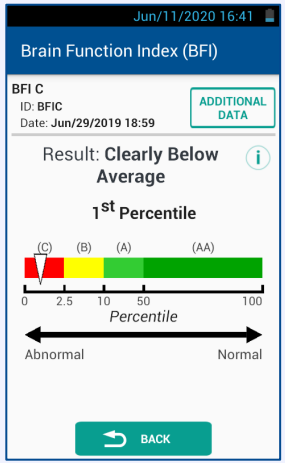
Structural and functional assessments reported at the same time from the same EEG signal inputs

Structural
Structural Injury Classifier (SIC)



The Structural Injury Classifier (SIC) accurately, rapidly and objectively **assesses the likelihood of a brain bleed** (≥1cc)

Functional
Brain Function Index (BFI)



BrainScope's Brain Function Index (BFI) **assesses brain function impairment and scales with severity**; computed at the same time as the SIC

BrainScope is an All-Taker Test

Includes alcohol-impaired and drug-impaired patients[1]

Between 30-50% of people with TBIs are **injured while intoxicated** and about one-third are **under the influence of other drugs.**

Indications for Use

- Ages 18 – 85
- within 72 hours of injury
- Glasgow Coma Score (GCS) 13-15

1. *J. of Neuroscience Nursing 2019,* Triage of Mild Head-Injured Intoxicated Patients Could be Aided by Use of an EEG-based Biomarker Edward Michelson, J.Stephen Huff, John Garrett, Rosanne Naunheim,

BrainScope®

Setup and testing are simple, quick and intuitive

Prep Patient

5 min

+

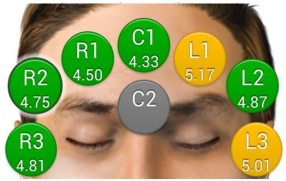
Run Test

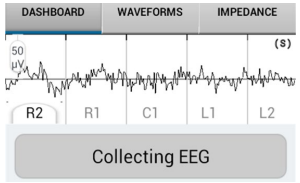
5 - 15 min

Start to Finish Results in 15-20 minutes

Quick and easy for operators to use

Real-time feedback for operator assures high quality recording





Fits into any workflow and can be operated by clinical or non-clinical staff

BrainScope can significantly improve ED throughput

Hospital ED mild brain injury triage process

without BrainScope®

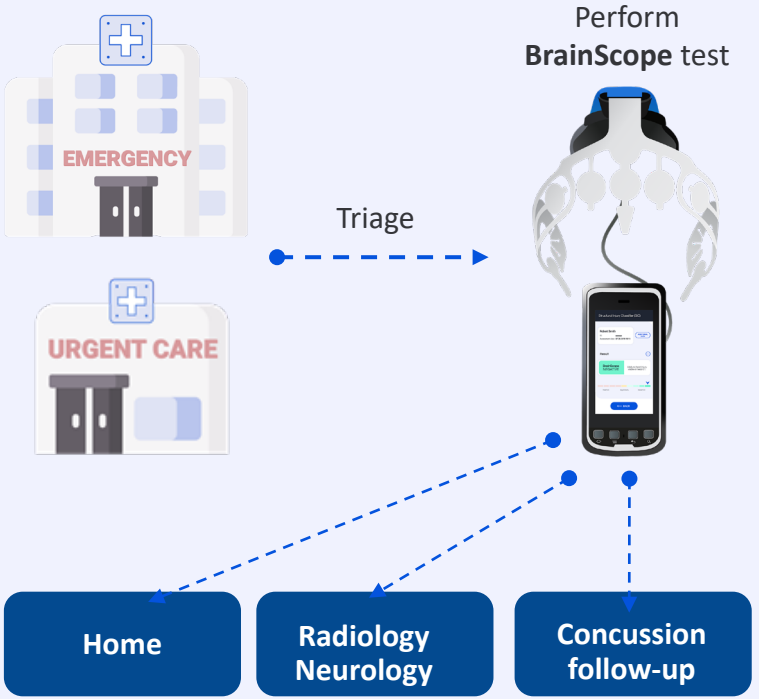
1. Patient check in
2. Triage
3. Waiting Room
4. Clinician/Physician Assessment
5. Wait for CT
6. Transport to CT
7. CT Scan
8. Transport from CT/radiologist reviews CT
9. Return to ED, CT review, Clinician Reassessment
10. Physician Reassessment
11. Discharge

Total time 6+ Hours

with BrainScope®

1. Patient check in
2. Triage + BrainScope
3. Clinician Assessment
4. Discharge

Much shorter + adds Concussion data



Source: Michellson EA, Huff JS, Loparo M, et al, Emergency Department Time Course for Mild Traumatic Brain Injury. West J Emerg MEd. 2018;19(4):635-640. doi: 10.5811/westjem.2018.5.37293

BrainScope can have an immediate impact on cost and care

>$300/patient

Average 3rd party BrainScope reimbursement using CPT/APC codes

$350/hr.

Opportunity cost benefit for each hour of patient wait-time avoided

$$

Continuum of care referrals to appropriate follow-up care

More patients seen faster

Increased throughput and productivity in ED

Improved patient satisfaction

Get answers without radiation and in less time

Fit with current initiatives

Choosing Wisely®

APPROPRIATE USE CRITERIA

MIPS (Merit-Based Incentive Payment System)

Thank you.

BrainScope®

For more information, please contact:

Kent Butler
Vice President of Sales – North America
Kent.Butler@brainscope.com
Cell: 586.855.1647