BrainScope User Manual

Rx ONLY

Revision: 004 Issued: August 2024

Supported Models: Ahead 500 P/N 50-1801-203

Customer Responsibility

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Parts which may be broken or missing or are plainly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from BrainScope Company, Inc. The responsibility of BrainScope Company, Inc. for a malfunctioning product is limited by the warranty set forth in this manual. Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from BrainScope Company, Inc., prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the unit is functioning properly and ready for use. The owner of this product has sole responsibility for any malfunction resulting from improper use or maintenance, or repair by any other than BrainScope Company, Inc., and from any malfunction caused by parts that are damaged or modified by anyone other than BrainScope Company, Inc.

Software License Notice

The BrainScope Company, Inc., BrainScope contains software that is installed by BrainScope Company, Inc. (“BrainScope”). BrainScope owns this software and it is subject to the licensing terms and conditions outlined at http://www.brainscope.com/brainscope-one-terms-and-conditions.

Patents and Trademarks

BrainScope® is a registered trademark of BrainScope Company, Inc., in the United States or other countries.

For a virtual patent marking, visit www.brainscope.com/sciencetechnology

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CHAPTER 1: General Information

1.1 About this Manual

This user manual is designed to provide information on the proper use of BrainScope, its functions, specifications, operation, and routine operator care and maintenance. It is recommended that the user read this entire manual, specifically the safety-related information, before operating BrainScope. Although this manual is intended for trained medical personnel, it does not assume prior knowledge or experience with operator-programmable medical electronics devices.

1.2 About BrainScope

BrainScope Head Injury Assessment Tools:

1. EEG and Multi-modal Assessments (see Chapter 3 for detailed instructions)
    - Structural Injury Classifier (SIC)
    - Brain Function Index (BFI)
    - Concussion Index (CI)
2. PECARN Decision Rule (see Appendix 2 for detailed instructions)
3. Cognitive Performance (see Appendix 1 for detailed instructions)
    - Procedural Reaction Time
    - Simple Reaction Time
    - Match to Sample
    - Go/No-Go
    - Simple Reaction Time Repeated
4. SCAT5 (Sports Concussion Assessment Tool 5)
5. MACE 2 (Military Acute Concussion Evaluation 2)
6. NPC (Near Point of Convergence)

In compliance with the intended use and indications for use of the BrainScope stated below, Table 1.2-1 provides details on the appropriate patient ages for each BrainScope assessment on the device.

Table 1.2-1 Patient ages for BrainScope assessments

BrainScope Assessment	Appropriate Patient Age
Structural Injury Classifier (SIC)	Ages 18-85
Brain Function Index (BFI)	Ages 18-85
Concussion Index (CI)	Ages 13-25
PECARN Decision Rule	Ages 2-17
Cognitive Performance	Ages 13-85
SCAT5	Refer to assessment's general instructions
MACE 2	Refer to assessment's general instructions
NPC	Refer to assessment's general instructions

1.3 Intended Use

Intended for use to analyze a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition.

Intended use as an adjunct to standard clinical practice to aid in the triage of patients who are suspected of a traumatically induced structural brain injury.

Intended to record, measure, and display brain electrical activity.

Intended to be used in Emergency Departments, Urgent Care Centers, Clinics and other environments where trained medical professionals and practitioners practice medicine under the direction of a physician.

1.4 BrainScope Summary of Indications for Use

- BrainScope is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion / mild traumatic brain injury (mTBI)).

- BrainScope provides a multi-parameter measure (Concussion Index (CI)) to aid in the evaluation of concussion in patients between the ages of 13-25 years who present with a GCS score of 15 following a head injury within the past 72 hours (3 days), in conjunction with a standard neurological assessment of concussion. The CI is computed from a multivariate algorithm based on the patient's electroencephalogram (EEG), augmented by neurocognitive measures and selected clinical symptoms.

- The BrainScope Structural Injury Classification ("SIC") uses brain electrical activity (EEG) to determine the likelihood of structural brain injury visible on head CT for patients between the ages of 18-85 years (GCS score 13-15) who have sustained a closed head injury within the past 72 hours (3 days) and are being considered for a head CT. BrainScope should not be used as a substitute for a CT scan. Negative likely corresponds to those with no structural brain injury visible on head CT. Evaluate likely corresponds to those in whom a structural brain injury visible on head CT could not be ruled out. Equivocal corresponds to those who are SIC negative and close to the positive cutoff. May indicate the need for further observation or evaluation.

- BrainScope provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment, in patients 18-85 years of age (have a GCS score of 13-15) who have sustained a closed head injury within the past 72 hours (3 days).

- The BrainScope device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (QEEG) parameters from frontal locations on a patient's forehead. The BrainScope calculates and displays raw measures for the following standard QEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.
- BrainScope also provides clinicians with quantitative measures of cognitive performance in patients 13-85 years of age to aid in the assessment of an individual's level of cognitive function. These measures interact with the CI and can be used stand alone.

- BrainScope also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.

1.5 Considerations for Using BrainScope

This device is intended to be used in patients who sustained a closed head injury with a Glasgow Coma Scale (GCS) score of 13-15. The safety and effectiveness of BrainScope in patients with GCS scores less than 13 has not been established.

BrainScope is a prescription use device.

Clinical decisions about patients will be made by medical professionals, and BrainScope is an adjunct to standard clinical practice. Clinical judgment should always be used when interpreting the BrainScope clinical outputs, and the device should not be used as a stand-alone diagnostic device.

As with any monitored physiological parameter, artifacts and poor signal quality may lead to inappropriate BrainScope performance.

1.6 Intended Operators

BrainScope is intended as an adjunctive tool for use by properly trained medical professionals and practitioners. Training of BrainScope operations will be provided by qualified BrainScope Company, Inc. staff through didactic and hands-on education.

NOTE:
BrainScope was cleared by the U.S. Food and Drug Administration under the Trade/Device Name Ahead 500 (K-190815).

1.7 Clinical Study Summary (CAS Validation Study)

The CAS (Concussion Assessment Study) study was a multi-center, prospective clinical study with subjects enrolled at 10 clinical sites in the U.S. It was established as a non-significant risk study in accordance with 21 CFR 812.2(b) (1) (ii). The study was conducted in accordance with the ethical principles of Good Clinical Practice (GCP).

Patient Population: Males and females ages 13 to 25 years, with GCS 15 were included in the study. Subjects included those who were observed to sustain a head impact and were removed from play according to site guidelines, matched non-injured controls and healthy volunteers. All subjects who were removed from play by site criteria were deemed to have a concussion according to the clinical protocol. The clinical reference standard used was fully consistent with the guidelines published in International Conference on Concussion in Sport guidelines (McCrory 2017; 2013) as well as National Collegiate Athletic Association (NCAA) concussion policy. After subjects were removed from play, additional follow-up evaluations were conducted including CSI, SCAT3/SCAT5, history and neurocognitive assessments.

Methods: The CAS Validation study was conducted to validate the Concussion Index (CI) on the BrainScope device. The study was conducted on an independent population of closed head injured and control subjects, assessed at multiple time points, to demonstrate that the multimodal CI can assist the clinician in the assessment of concussion.

Study Objectives

Primary Objective: The primary objective of this Validation study was to demonstrate efficacy of the multivariate, multimodal Concussion Index (CI) as an aid in evaluation of concussion following closed head injury in an independent population of subjects (not used to derive the algorithm).

Secondary And Additional Objectives: To demonstrate that the change in CI over time in the non-head injured population shows that the CI is a stable measure and that the change can be interpreted reliably. And to demonstrate the relationship between CI and total symptom burden (total Concussion Symptom Inventory, CSI).

Results: The total number of completed cases included in the statistical analyses of the Validation study was 580. A completed case was required to have a BrainScope evaluation at time of injury and at RTP as well as completed neurocognitive and symptom assessments. There were 373 matched controls and healthy volunteers and 207 subjects with witnessed head impact who were removed from play. All study subjects had a Glasgow Coma Scale (GCS) score of 15 (normal).

The Primary Endpoints successfully achieved statistical significance above performance goals. The performance goals that were defined in the Statistical Analysis Plan (SAP) for the co-primary endpoints were 69% for sensitivity and 56% for specificity. The estimate of sensitivity was 85.99% with 95% two-sided confidence limits of (80.50%, 90.41%). The estimate for specificity was 70.78% with 95% two-sided confidence limits of (65.88%, 75.35%). Thus, these endpoints achieved their respective performance goals at a one-sided alpha of 0.025.

The Secondary Endpoints demonstrated the following:
The change in CI over time in the non-head injured population demonstrates that the CI is a stable measure and that the change can be interpreted reliably. The stability of the CI was tested on a population-based level, and the test-retest reliability has not been evaluated at the level of the individual patient.

Additional analyses showed a statistically significant relationship between the CI discriminant score and the 12-question Concussion Symptom Inventory (CSI) total score ($r = 0.8047$, $R2 = 0.6475$) as well as 22-question CSI total score ($r = 0.7971$, $R2 = 0.6354$).

There were no adverse events reported in this study.

1.8 Clinical Study Summary (B-AHEAD III Study)

The B-AHEAD III Study was a multi-center, prospective clinical study with subjects enrolled at 11 clinical sites in the U.S. It was established as a non-significant risk trial in accordance with 21 CFR 812.2(b) (1) (ii). The study was conducted in accordance with the ethical principles of Good Clinical Practice (GCP).

Patient Population: Subjects included males and females ages 18 to 85 (the entire age range) who were admitted to the ED and suspected of a traumatic, closed head injury within 72 hours. The GCS needed to be between 12-15 closest to Ahead 200iC (investigational study device) assessment even if GCS was lower prior to arrival to the ED (e.g., at the time of injury).

Methods: The validation was accomplished by comparing the BrainScope output score to the adjudicated result of the CT scan. CT Scans performed at the clinical sites were submitted in DICOM format for independent review and over-read by experts at the Johns Hopkins University School of Medicine Brain Injury Outcomes Center (BIOS) and final classification of the CT was determined. In cases where subjects were not referred for CT scans by standard clinical practice, they were deemed CT negative if the subject met the following conditions: Glasgow Coma Scale score (GCS) of 15, and sustained a loss of consciousness (LOC) or amnesia and did not have any "clinical" items on the New Orleans Criteria.

Study Objectives

Primary Objective(s): The primary objective of this study was to validate the clinical utility of the BrainScope device for the acute identification of structural brain injuries in the TBI population, following closed head injury. In addition, the study aimed to extend findings of the B-AHEAD II Study in a large population and replicated and extended the trial using BrainScope device with respect to the device's target intended use and indications for use.

Secondary Objective(s):

1. Demonstrate the utility of the EEG Brain Function Index (BFI) score from a given subject presented a percentile of the normal population and an index score.
2. Evaluate the utility of creating a three-tier system for CT+ (CT-, Equivocal Zone, and CT+).

Results: The total number of completed cases (subjects) in this study was 720 resulting in 564 classified as patients without structural brain injury visible on CT (CT-) and 156 classified as patients with structural brain injury visible on CT (CT+). The mean Glasgow Coma Scale (GCS) score for the entire group was 14.97 (SD=0.23), with 99.86% being between 13-15.

The co-primary endpoints successfully achieved statistical significance against performance goals. The estimate of sensitivity is 92.31% with 95% two-sided confidence limits of (86.95%, 95.96%). The estimate for specificity is 51.60% with 95% two-sided confidence limits of (47.38%, 55.79%). Thus these endpoints achieved their respective performance goals at a one-sided alpha of 0.025.

The first and second secondary endpoints demonstrated that the Brain Function Index was associated with functional injury impairment and that the classifier for structural injury visible on CT can be presented in three meaningful groups instead of two (Negative, Equivocal, and Evaluate). The third secondary endpoint, the predictive values estimated across prevalence values more likely to be found in practice indicated that the negative predictive values was consistently above 95% for prevalence below 25% and was 99% at a prevalence of 5%.

There were only six adverse events reported in this study with only one related to the device. One subject complained of a reported a burning sensation on the forehead 1/969 = 0.10% (0.00%, 0.57%). The remaining five adverse events were serious adverse events (SAE) associated with the injury. The estimated rate for SAE is 5/981=0.52% (0.17%, 1.20%).

In previous data sets, the Brain Function Index percentile and raw score have been shown to be predictive of the severity of TBI, i.e., there was a continuum of functional abnormality which was demonstrated by increasing abnormality in the metric. The table below shows the percentage of each subgroup (with increasing functional impairment) from an independent hold-out population that fell below the 10th percentile of a normal, non-injured population. This data demonstrates that the BFI was associated with functional injury impairment.

Table 1.7-1 Classes of Non-Head Injured Subjects by the EEG Brain Function Index for the Hold Out Population[a]

Description/ Category	Uninjured Normal Controls (0)	Head Injured Controls (1)	Mild Functional Abnormality (2)	Moderate Functional Abnormality (3)	CT+ (No Measurable Blood) (4)	CT+ (Measurable Blood) (5)
N	318	167	166	153	68	28
<10th Percentile	10.06%	9.82%	16.02%	23.30%	39.46%	52.96%
Standard Deviation	0.00	1.28	3.23	4.32	6.22	7.10

[a] The hold out population is comprised of categories 1-5 that were not used in the creation of the normal percentiles.

Figures 1-1 and 1-2, which follow, show the relationship between the SIC discriminant scores and the clinical classification of the subjects from the FDA Validation Study. The clinical classes progress from Class 1 (control/normal) to Class 5 (brain injury visible on CT).

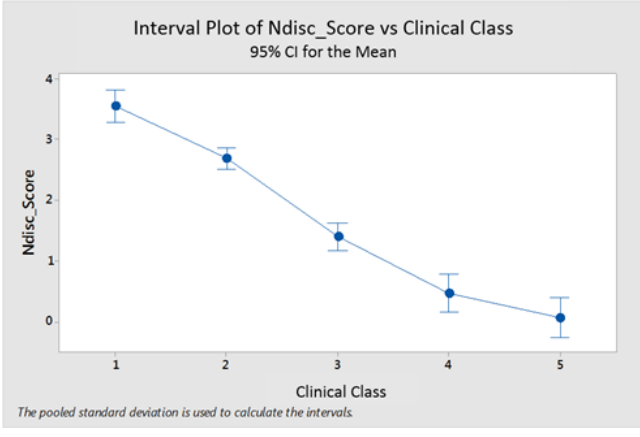


Figure 1-1:
Plot of Means and 95% Confidence Limits
of Discriminant Scores by Clinical Class

Figure 1-1 shows the mapping of the Discriminant Scores as a function of the clinical class. A downward trend can be seen between successive Clinical Classes (increasing injury), highest for class 1 and lowest for classes 4 and 5. Note that discriminant scores decrease as abnormality increases.

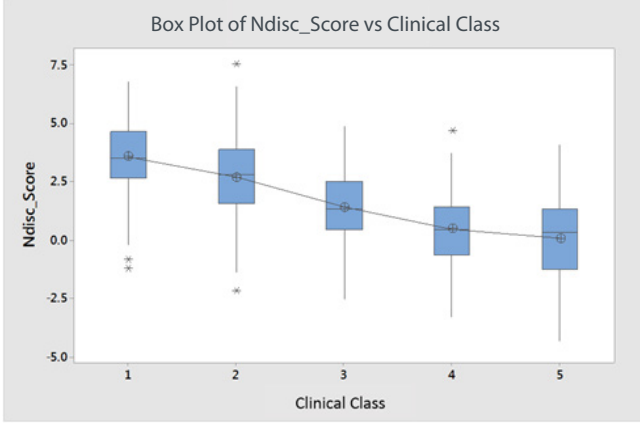


Figure 1-2:
Box Plots of Discriminant Scores by Clinical Class

The box plots shown in Figure 1-2 are computed from the same data as above. Note the decrease in both median (horizontal bar within each box) and mean (circle within each box) discriminant scores with increasing injury by clinical class.

Figures 1-3 and 1-4, which follow, show the relationship between the BFI percentile (derived from the discriminant scores) and the clinical classification of the subjects from the FDA Validation Study.

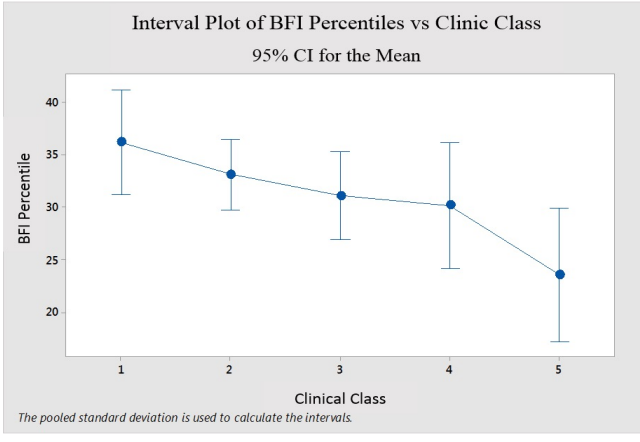
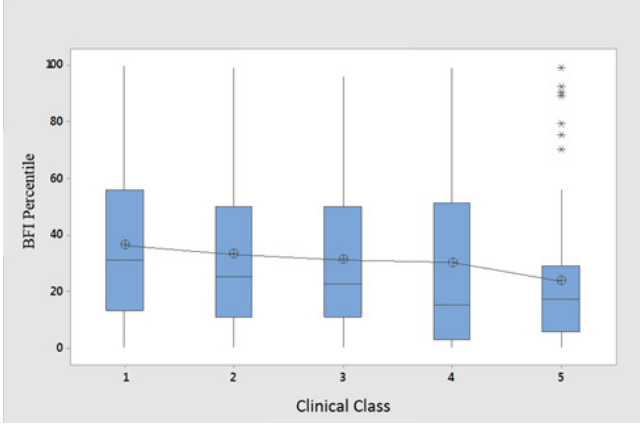


Figure 1-3 shows the mapping of the Discriminant Scores shown above (Fig, 1-1) to percentiles. Note the downward trend between combined Clinical Classes 4 and 5, and each of the three lower classes. Recall that the percentiles are inversely related to severity of injury hence the downward trend.

Figure 1-3:
Plot of Means and 95% Confidence Limits of Percentiles of Normal by Clinical Class



The box plots shown in Figure 1-4 are computed from the same data as above for percentiles. A decrease in means (solid line in each box) can be seen. The overlap between categories is emphasized in the box plots.

Figure 1-4:
Box Plot of BFI Percentile by Clinical Class

1.9 Safety Summary

The words WARNING, CAUTION and NOTE have special meaning and should be reviewed.

	WARNING!	Users should pay particular attention to WARNING information. Disregarding WARNING information may compromise the safety of the patient and/or health care staff and may result in injury.
	CAUTION	Users should pay particular attention to CAUTION information. Disregarding CAUTION information may compromise product reliability and may result in damage.
	NOTE	NOTE information supplements and/or clarifies procedural information.

WARNING!

1. Only trained and experienced health care professionals should use this equipment. Before using any system component or any component compatible with this system, read and understand the instructions.
2. This device is intended to be used in patients who sustained a closed head injury with a Glasgow Coma Scale (GCS) score of 13-15.
3. The safety and effectiveness of BrainScope in patients with GCS scores less than 13 has not been established.
4. BrainScope is intended for use by physicians, or under the direction of a physician, who have been trained in the use of the device.
5. Clinical decisions about patients will be made by medical professionals, and BrainScope is an adjunct to standard clinical practice.
6. Clinical judgment should always be used when interpreting BrainScope clinical results and the device should not be used as a stand-alone diagnostic device.
7. An Evaluate BrainScope Structural Injury Classification does not establish the presence of a structural brain injury visible on head CT, since an Evaluate result may be obtained on individuals with abnormal brain electrical activity that do not have a structural brain injury visible on head CT.
8. The Cognitive Performance tests do not identify the presence or absence of clinical diagnoses.
9. When evaluating patients using BrainScope, take into consideration any medications that the patients could be taking.

10. As with any monitored physiological parameter, artifacts and poor signal quality may lead to inappropriate BrainScope performance.

11. Standard clinical assessment of the patient should proceed in the event that insufficient clean (artifact-free) EEG data is collected.

12. Pay special attention to WARNING information. Become familiar with the system components prior to use. Failure to comply may result in patient and/or health care staff injury.

13. The Concussion Index and the Brain Function Index do not indicate the presence or absence of structural brain injury.

14. Upon initial receipt and before each use, inspect system components for damage. DO NOT use if damage is identified. If the internal battery appears to be damaged or leaking, avoid direct contact with the battery and do not use BrainScope device.

15. Only trained and experienced health care professionals should maintain this equipment. Failure to comply may result in patient and/or health care staff injury.

16. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orientation or relocation of the device or shielding the location.

17. DO NOT use BrainScope for uses other than specified by the Indications for Use.

18. DO NOT attach BrainScope to the patient when connected to the USB-A Charger.

19. BrainScope is powered by an internal lithium-ion battery. To prevent injury and/or property damage: do not expose BrainScope to temperatures in excess of 70 °C (158 °F), do not drop, open, or puncture the battery, and avoid exposure and/or immersion in liquid.

20. DO NOT use BrainScope on a patient being defibrillated.

21. The DAB module may become hot during prolonged, continuous operation. Monitor the patient as they may experience pain or discomfort. Limit exposure of the DAB to the scalp/hair to minimize any potential hazard.

22. The maximum temperature of the enclosure under worst-case ambient conditions is 42.1°C (107.8°F).

23. Never use the device without the DAB jacket attached to the base of the module. Heat transmission to the patient is reduced by ensuring the DAB jacket is in place during operation.

24. Explosion Hazard: DO NOT use BrainScope in a flammable atmosphere or where concentration of flammable anesthetics may occur.

25. To reduce the hazard of burns, DO NOT use BrainScope with high-frequency surgical equipment.

26. Shock Hazard: DO NOT remove the device covers.
27. Shock Hazard: BrainScope meets the ground leakage current and the patient safety current limits specified by the applicable safety standards. As a matter of safe practice, the institution should conduct periodic tests to verify these currents. In the event of spillage of blood or solutions, re-test before further use.
28. Shock hazard: DO NOT attempt to disconnect the power cord with wet hands. Ensure your hands are clean and dry before touching the power cord.
29. Shock hazard: Keep the device away from water and other fluids. Ingress protection is not guaranteed during battery charging. Avoid charging the BrainScope battery outdoors or in wet environments.
30. Routinely inspect system components for possible exposure to liquid.
31. BrainScope should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
32. No modification of this equipment is allowed.
33. BrainScope is "MR Unsafe" and while its safety in Magnetic Resonance Imaging (MRI) environments has not been specifically evaluated, it contains materials that are known to pose hazards in all MRI environments.
34. MR Unsafe - Keep the device and system components away from magnetic resonance imaging (MRI) equipment.

NOTE: Currently the BrainScope screens are not optimized for visually impaired users.

1.10 User Manual Conventions

- Phrases in bold and all capital letters refer to ACTIONS/TRIGGERS on the handheld screen that should be tapped to execute a specific action.
  - Example: SETUP – takes you to the setup screen to set date and time, enter new operators, etc.
- Phrases in bold and italics represent Screen Names that are displayed at the top left on the handheld and can help with navigation.
  - Example: *Information Hub* – the first screen you see when the handheld is ready for use.

CHAPTER 2: Getting Started

> WARNING!
> To avoid injury, read important safety information in Section 1.9 before using BrainScope.

This section provides information for preparing BrainScope for the first time. It also can be used as a reference for setting up the device at a later time.

2.1 System Equipment and Supplies

BrainScope consists of the following system equipment (Figure 2-1):

1. EEG Acquisition Unit (Handheld Computer for data collection and results display)
   a. The touch screen is the primary interface for handheld operation. The screens change as the handheld is operated.
   b. The front panel has three physical buttons, an indicator light, and a touch screen display.

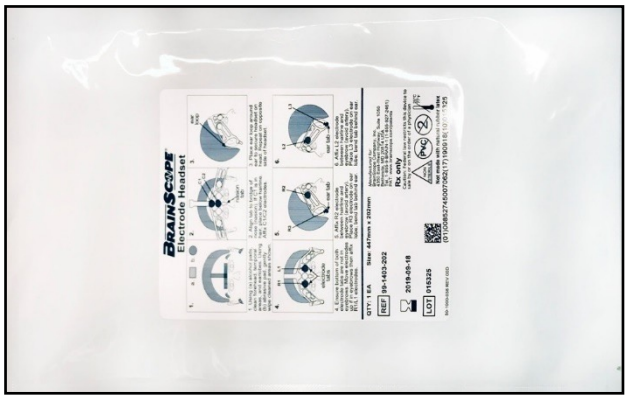
2. Data Acquisition Board (DAB) Module
   a. The DAB connects to the handheld and is the interface between the headset and the handheld for data acquisition. The DAB will be placed on top of the patient's head when the headset is applied. The DAB also contains a micro-USB port that allows for charging of the system when not applied to a patient.

3. Charging Accessories
   a. Charging kit for recharging the internal rechargeable battery pack in the BrainScope handheld.
   b. Connects to the DAB while charging.

Figure 2-1: BrainScope System Equipment

BrainScope consists of the following accessories (Figure 2-2):

1. Electrode Headset (a proprietary electrode sensor)
    a. Collects EEG signals from the frontal regions of the brain and sends them to the handheld.



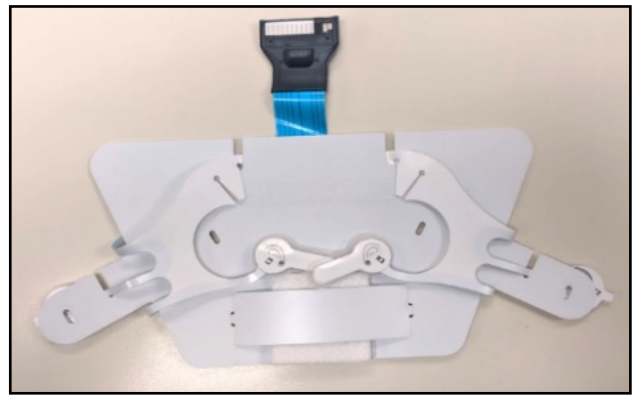


Figure 2-2: Electrode Headset (package and insert)

2.2 Charging Accessories

WARNING!

- Use only the charging accessories shipped with BrainScope to charge the BrainScope EEG Acquisition Unit (Figure 2-1). Unapproved power supplies may cause damage to the device and increase the risk of electrical shock. Use of the supplied charging kit to power other devices could cause damage.
- Do not utilize a computer using the USB connector as a primary method to recharge the device's battery. Use of the supplied charging kit on other devices could damage them.
- The handheld contains a lithium-ion rechargeable battery. If the battery becomes worn out or damaged, it must be removed by a qualified service technician and disposed of or recycled in accordance with national, state and local laws. Do not attempt to incinerate or dispose of the device or the battery yourself. Improper disposal poses a risk of fire or explosion.

CAUTION: DO NOT disconnect or reconnect the DAB cable with the system power turned on. Damage to the handheld may occur.

BrainScope is internally powered by a lithium-ion rechargeable battery pack. A separate charging kit is provided for battery charging (Figure 2-3). A new BrainScope will come with the battery partially charged and it will be necessary to charge the battery completely before using it for the first time. The battery should be fully charged for before first use. If the battery has been stored for longer than six months, charge it completely before use.

Charging BrainScope:

NOTE: Use only the charging accessories supplied with BrainScope, do not attempt to charge via any computer USB port.

1. Plug the USB-A end of the USB-A to Micro-B USB Cable into the USB-A port on the USB-A Charger.
2. Plug the other end of the USB-A to Micro-B USB Cable into the receptacle on the front on the DAB.
3. Insert the plug of the USB-A Charger into an AC outlet (100-240 V, 50-60 Hz).

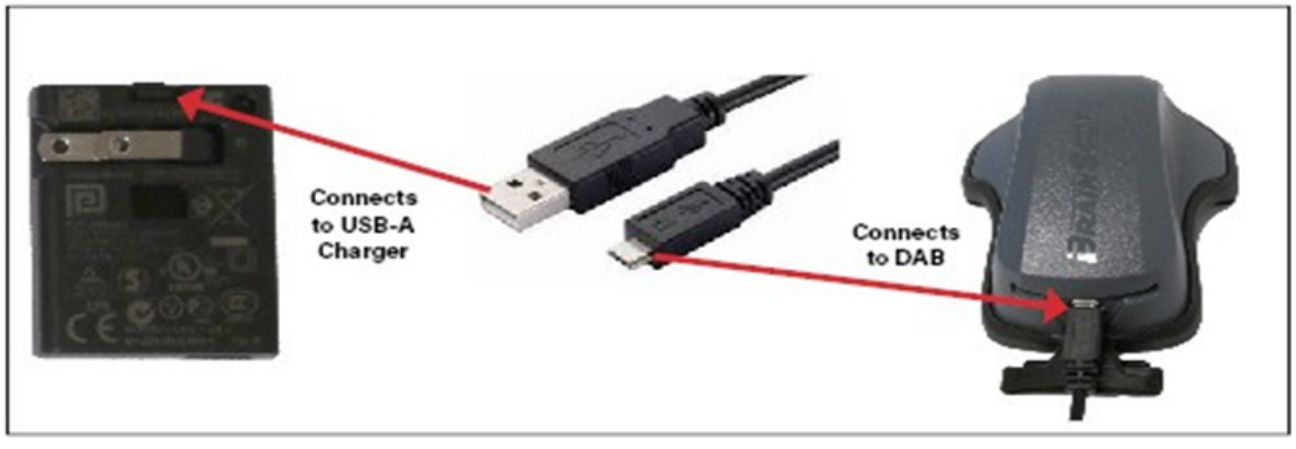


Figure 2-3: Assembly of the charging kit

The battery will charge continuously when the handheld is connected to the USB-A Charger and the USB-A Charger is plugged into an outlet, even when the handheld is turned off.

NOTE: While the Micro-B USB port is connected to a power source, the DAB Module electronics are powered off for safety purposes.

Unplugging the USB-A charger from the handheld or from the AC outlet automatically switches the handheld to battery mode. Prior to complete battery discharge, an indication will appear notifying the operator of the handheld's low battery status.

The handheld will have to be returned for service should the battery need replacement. The handheld should never be opened by the operator.

NOTE: The LED on the handheld indicates the battery power or charging status, and operating system notifications, as shown below:

LED State	Handheld/Battery State
Blue	Handheld is charging & Battery is more than or 90%
Solid Red	Handheld is charging & battery is less than 90%
Flashing Red	Low battery, less than 12% charge remaining

2.3 Battery Gauge Icon

On every screen, a battery gauge icon (Figure 2-4) in the upper right corner indicates the remaining battery level in the internal rechargeable battery.

When the battery level has less than 15% remaining, the battery guage icon will turn RED.

When the charge level reaches 5%, a warning message will appear requesting to check the battery status before continuing with testing. (Figure 2-5)

If use of the handheld is continued without charging, the battery warning indication will continue to appear until the handheld has been connected to the USB-A charger.

If the battery becomes less than 3% charged and a session is not running, a warning indication will appear. Tapping OK on the warning screen shuts down the handheld. (Figure 2-6)

Figure 2-4:
Battery Gauge Icon

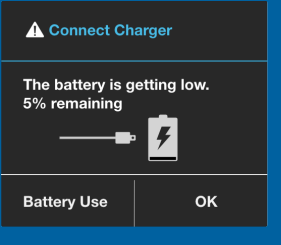


Figure 2-5:
Warning that less than 5% of battery level remains

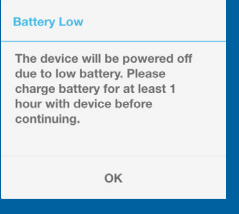


Figure 2-6:
Warning the handheld will power off

2.4 Buttons

2.4.1 Physical Buttons

To execute most activities on the BrainScope handheld the user will TAP the touchscreen. There are, however, several physical buttons that are used to control basic functions, such as powering BrainScope ON/OFF or quick access to help content.

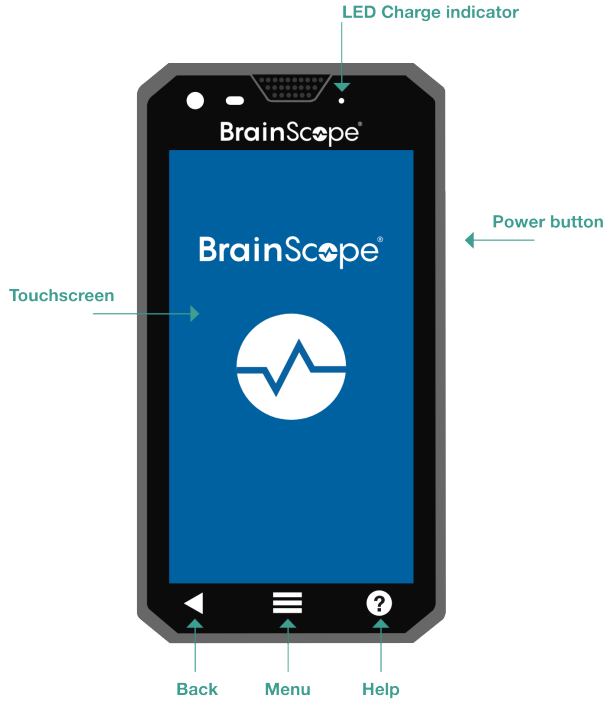
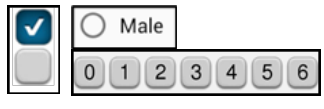
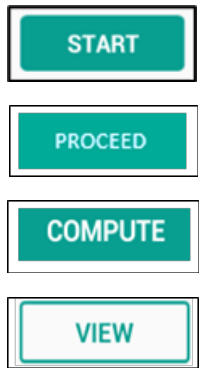


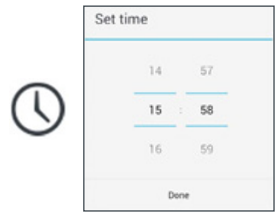
Figure 2-7: BrainScope Front Panel Buttons

Front Panel Buttons	
Menu	• The menu button provides access to the following options while not in a patient session: Main Menu, Help, and Logout. • While in a patient session, the menu button displays these additional options: Return to Patient History, Generate PDF Report, Export EEG as EDF, and Close Session.
Back	• When not currently in an assessment test, returns to the Previous Screen or dismisses the currently displayed message or menu. • If pressed during an assessment test, will return to the Information Hub. You will be asked if you are sure you want to exit the current screen. Data loss if exited from an assessment will occur. • When pressed during EEG, the EEG menu appears.
Help	• When pressed, this will display a list of help topics and information.
Power	• Powers on and off the device.

2.4.2 Touchscreen Controls

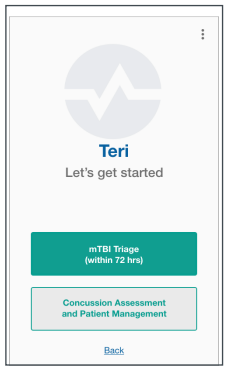
The main operation of BrainScope is controlled via the touchscreen interface display, which comprises touch-sensitive display fields and controls for entering, navigating and displaying information on BrainScope. When a control is tapped, additional screens may appear to allow for data entry, navigation and selection of actions. To use touchscreen controls, tap on the touchscreen with a fingertip. Examples of each of the common touchscreen controls are provided below:

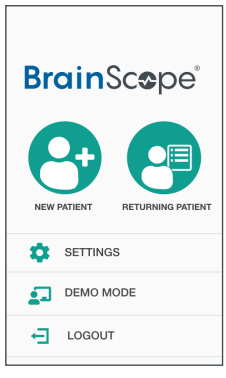
Control Type	Example	Action
Dialog Box	Ok, Dismiss, Save, Quit, Done, Yes. No Example of a dialog box: 	• Tapping will perform an action such as closing the dialog box.
Screen Navigation	Next, Close, Save, Confirm, Previous, Proceed Example of a screen navigation button: 	• Displayed at the bottom of a screen these controls allow for navigating to next or previous screens, saving and closing screens, etc. When deactivated it will be greyed out.
Selection Boxes	Checkboxes, radio buttons, scoring 	• Box that can be selected or deselected by tapping.
Hub Actions		• The Hub Action controls are displayed on the Information Hub next to each assessment. • START shows when no components have been completed for an assessment • PROCEED shows when at least one assessment component has been completed • COMPUTE shows when all assessment components have been completed • VIEW shows when assessment results have been computed and are available.
Text entry fields		• Text entry fields are identified with an empty box and a text prompt. When tapped the onscreen keyboard will appear allowing text entry.
Onscreen Keyboard		• The onscreen keyboard lets you enter text when needed. Tapping DONE or NEXT on the onscreen keyboard will close the keyboard.

Control Type	Example	Action
Calendar		• Tapping the calendar icon button will display a dialog box. Using your finger, swipe vertically through each field to set the month (Jan, Feb, Mar, Apr, etc.), date (1-31), and year (e.g. 1980,1981, etc.). Tap DONE when all information is entered.
Time		• Tapping the time icon button will display a dialog box. Using your finger, swipe vertically through each field to set the hour (01, 02, 14, 18, etc.) and the minute (01, 02, 55, etc.). Tap DONE when all information is entered.

2.5 Start & Main Menu screen

The Start screen appears after an operator has been selected (Figure 2-8.1), and the Main Menu screen appears after an operator has logged into the device. (Figure 2-8.2)

Start Screen	Menu Item	Access Level	Options
 Figure 2-8-1 Start Screen	mTBI Triage	All Users	Access mTBI Triage pathway for rapid assessment of injuries (within 72 hours of occurrence).
	Concussion Assessment and Patient Management	Authenticated Operators	Access entire battery of concussion and neurocognitive assessments. Includes access to patient management/ exporting patient reports and device configuration.
	Back	All Users	Returns to operator list

Main Menu Screen (Concussion Assessment & Patient management)	Menu Item	Access Level	Options
 Figure 2-8-2: Main Menu	New Patient	Authenticated Operators	Add new patients to the database. When selected proceeds to the Patient Information screens (refer to sections 3.3 and 4.2 for instructions)
	Returning Patient		When selected proceeds to the patient database list where patient information can be reviewed and edited. (refer to section 4.1 for instructions)
	Settings		Operators have access to a limited set of settings such as screen brightness, and battery information, and Administrators have access to additional settings such as software updates and operator settings.
	Demo Mode		Operators can access demo mode in order to conduct mock patient sessions for demonstration and training purposes. Note: Assessment results produced in demo mode are for demonstration purposes only and are not intended to reflect the patient's actual condition.
	Logout		Logs out the current user of the device.

2.5.1 Adding New Operator

During initial set up of a new handheld, an Administrator must be setup with privileges to add new operators (or approve limited operators) who will be granted access to use the BrainScope. (See section 3.4.1 for detailed instructions)

Only Administrators have access to add new operators or approve self serve operators who have limited roles & access.

2.5.1.1 Administrator Adding New Operator

1. Log in to the device using credentials for an Administrator.
2. From the Main Menu Screen tap SETTINGS to access the Settings Screen.
3. Select OPERATORS from the list of options, tap EDIT OPERATORS and tap the + icon in the upper right corner to add a new operator.
4. Tap USERNAME and the on-screen keyboard will appear.
5. Enter a username (initials or Employee ID).

NOTE: If the new operator is not to be granted rights to be an Administrator, uncheck the Administrator box.

6. Tap the cursor under the Operator First Name and enter the operator's first name. Repeat and enter the operator's last name.
7. Tap the cursor under the Operator Password and enter a password to be assigned to this operator, verify password by entering it again (See section 2.5.6 for all options).
8. When complete, tap CREATE OPERATOR.

NOTE: To add more operators, repeat steps above.

9. When complete, press the physical BACK button twice to return to the Settings Screen.

2.5.1.2 Limited Operators

Operators may add themselves as Limited Operators by tapping on START HERE on operator list screen (figure 2-10.1). This displays a screen where they can add themselves to the operator list as Limited Operators.

1. Limited Operators may only access the mTBI Triage workflow
2. Limited Operators do not have access to any patient data previously generated on the device
3. For full access, an Administrator must enter operator log in credentials (figure 2-10.2)

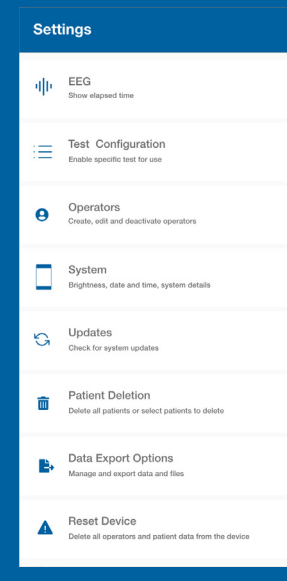


Figure 2-9:
Settings Screen

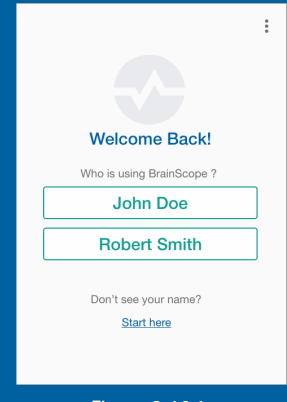


Figure 2-10.1:
New Operator Set-up

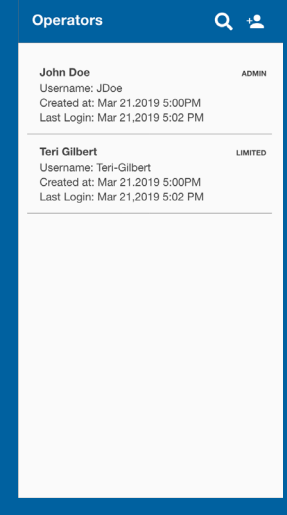


Figure 2-10.2:
Operator list

2.5.2 Test Configuration

The Administrator can configure BrainScope for which assessments will be available to users.

NOTE: Only an Administrator can access the Test Configuration.

1. Log in to the device using credentials for an Administrator.
2. From the Main Menu Screen tap SETTINGS to access the Settings Screen.
3. Tap TEST CONFIGURATION.
4. To enable an assessment, slide the toggle for that assessment to the right.
5. To disable an assessment, slide the toggle for that assessment to the left.
6. When the Cognitive Performance assessment is configured ON, individual Cognitive Performance tests can be added or removed from the battery by checking or unchecking the corresponding checkbox.

NOTE: The Simple Reaction Time test assesses fatigue following repeated tasking of the patient. As a result, The Simple Reaction Time Repeated test can only be configured ON when all other Cognitive Performance tests are configured ON (See Appendix 1 for additional details).

7. When complete, press the physical BACK button to return to the Settings Screen.

NOTE: The mTBI Triage workflow will not be available if SIC is turned off.

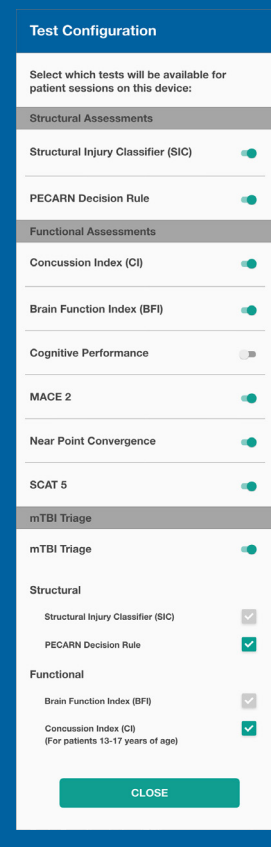


Figure 2-11:
Test Configuration Set-up

WARNING!

The BFI and the Concussion Index do not indicate the presence or absence of structural brain injury.

2.5.3 System Settings – Device Information

Brightness

1. On the Settings Screen, use your finger and slide the blue dot shown under Brightness to make the screen brightness darker or lighter.

Alternatively, toggle Adaptive brightness ON to optimize brightness level for available light.

Battery

On the System Settings Screen, you can view the remaining percentage (%) of battery level. The percentage will be displayed next to BATTERY.

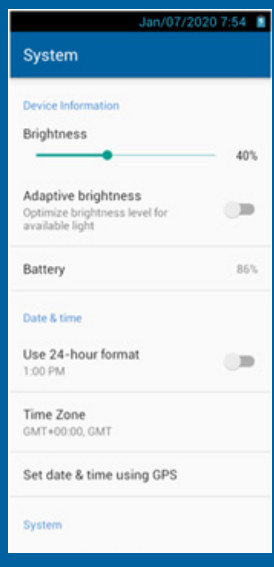


Figure 2-12:
System Settings

2.5.4 EEG Settings

Show Approximate Time Remaining:

From the Settings menu, select EEG to access the Approximate Time Remaining setting. This setting determines whether the EEG Acquisition Dashboard will display the approximate time remaining or the elapsed time during an EEG recording. The setting is toggled ON by default and will display the approximate time remaining for the EEG session. When the setting is toggled OFF, the application will instead display the elapsed time. Figure 2-13 shows an example of the EEG Acquisition Dashboard screen with Elapsed Time and Approximate Time Remaining displayed.

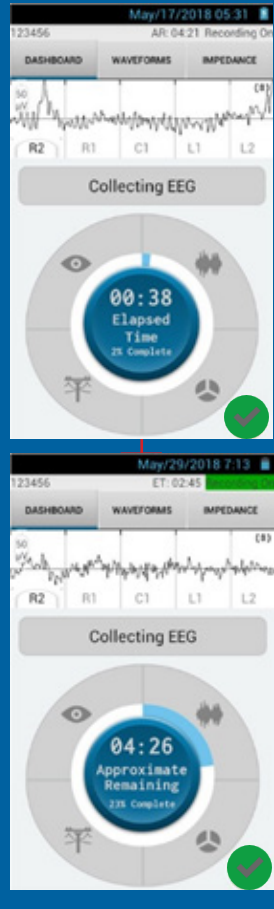


Figure 2-13: Examples of Elapsed and Approximate Remaining Time on the EEG Acquisition Dashboard

2.5.5 System Settings - Other

Date and Time

1. Navigate to the System Settings Screen to access the Date and Time settings.

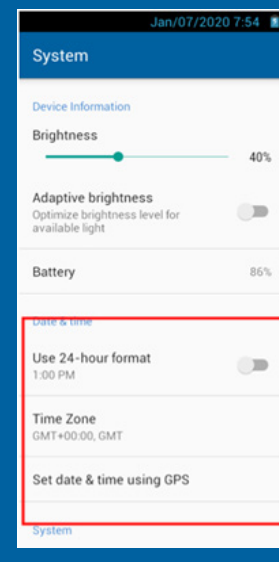


Figure 2-14:
Setting date and time

Set Time Format

Tap USE 24 HOUR FORMAT toggle to toggle between 24 hour and 12 hour.

Set Time Zone

1. Tap TIME ZONE and a list of time zones will appear.
2. Use your finger to scroll and set the desired time zone.

Set Date & Time Using GPS

1. Tap SET DATE & TIME USING GPS and a dialog box will appear showing the handheld is acquiring the GPS Time. A pop-up box will appear when the date and time are acquired.
2. Tap DISMISS when complete.

NOTE: For best results, the handheld should be outdoors with a clear view of the sky while acquiring GPS time. The handheld should not be connected to a charger while acquiring GPS Time so that the clocks on both the handheld and DAB can be set to the correct time.

About

To lookup handheld specific information such as Serial Number, Software version, etc.:

1. Navigate to the System Screen, inside Settings to access the About Screen information. Tap SYSTEM, and then scroll down and tap ABOUT and you will see the About Screen (Figure 2.15).
2. Swipe down in the About Screen to display all supporting software libraries with required licensing information.
3. Press the physical BACK and you will move back to System Screen

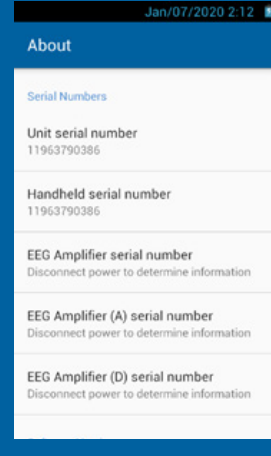


Figure 2-15:
BrainScope About Screen

2.5.6 Operator Settings

The Operator Settings option allows the Administrator to set an operator timeout that will automatically log an operator out after a set amount of inactivity. This option also allows the Administrator to edit passwords and change Administrator rights. Only Administrators have access to Operator Settings.

1. Navigate to System Settings Screen
2. Tap OPERATORS to display the Operator Settings Menu (Figure 2-16).
3. When the Inactivity Timeout is set to OFF, the operator timeout is disabled. When the Inactivity Timeout is set to ON, the operator timeout is enabled.
4. The time of inactivity can be set to either 1, 2, 3, 5, 10, 20, or 30 minutes.

NOTE: After 35 minutes of inactivity, the device will automatically power down.

5. Tap EDIT OPERATORS and the Operators List will display listing the operator names and usernames.
6. Select the Operator from the list to go to Edit Operator. Follow the guidelines below when creating and editing operator passwords:
    a. Default Operator Password must:
        - Be between 7 and 20 characters
        - Contain letters, at least one uppercase, and one lowercase each, along with at least one number/ special character (except @)
        - Not be one of the last 7 passwords
7. Tap the ENTER PASSWORD field and enter a new password.
8. Tap the RE-ENTER PASSWORD field and re-enter the new password assigned.
9. Tap SAVE OPERATOR to save the record, or press the physical back button to cancel.
10. Check the Administrator box if the operator is being given Administrator rights, or uncheck the Administrator box to remove the operator from the Administrator list.
11. To assign a password and approve an operator for full access, uncheck the Limited box.

NOTE: Only Administrators have rights to check and uncheck these boxes.

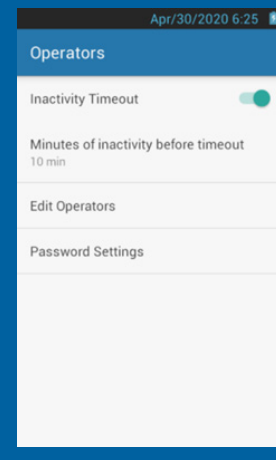


Figure 2-16: Operator Settings Menu

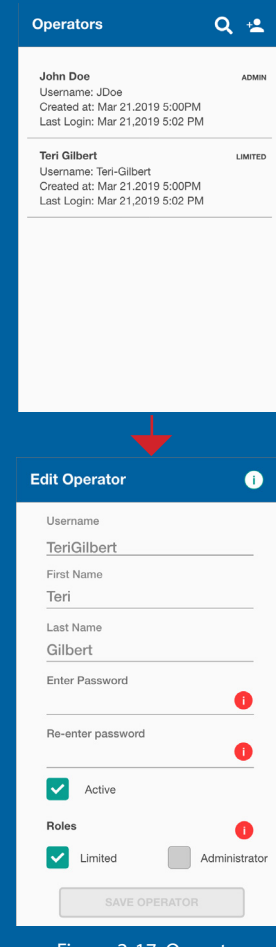


Figure 2-17: Operator List and Edit Screens

2.5.7 Operator Password Settings

The password settings section can be used to define how strong the operators password should be. By default the recommended password strength is strong. It can be customized as per needs using the options listed in Figure 2.18

1. Navigate to the Operators Screen, inside Settings Screen. Tap Password Settings in the Operators screen.
2. Tap in the toggle next to recommended settings, to set custom password parameters.
3. The parameters that can be defined are
    - Minimum Characters
    - Numeric requirements
    - Disable prior password reuse, with count
    - Text CASE requirements
    - Special Character Requirement

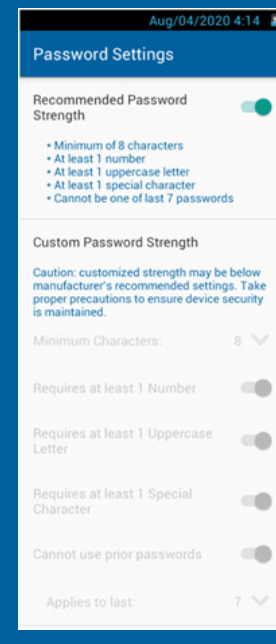


Figure 2-18:
Operator Password Settings

2.5.8 Patient Deletion Settings

The patient deletion settings allow an Administrator to delete patients on the handheld. Only Administrators have access to Patient Deletion Settings.

1. Navigate to the Settings Screen to access patient deletion settings.
2. Tap PATIENT DELETION to display the Patient Deletion Settings Menu (Figure 2-19).
3. The Patient Deletion Settings allow for the following manual deletion actions:
    - Delete All Patients - all patient data will be permanently deleted from the handheld. Tap CONTINUE to confirm deletion, or tap CANCEL to return to Patient Deletion Settings.
    - Delete Patient – data for a single patient, selected by the operator, will be permanently deleted from the handheld.

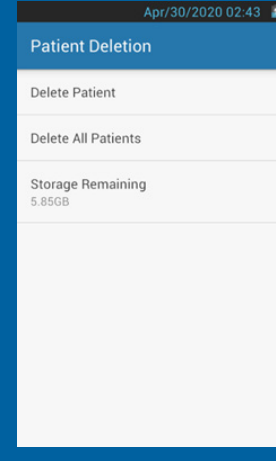


Figure 2-19:
Patient Deletion
Settings Menu

CHAPTER 3: Principles of Operation

3.1 Introduction

This section describes the principles of device operation. It is assumed that the BrainScope handheld has been set up with operators and test configurations already. If initial set up has not been completed, please refer to Chapter 2 for instructions on how to do so before proceeding with this chapter.

Read this chapter before operating BrainScope in a clinical setting.

3.2 Power ON / OFF

Turn on the handheld by pressing the power switch (1) located on the right side of the handheld (Figure 3-1).

Before collecting data, make sure that BrainScope has sufficient charge. The Battery Gauge icon should indicate at least 15%. If not, recharge the battery (see Chapter 2).

To power off the handheld, press and hold the power button. A dialog box will appear: tap POWER OFF and a second dialog box will appear to confirm shutdown. Tap OK to confirm the shutdown and the handheld will power off. Operator can also tap CANCEL to cancel the shutdown and return to the screen.

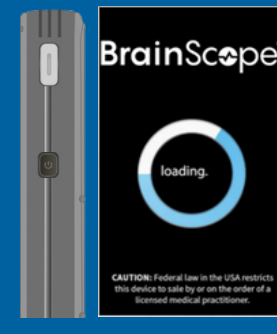


Figure 3-1:
Power ON/OFF

3.2.1 Initial Set Up

During setup of a new handheld, an operator must be created with administrator privileges. Only Operators with administrator privileges can add new operators, who can then access and use BrainScope.

1. Following device boot-up, the application will proceed to the Device Activation Screen (Figure 3-2.1).
2. Enter the device activation code that has been provided by BrainScope.
3. Tap ACTIVATE.
   a. The New Operator screen will then be displayed with the Administrator field checked (Figure 3-2.2).
4. Tap Username' text box and the onscreen keyboard will appear.
5. Enter a Username (i.e. initials or Employee ID).
6. Tap the cursor under the Operator First Name and enter the operator's first name. Repeat and enter the operator's last name.
7. Tap the cursor under the Operator Password and enter a password to be assigned to this operator.
8. Re-enter the password, then tap CREATE OPERATOR.
9. Once the Administrator has been added, tap PROCEED on the Notice screen to advance to the Operator list.

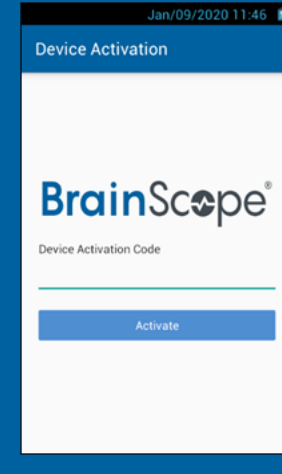


Figure 3-2.1:
Device Activation Screen

10. Tap on your name and proceed to the Start screen Figure 3-2.3 (if mTBI Triage workflow is enabled) or the Main Menu (if mTBI Triage Workflow is disabled) see section 3.4 for detailed information.

NOTE:

1. When an operator is logged into the device and the device remains inactive for a set amount of time (defined in the Administrative Settings) the device will timeout and shutdown. See section 2.5.6 Operator Settings for details.
2. If the ACTIVE checkbox is unchecked for an operator, then that operator account will be disabled and the operator will not be able to login to the device.
3. Un-Check the LIMITED checkbox to approve an operator and assign a password.

3.3 mTBI Triage Workflow

3.3.1 Initial setup

The mTBI Triage workflow is intended for use within 72hrs of injury. This workflow is by default enabled. To disable/enable this workflow, device Administrator must go to settings.

NOTE: Structural Injury Classifier (SIC) must be enabled for mTBI workflow to be available.

3.3.2 Workflow execution

1. Tap mTBI Triage on start screen to begin assessment.
2. Carefully enter the Patient ID as given in the patient file, optionally add patient initials. When finished tap Done.
3. Carefully enter the patient date of birth (Figure 3-2.5), tap Next and confirm entered details.

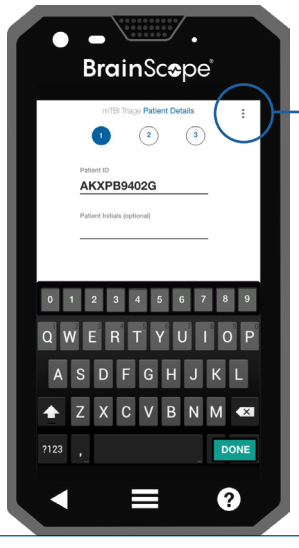
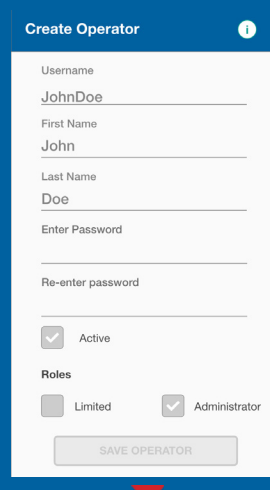
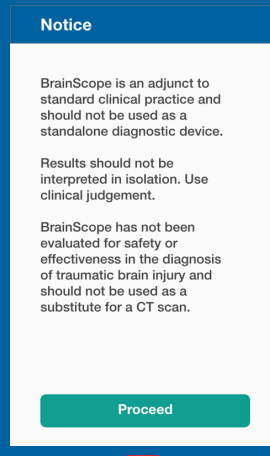


Figure 3-2.4
Using the overflow menu, change the keyboard to numeric or alphanumeric depending on patient ID format.





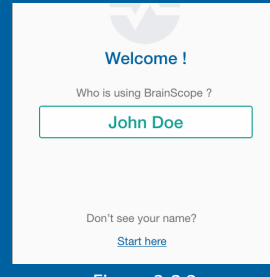


Figure 3-2.2:
Initial Administrator Operator Entry

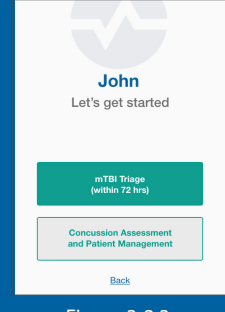


Figure 3-2.3:
Start screen if mTBI workflow is enabled

4. Review entered details (Figure 3-2.6) and correct if necessary.

5. Assessments consistent with the IFU's will be triggered depending on patient demographics & device configuration. Device will prompt for patient details, presenting symptoms, GCS and injury details. Figure 3-2.7 is a representative screen.
6. Review and confirm accuracy of entered information (Figure 3-2.8), then continue to EEG assessment or digitized clinical assessment as applicable for patient.

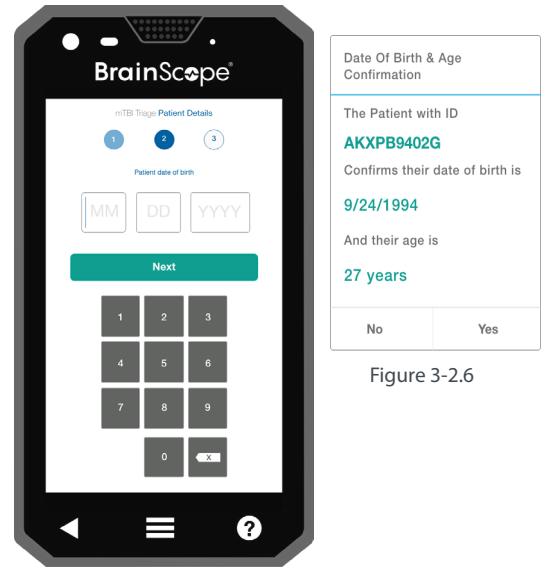


Figure 3-2.6

Figure 3-2.5

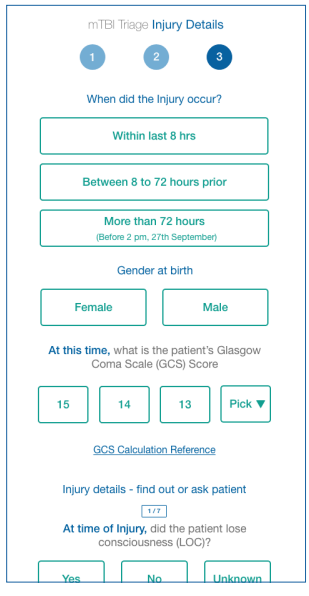


Figure 3-2.7

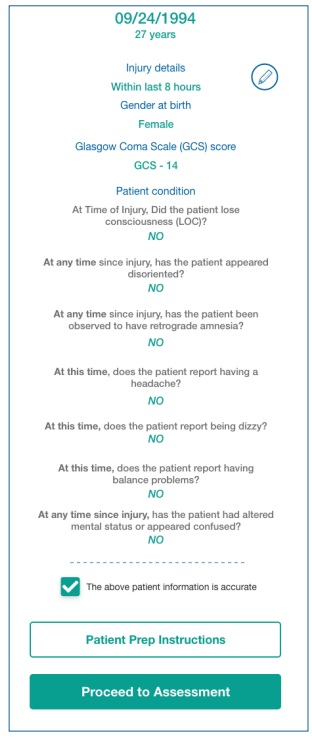


Figure 3-2.8

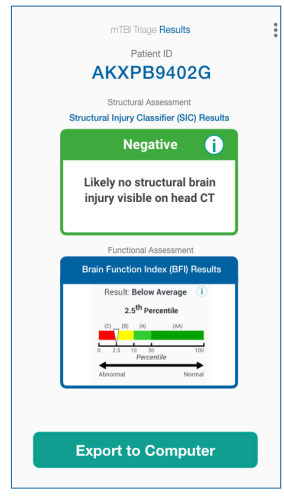


Figure 3-2.9

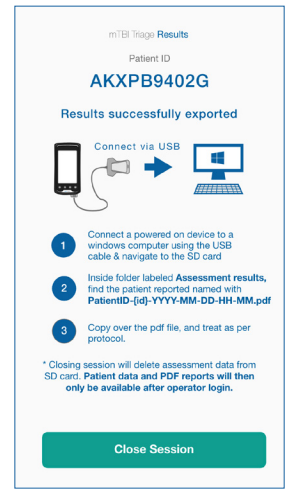


Figure 3-2.10

7. Device will proceed to EEG collection if applicable. See section 3.5 for details on applying electrode headset and collecting EEG data.

8. Once data collection is complete, results will display and can be exported as a PDF. If needed, the EDF file can also be included by tapping on the overflow menu at the top right of screen (Figure 3-2.9)

9. The operator can immediately access the patient PDF report and copy it from the device SD card by connecting to a Windows computer.
    1. Navigate to SD card
    2. Inside folder labeled Assessment results, find the patient report named with PatientID-{id}-YYYY-MM-DD-HH-MM.pdf

3.4 Concussion Assessment and Patient Management

3.4.1 BrainScope Information Hub

The Information Hub provides the following functions:

- Manage Patient Information – patient demographics as well as session and injury specific information
- Access all assessment modules that have been configured – starting a new test, reviewing test results, and entering detailed tests results screens

To perform Operator Authentication:

1. Tap on your name in operator list upon device bootup. If mTBI Triage workflow is enabled (Figure 3-2.3), tap on Concussion Assessment and Patient Management to see login screen.
2. The Username field will be pre-populated.
3. Tap Next' on the keyboard, or tap the Password field and enter the corresponding password.
4. When complete, tap Done on the onscreen keyboard.
5. Tap LOGIN.

NOTE :
If the operator Username and the Password do not match, contact your authorized administrator for credentials.

The following describes each area of the Information Hub:

Information Hub – Menu Options:

While on the Information Hub (Figure 3-3.2), the physical MENU button can be used to display additional options and allow the user to leave the session (Figure 3-3.3). The menu options support the following functions:

- Return to Patient History: returns the application to the Patient History screen for that patient.
- Generate PDF Report: produces a PDF report for the session, which can then be accessed on the SD card over a USB connection.
- Export EEG in EDF: produces an EEG file for the patient's collected EEG data, which can then be accessed on the SD card over a USB connection.
- Close Session: permanently closes the session and prevents further modifications to the record.
- Main Menu: exits the current session and returns the application to the Main Menu screen.
- Help: displays troubleshooting information related to common device operation and user issues.
- Logout: exits the current session and logs out the current operator.

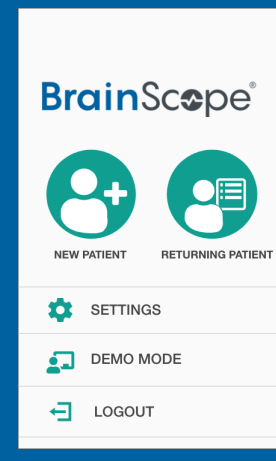


Figure 3-3.1:
Main Menu after operator login

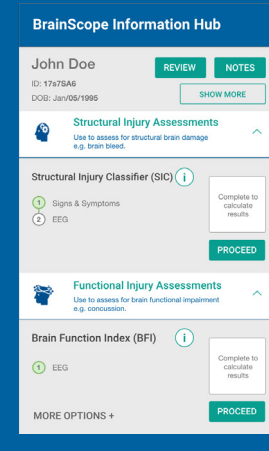


Figure 3-3.2:
Information Hub

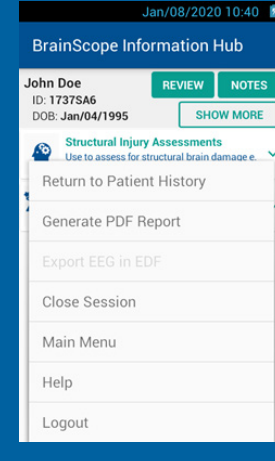


Figure 3-3.3:
Menu Options from
Information Hub

Patient Information Section

a. The Patient Information section displays the information entered on the Patient Information screens including the Date and Type of Session, Date/ Time of Injury, and the GCS score entered (when applicable). Tap REVIEW to review detailed patient information.

Assessments Sections:

Each assessment configured on BrainScope will be listed on the Information Hub, provided that the assessment is available for the given session type and patient age. Each assessment is listed by its name along with the required test components that must be completed to get results.

The Information Hub is segmented into 2 Assessment Sections, which can be collapsed or expanded:

1. Structural Injury Assessments
2. Functional Injury Assessments

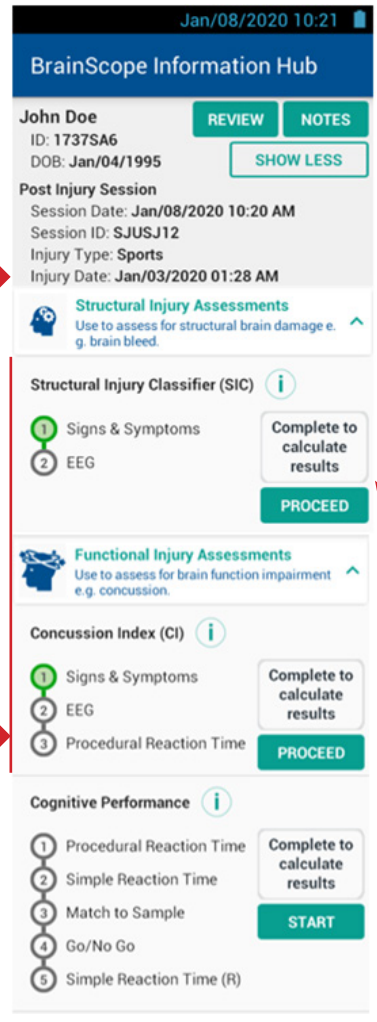


Figure 3-4: Active Information Hub when both BFI and CI are configured ON

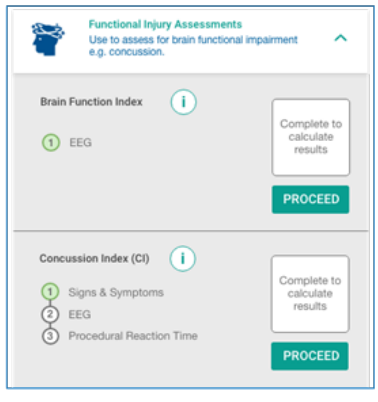


Figure 3-5: Functional Assessments section when 'MORE OPTIONS' has been tapped (when BFI and CI are configured ON).

Assessments will display START to the right in the Results area until a test has been completed, or PROCEED if the assessment has already been started. The assessment test components will turn green once they are completed.

Once a test has been completed, the test summary Result/Score will be displayed in place of START.

For a given session only one functional EEG assessment can be executed and results computed, even if both BFI & CI are configured ON.

Any menu options that appear grayed-out are not applicable for the current encounter.

The physical BACK button can also be used while on the Information Hub to leave the session. When pressed, the application will return to the Main Menu after the user confirms that they want to leave the session.

NOTE:
To protect patient information, exportable patient data (the PDF Report and EEG EDF file) is deleted from the SD card on every device restart. To access patient data after device restart, follow the steps in section 3.3.2 (step 9) above to re-generate the PDF report or re-export the EEG EDF file

3.4.2 New Patient Entry

Select NEW PATIENT on the Main Menu Screen to advance to the New Patient Entry screens.

Prior to starting a test, the following patient information is required.

- Patient ID
- Date of Birth (DOB)
- Gender (using gender assigned at birth is recommended)
- Dominant Hand

CAUTION: The patient ID may appear in unencrypted files generated by BrainScope.

1. Enter all of the information by selecting the field and typing the information using the onscreen keyboard.
   a. Tap 'Done' on the onscreen keyboard when completed with that field.
   b. Tap CALENDAR to enter the patient's Date of Birth (DOB).
   c. tap the checkbox to select the gender and dominant hand.

2. When complete, tap CONTINUE.

NOTE:

- If the Patient ID entered matches a Patient ID that exists in the handheld database, the Patient Name, Date of Birth, Gender and Dominant Hand are automatically populated, but disabled.
- If CONTINUE is selected and the Patient ID, DOB, Gender, and/or Dominant Hand is not populated, a dialog box will appear informing the operator to enter the information.

3. Verify the DOB in the dialog box (Figure 3-7):

   a. If the age calculated from the DOB is correct, tap YES to continue.

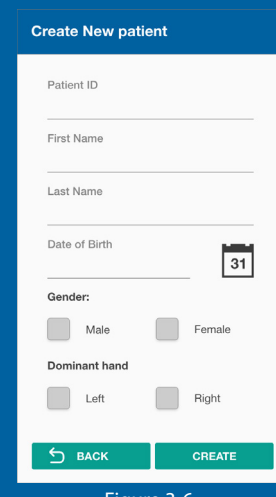


Figure 3-6:
New Patient Entry

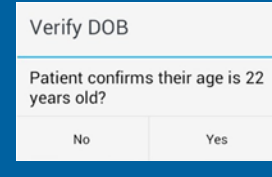


Figure 3-7:
Verify DOB Message

b. If the age is not correct, tap NO and the dialog box will return the operator to New Patient Entry to edit the DOB. Re-enter the correct DOB using the instructions above.

CAUTION: Patient Information, including DOB, Gender, and handedness, may impact device performance and availability of assessments. Ensure all information is accurate before proceeding.

NOTE: The date of each patient session and individual assessment will be automatically entered into the patient's record when the test is initiated. Age will be automatically calculated from the DOB.

4. Once the new patient is created, the device will advance to the Patient History screen for the patient. This screen lists existing sessions for the patient that have been conducted on the device (note that a new patient will not have any previous session records on the device) (Figure 3-8).

   - For new patients, Select NEW SESSION to start a new session for the patient.
   - For returning patients, Select NEW SESSION to start a new encounter for the patient, or the operator can select to resume or review an existing session (Figure 3-8).
     - Only the most recent session can be resumed. All older session records will only be available to review.

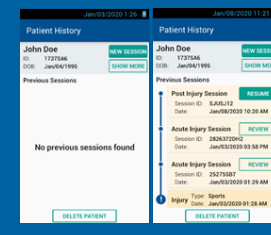


Figure 3-8: Patient History screen (Left: new patient; Right: returning patient with previous sessions)

5. Select NEW SESSION to advance to the Session Information Screen (Figure 3-9)

   - The Session Information screen allows the operator to:
     - Enter an optional Session ID, if desired.
     - Indicate whether the session type is for the assessment of an Injury or for a Baseline.

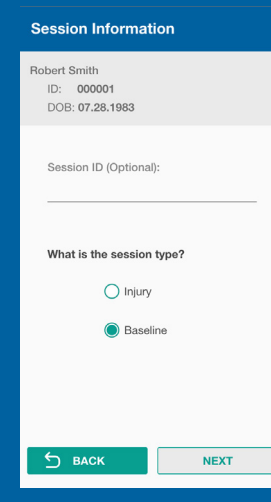


Figure 3-9: Session Information screen

6. Select the appropriate session type, and then select NEXT to proceed with the entry of patient and session information.

   - For a Baseline session, the application will advance to the Patient Information screens (See section 3.4.3)
   - For sessions related to an injury, the application will advance to the New or Existing Injury screen (Figure 3-10)

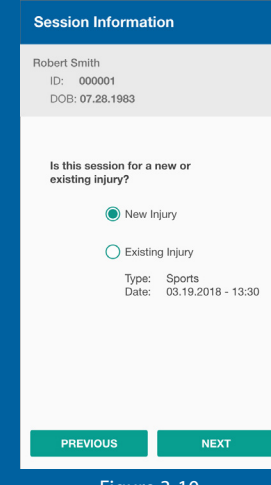


Figure 3-10: Create or Select an Injury screen

7. On the New or Existing Injury screen, the operator has the option to create a new injury or select the patient's most recent injury (if one exists on the device).

- If the operator elects to assess a new injury, the application will proceed with the first Patient Information screen so that the Date, Time, and Type of injury can be captured.
- If the operator selects the patient's most recent injury, then the application automatically captures the known Date, Time, and Type of Injury and advances to the next applicable Patient Information screen.

3.4.3 Patient Information, Session, and Injury Entry

The Patient Information, Session, and Injury Entry screens gather details about the type of patient session, patient signs and symptoms, as well as details about the injury event (if applicable for the session).

There are 8 Patient Information and Injury Entry screens (one example is shown in Figure 3-11) to record the following information:

- Date and Time of Injury
- Type of Injury Event
- Glasgow Coma Scale (GCS) Score (at time of assessment)
- Loss of Consciousness (witnessed and duration at time of Injury)
- Disorientation (at any time since injury)
- Retrograde Amnesia (at any time since injury)
- Headache (at time of assessment)
- Dizziness (at time of assessment)
- Balance (at time of assessment)
- Altered Mental Status (at any time since injury)

For Baseline sessions, which are not related to an injury, the device will only prompt the user to enter patient information related to headache, dizziness, and balance.

Information entered on each of the screens will be entered by a combination of checkboxes, text fields, calendar and time entry. At the bottom of each screen tap either NEXT to navigate to the next screen or PREVIOUS to return to the previous screen.

NOTE:

- On the Patient Information Screen related to GCS score, a GCS Calculator option is available to assist with determining the patient's GCS score. If the GCS score is less than 13, tap the SELECT field and a drop down box will appear. Choose the GCS value.
- On the Patient Information Screen related to Loss of Consciousness, decimal minutes can be entered, such as 2.5 to indicate 2 minutes and 30 seconds.

CAUTION: Ensure Patient Information is accurate. Accuracy of patient info may impact device performance.

When all information is entered, the information entered will display in the Patient Information Summary (Figure 3-12). The Patient Information Summary provides a comprehensive list with results for the clinician to use in their clinical assessment of the patient. When all information has been reviewed, check the box at the bottom of the screen to confirm that the information is accurate, then tap CONFIRM.

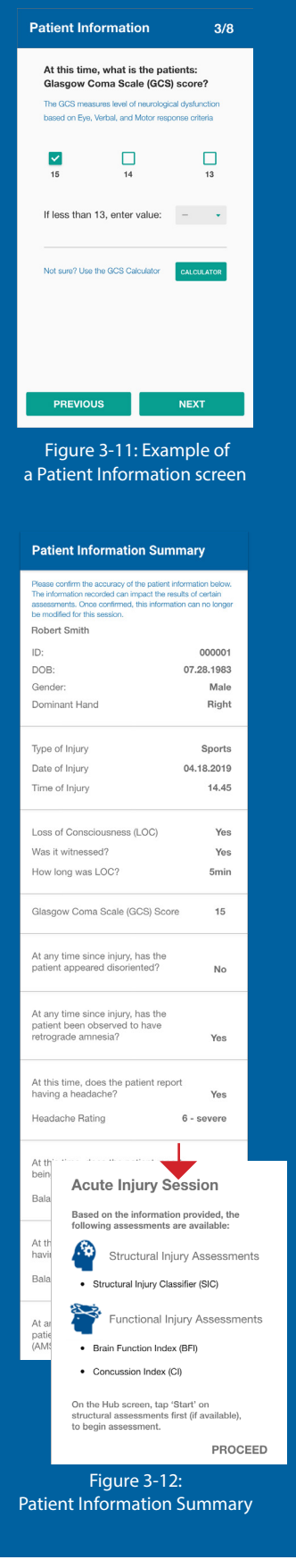


Figure 3-11: Example of a Patient Information screen

Figure 3-12: Patient Information Summary

If any of the responses need to be corrected, tap PREVIOUS to return back to the last data entry screen. NEXT and PREVIOUS can be used to navigate through the various screens for the purpose of making corrections. For more information on reviewing patient information, see Section 4.3.

When CONFIRM is tapped the device will display a pop-up that indicates the type of session and also provides a list of Configured Assessments that are available to be conducted during that session.

The possible session types include:

- Baseline Session: an encounter that is not related to an injury
- Acute Injury Session: an encounter to assess an injury that occurred within 72 hours
- Post Injury Session: an encounter to assess an injury that occurred greater than 72 hours in the past

The available assessments on the Information Hub are determined based on the Session Type and Patient Age. Table 3-1 provides a breakdown of assessment availability.

Table 3-1: Assessment Availability

Assessment	Baseline Session	Acute Injury Session	Post Injury Session
Structural Injury Classifier (SIC)	Not Available	Available (ages 18-85)	Available (ages 18-85)[1]
Brain Function Index (BFI)	Not Available	Available (ages 18-85)	Available (ages 18-85)[1]
Concussion Index (CI)[2]	Available (ages 13-25)	Available (ages 13-25)	Available (ages 13-25)
PECARN Decision Rule[3]	Not Available	Available (ages 2-17)[3]	Available (ages 2-17)[3]
Cognitive Performance	Available (ages 13-85)	Available (ages 13-85)[3]	Available (ages 13-85)
SCAT5	Available[4]	Available[4]	Available[4]
MACE 2	Available[4]	Available[4]	Available[4]
NPC	Available[4]	Available[4]	Available[4]

[1] At their discretion, Clinicians can use the BrainScope SIC and BFI assessments for times greater than 72 hours since injury. Such use is outside of the indications for use and the device will display a warning before the assessment can be conducted.
[2] For patients ages 18-25, if the CI assessment and the BFI assessment are both configured ON, the device will only produce results for one of the two assessments for a given patient session. The device will default to computing the BFI but gives the user the option to calculate the CI if desired. These assessments can be configured ON/OFF under Test Configuration in Settings.
[3] The PECARN assessment is indicated for patient ages 2-17, with GCS scores 14-15, and within 24 hours of head trauma. Use of PECARN is accompanied by a display of the indications to alert the user before proceeding. PECARN is a standardized assessment that does not use EEG data.
[4] Refer to assessment's general instructions for suitable patient age ranges.

Tap PROCEED on the pop-up to navigate to the Information Hub.

3.5 Electrode Headset Preparation

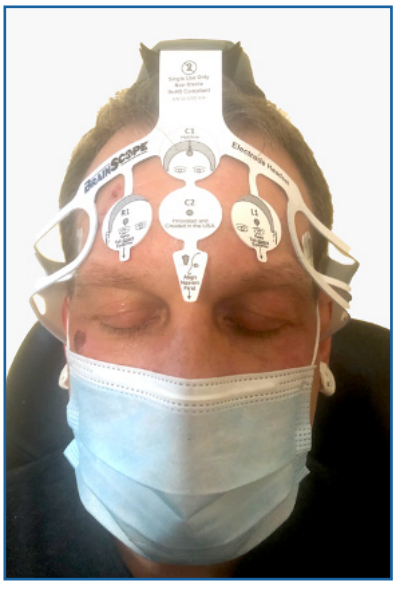


Figure 3-13: Electrode Headset

The headset (Figure 3-13) is a single-use, disposable intended to be rapidly and easily applied to the patient's forehead. The headset utilizes an adjustable array of integral electrodes with an ergonomic and aesthetic design that focuses purely on the forehead and ears.

The electrodes on the headset are attached to the patient at the following locations: Fp1, Fp2, AFz, F7, F8, Fpz, A1, and A2, in accordance with the expanded International 10-20 System of Electrode Placement.

The table (Figure 3-13a) below shows the corresponding headset labeling and position on the patient's head.

Headset Labeling	International 10-20 System Labeling
L1, R1, C1, C2	Fp1, Fp2, AFz, Fpz
L2	F7
R2	F8
L3	A1
R3	A2

Figure 3.13a

The headset is packaged with skin preparation materials to aid in the preparation of the patient: (Figures 3-14 and 3-15):

- 2 individually sealed alcohol wipes, and
- 1 headset skin prep pad
- 1 electroconductive gel packet

Figure 3-14: Electrode Headset and Skin Preparation Materials

NOTE: The pouch that the headset is packaged in contains instructions for use as well as important safety and manufacturing information.

To prepare a headset for application, the headset and skin preparation materials will need to be removed from the plastic packaging insert. Figure 3-15 shows the headset and skin preparation materials still packaged in the plastic insert. Remove the plastic covers and gently detach the headset from the plastic insert.

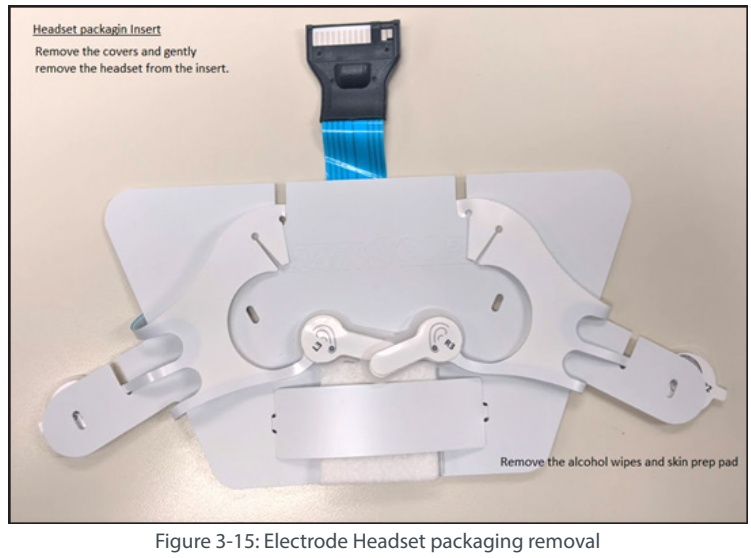


Figure 3-15: Electrode Headset packaging removal

3.5.1 Electrode Headset Placement on Patient's Forehead

WARNING!

- Observe universal precautions to prevent contact with blood or other potentially infectious materials.
- Moderate to severe skin reactions from the headset can occur in patients with very sensitive skin. Use caution when using the headset prep pad.
- The disposable headset is intended for Single Patient Use Only and should be discarded after use. Place contaminated materials in a regulated waste container.
- If the headset cannot be applied per the instructions (i.e. the electrodes are not able to be positioned over the target anatomical locations), the test should not be performed.
- More than one headset may be required to conduct a complete test should the electrode adhesive become compromised.
- Reuse, including cleaning, disinfecting, or other efforts made in an attempt to reuse the headset may compromise system performance and may cause a potential patient hazard. Performance is not guaranteed if reused.
- The DAB module may become hot during prolonged, continuous operation.
- Monitor the patient as they may experience minor pain or discomfort. Limit exposure of the DAB to the scalp/hair to minimize any potential hazard.
- The maximum temperature of the enclosure under worst-case ambient conditions is 42.1°C (107.8°F). Heat transmission to the patient is reduced by ensuring the DAB jacket is in place during operation.
- Never use the device without the DAB jacket attached to the base of the module.

- Do not use electroconductive gel on patients with a known history of skin allergies to parabens

CAUTION!

- Avoid a thick gel layer/clumps or pools of gel on patient skin.
- Do not use the Electrode Headset or electroconductive gel if the packaging pouch is damaged or there is evidence of contamination.
- Proper Electrode Headset placement is critical to the operation of BrainScope. Pay close attention to headset placement.
- Handle the headset with care. Do not fold or crease the plastic ribbon containing the lead wire(s).
- BrainScope should not be used if the headset does not sufficiently fit the patient, such as the electrodes are not able to be positioned over the target anatomical sites.

NOTE:

- Avoid areas where skin is broken, irritated, or inflamed and avoid applying excess pressure if a skull fracture is suspected.
- The BrainScope handheld must be used in conjunction with the headset that incorporates integrated electrodes. Application instructions can be found on the headset packaging pouch.

Prior to conducting a new EEG test, the patient's skin should be prepared for placement of the headset. Before beginning skin preparation, ensure patient's hair has been pulled back to expose the forehead. When START or PROCEED has been tapped for any of the EEG-based assessments, the device will provide onscreen steps for preparing the patient for the headset. Tap NEXT to follow the onscreen steps or tap SKIP TO EEG to proceed to impedance check.

1. Start preparing the skin by using alcohol wipes to remove dirt, oil, and / or make-up from the forehead, temples and earlobes. Pay special attention to the earlobes, which can contain an excessive amount of oil.

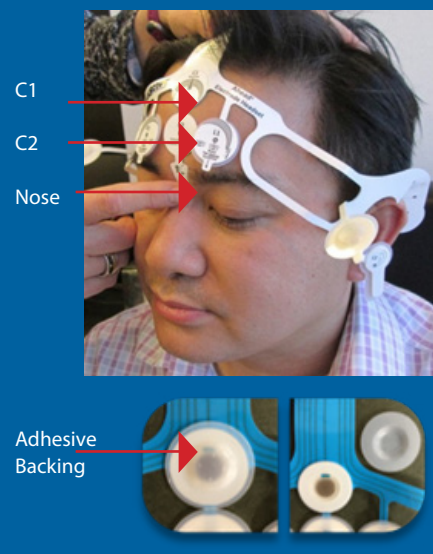
2. Dispense 3/4 inch line of gel on white prep pad. Fold pad in half and rub to spread gel evenly on the pad.

3. Swipe forehead to evenly spread a thin layer of gel visible on skin. Dispense additional gel if needed, don't forget temples & earlobes!
   - Ensure there is a visible thin layer of gel on skin in the area of each electrode.
     - Avoid a thick gel layer or clumps of gel
     - Keep clear of hair
   - If gel is not available, use white prep pad to exfoliate skin.
     - Swipe forehead, using firm pressure, to trace an inverted T across forehead with white prep pad. Repeat this process twice.
     - Be sure to cover temporal areas and earlobes. Repeat if necessary.

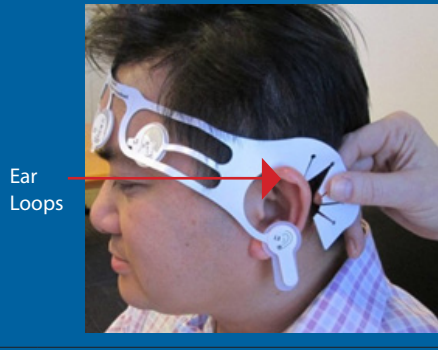
4. Before placing headset, align the lower edge of the nose tab with the bridge of the patient's nose and check to see whether the C1 electrode will fall in the hairline. If C1 falls under the hairline, remove adhesive backing from center electrodes C1 and C2, and apply the electrodes making sure the headset is centered.

   If C1 is in the hair, lower the headset by the minimal distance needed to affix C1 just below the hairline. It is acceptable if part of the adhesive ring is in the hairline, but no hairs should fall under the electrode or gel area.

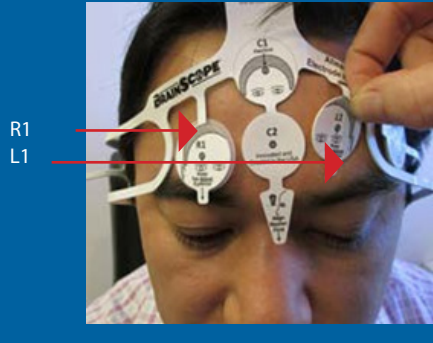
   Once the headset appears to be centered, it may be applied to the skin. Ensure that both electrodes are firmly affixed to the skin by pressing down on the electrode.



5. Place the ear loops behind each ear securing the headset. DO NOT apply the electrodes to the earlobes at this point.

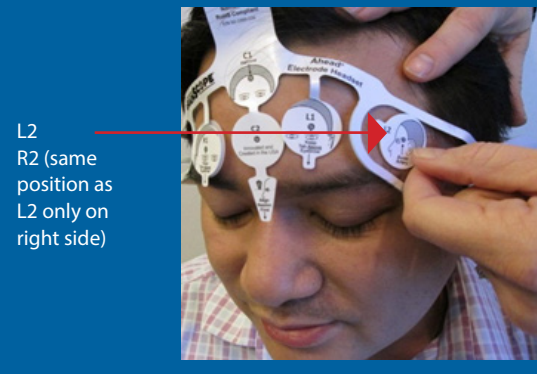


6. Locate L1 and R1 above the eyebrows. If the tab on either electrode is touching the eyebrows, raise the electrode upwards so the end of the tab touches the eyebrow but is out of the eyebrow hairs. Ensure that the electrode falls just above the eyebrow bone and firmly affix it to the skin by pressing down on the electrode.
   Keep in mind that the two electrodes should lie on the same horizontal line, and equidistant from the C2 electrode.



6. Locate L2 (left) and R2 (right) approximately 1 cm to the side of the eye and 1 cm above the eyebrow. Remove cover and place the electrodes.

NOTE: Avoid placing the electrodes directly on top of the temporal artery where the person's pulse will be detected. It is also important to provide symmetry between the R2 and L2 locations. As a guide for placement, the distance between R1 and R2 or L1 and L2 should be the same as the distance between the R1 and L1 electrodes.



7. After removing the adhesive to the earlobe electrodes locate and place electrodes on the center of each earlobe, L3 (left) and R3 (right). Once applied, the earlobe tab should be bent behind the earlobe for additional support and stability

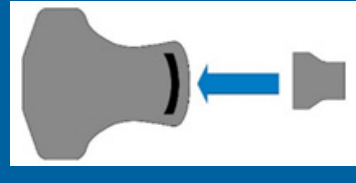
NOTE: If the patient has small and/or attached earlobes, pull them gently away from the skin to ensure the earlobe tab properly bends behind the earlobe.

8. Once the headset is firmly in place, apply pressure to all of the electrodes to ensure adhesion to the patient's skin.

9. Alternatively, all Left side electrodes (L1, L2 and L3) and then all Right side electrodes (R1, R2 and R3) (or vice-versa) can be placed if convenient for the operator. Ensure to keep electrode symmetry in placement as noted above.

10. Place the DAB on top of the patient's head. Connect the headset to the DAB. Insert the headset straight and level into the device port until resistance is met.

- The headset will not click when inserted.
- If necessary, disconnect the headset in a straight outward path.
- Avoid insertion or removal at any angle.



NOTE: The single-use headset can be inserted and removed as many times as necessary. However, the time between first insertion and last insertion must be within 60 minutes.

3.6 Performing an EEG Session

CAUTION: The operator will need to monitor the patient during data collection to observe the patient for excessive movement, excessive sweating, or shivering as these conditions will affect clean data acquisition. Patient positioning is also critical to clean data collection. Patient should be seated and relaxed with their eyes closed but should remain alert and avoid meditation or sleeping. The operator should coach the patient during data collection and address these conditions if they arise and are impeding clean data collection.

Once the Patient Information has been entered and the headset has been attached to the patient and connected to the DAB, the BrainScope is ready to perform an EEG session.

Prior to starting the test, for ease and speed of collection the patient should be instructed to relax with eyes closed in a comfortable position

1. Tap START or PROCEED in the Information Hub for the desired EEG-based assessment (SIC, BFI, or CI).
2. The device will navigate through the Headset Placement Instructions. Tap NEXT to navigate through the instructions or tap SKIP TO EEG to navigate to the impedance check.
3. The EEG Acquisition Dashboard will display the Impedance tab and begin measuring impedance.

NOTE: While impedance is being measured the other tabs (Dashboard and Waveforms) on the EEG Acquisition Dashboard will be grayed out

Impedance - Displays the status of the measured electrode impedance for each electrode (Figure 3-16)

- Green - The impedance value is within the acceptable range (0.5 kΩ – <10 kΩ).
- Red - The impedance value is unacceptably high (≥10 kΩ) Re-prepping is required before recording can continue. If red, then re-prep the area until acceptable. Tap RE-PREP INSTRUCTIONS for assistance (Figure 3-17). (Refer to Chapter 6 for additional support troubleshooting impedance)
- Gray - The C2 electrode is the electrical ground and will not display an impedance value.

4. When all electrodes (except C2) are displaying acceptable impedances (Green), tap BEGIN to begin the recording

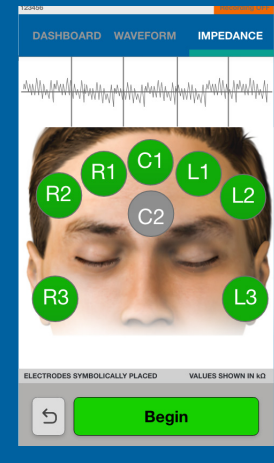


Figure 3-16: Impedance Screen - Begin (Headset)

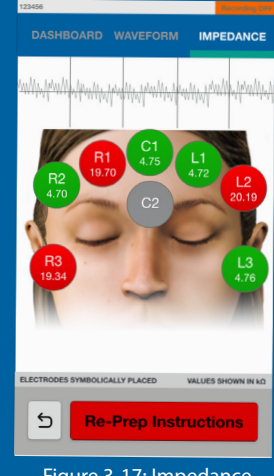


Figure 3-17: Impedance Screen Re-Prep (Headset)

NOTE:

- The headset is a single-use component. There are checks within the handheld to prevent the user from re-using a headset and that the age of the headset is within the expiration date. Although the headset is not re-usable, the user is permitted to insert the headset into the DAB multiple times, but completion of the collection must be completed within 60 minutes from the first insertion. The headset can only be used three times to calculate results within this 60 minute period.
- Headset Connectivity Messages appear when the headset is connected or disconnected from the DAB. Tap OK to dismiss the message.
- Warning messages will appear on the Impedance screen if using a headset that cannot be authenticated and the handheld will not allow the user to continue to a recording. Tap OK to dismiss the warning message and obtain a new headset to complete the test.

3.6.1 EEG Recording

EEG Acquisition Dashboard

The EEG Acquisition Dashboard will be displayed by default once the EEG recording has started. The EEG Acquisition Dashboard displays the EEG recording of a single lead (e.g. R2, R1, C1, etc.) (Figure 3-18)

Electrode lead being displayed. The remaining leads will be grayed out. To toggle between, tap the lead you want to display

Depending on the elapsed time settings, the EEG Acquisition Dashboard will dynamically display either the approximate time remaining for the collection of EEG data or elapsed time of the recording. In the header, the other EEG time setting will display as either "ET" - Elapsed Time or "AR" Approximate Remaining Time.

Additionally, the percentage of clean data collected will display.

The center blue circle is also a button to turn off or cancel EEG recording.

When clean EEG data is being collected, the progress circle will fill blue.

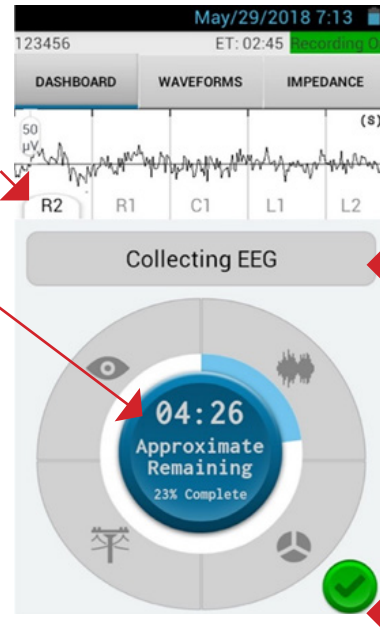


Figure 3-18.1: EEG Acquisition Dashboard Screen

The recording status of the EEG session will display either "Recording On" when EEG is being recorded or "Recording Off" when EEG is not being recorded.

EEG Collection Status Window to display collection status. See Figure 3-20 for details.

Artifact graphics for eye movement, muscle tension, electrical noise, and other artifacts. See Figure 3-19 for details.

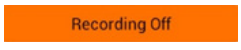
The check box in the lower right hand corner will be green if all electrical impedances are within acceptable levels.

Figure 3-18.2: Progress Circle

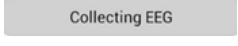
The BrainScope handheld includes software for automatic identification and rejection of non-brain-generated artifacts (Figures 3-19.1 and 3-19.2). This system replicates the process of visual editing usually performed by trained EEG technologists. The operator should pay attention to the circular display to identify artifacts that will hinder collecting clean EEG data. Four (4) types of artifacts will be displayed if detected by the handheld.

EEG Collection Status Window:

- The EEG Collection Status Window will display collection status:



- Recording Off" - if recording is off.



- Collecting EEG" - if recording is on and less than 20 epochs of clean data have been collected.

- "EEG Collection on Track" - if recording is on and more than 20 epochs of clean data have been collected. Indicates a result is likely to be successfully calculated based on the quantity of clean EEG already collected.

To see a cumulative listing of all the artifacts during the session, tap the EEG Collection Status Window and a dialog box will appear listing the artifacts.

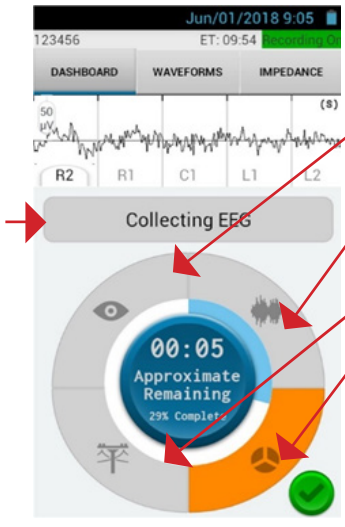


Figure 3-19.1
EEG Acquisition
Dashboard Artifacts

Artifact Indicators

- Eye Movement (Horizontal/ Lateral)
- Electromyographic (muscle activity EMG)
- External Noise High
- Other artifact

If an artifact is present the corresponding indicator will display orange.

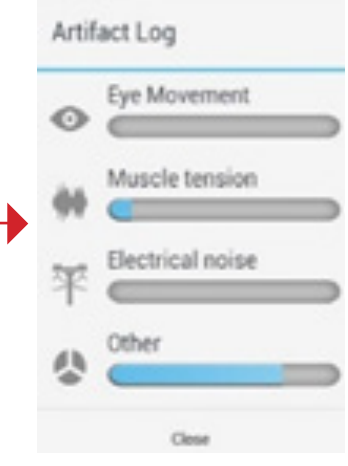


Figure 3-19.2
EEG Collection
Status Window

Turning off/on or cancel an EEG recording

To turn off the recording, tap the dark blue button in the center of the circle. A dialog box will appear (Figure 3-20) allowing the user to turn off the recording, cancel the EEG, or dismiss the dialog box and return to the EEG Acquisition Dashboard.

Tap RECORDING OFF to pause the recording, RECORDING ON will then display. The EEG Recording Menu will close, the EEG will not be recorded, and the EEG Collection Status Window will read "Recording Off ". To re-start the recording tap the dark blue button and the dialog box will appear again. Tap the RECORDING ON button. The EEG Recording Menu will close, and the EEG will continue recording.

To cancel the test, Tap the dark blue button and the dialog box will appear again, Tap CANCEL EEG. A dialog box (Figure 3-21) will appear asking to confirm. Tap YES to cancel the test, Tap NO to return to the EEG Acquisition Dashboard

NOTE: After 15 minutes of inactivity (no interaction with the user interface, physical buttons, or headset insertion/ removal) in Recording Off mode, the application will return to the Information Hub.

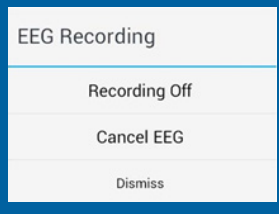


Figure 3-20:
EEG Recording
Dialog Box

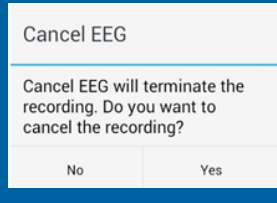


Figure 3-21:
EEG Recording
Cancel EEG

Waveforms

To view real-time wave forms during data collection, Tap the WAVEFORMS tab (Figure 3-22).

The Waveform screen displays up to 7 real-time EEG waveforms as they are collected during the session (Figure 3-22). The labels are Headset (10-20 system).

- R2 (A = Fp2-A)
- R1 (A = Fp1 -A)
- C1 (A = AFz-A)
- L1 (A = Fp2-A)
- L2 (A = F8 - A)
- L3 (AFz = A1 - AFz)
- R3 (AFz = A2 - AFz)

"A" designates the linked ears reference channel (A1 + A2) / 2 and the other electrode designations are according to the expanded International 10-20 System of Electrode Placement.

This screen also displays information about:

- Elapsed or approximate recording time
- Test progress indication as a status bar percentage complete to a sufficient amount of artifact-free data.

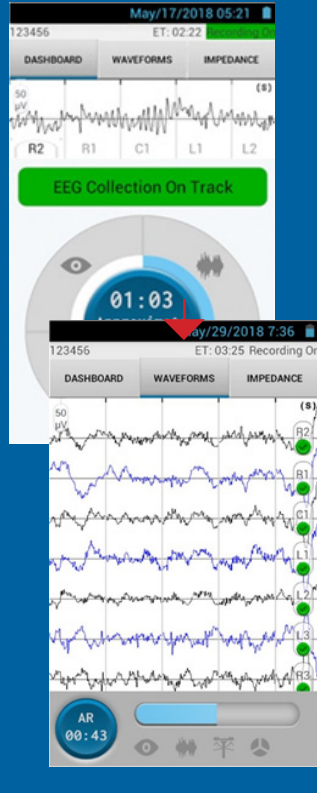


Figure 3-22:
Waveforms Screen

Recording Complete

Once sufficient artifact-free EEG data has been collected from the patient, the handheld will stop the EEG recording and proceed with the assessment (for SIC and BFI, results will be calculated; for CI, the assessment will continue with the Procedural Reaction Time neurocognitive test, which must be completed before results are calculated (See Appendix 1 for details on the Procedural Reaction Time test)).

To ensure accurate results, the Procedural Reaction Time test should be started within 1 hour of the completion of the EEG recording.

A warning message will alert the user when attempting to start the test after greater than 1 hour passed. Before proceeding, the user should disconnect the headset from the DAB.

Once the required assessment components have been completed, A Processing message will display while assessment results are being calculated (Figure 3-23).

NOTE: The Data Quality Failure dialog box will appear if enough clean EEG epochs are collected, but the data quality is inadequate to calculate results. (Figure 3-24).

NOTE: Typically, sufficient clean data is acquired within 5 minutes of EEG recording. If sufficient clean data is not acquired, an Artifacts Detected dialog box will appear (Figure 3-25) when less than 10 epochs of clean data have been collected in a moving window of 2 minutes and when elapsed time is less than 9 minutes. The message will indicate the amount of time completed for the EEG session, as well as the percent of clean data collected. In addition, a list of the top two artifacts detected along with tips to correct these artifacts will be displayed. Tap DISMISS to return to the EEG Acquisition Dashboard (if greater than or equal to 20 epochs have been collected).

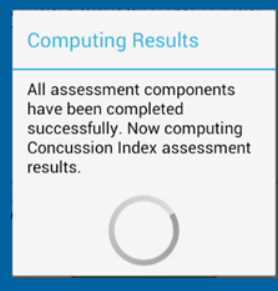


Figure 3-23:
Example Processing Message

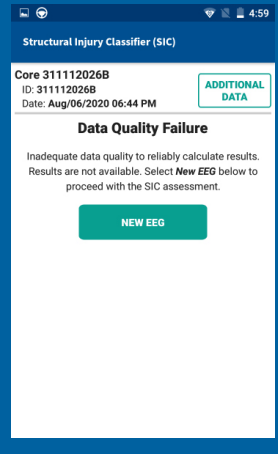


Figure 3-24:
Data Quality Failure

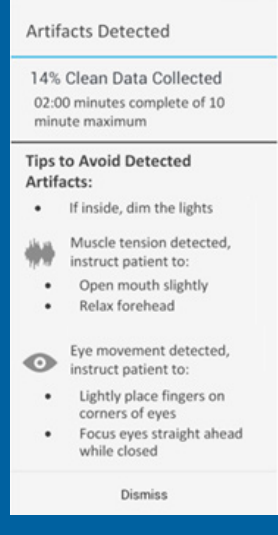


Figure 3-25: Artifacts Detected Message

NOTE: The recording continues up to the max duration of 10 minutes. After the max duration of EEG recording, collected clean data is typically considered sufficient and the recording is complete. If after the max duration of EEG recording the minimum required 20 clean epochs has not been collected, data will be considered insufficient to calculate results. Data will not be stored (Figure 3-26). Tap CLOSE to return to the Information Hub or tap NEW EEG to begin a new recording using the same headset. When NEW EEG is tapped Tips to Avoid Detected Artifacts will appear (Figure 3-27).

WARNING!

Standard clinical assessment of the patient should proceed in the event that insufficient clean (artifact-free) EEG data is collected.

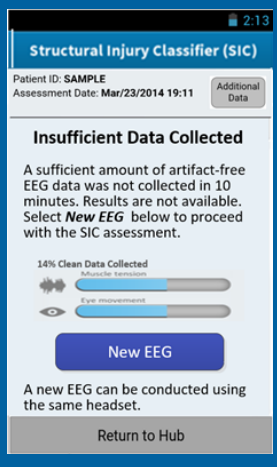


Figure 3-26:
No results EEG
Recording Status

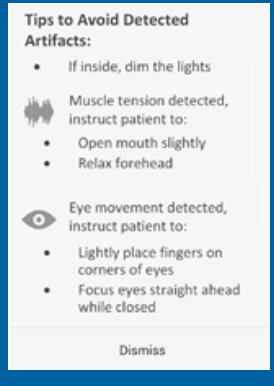


Figure 3-27:
Artifact Free Data
Tips Message

3.6.2 EEG and Multi-modal Assessment Results

Structural Injury Classifier Assessment

The Structural Injury Classifier Result screen displays the output of the structural injury classification algorithm, indicating the presence or absence of structural brain injury.

BrainScope output places a patient into one of three categories based on results of the Structural Injury Classifier using the patient's brain electrical activity. The classifications and their corresponding instructions are to be used in conjunction with other clinical assessments. Additional details on the result can be accessed by tapping "i" (information) on the result screens.

- A Negative BrainScope Structural Injury Classification (Figure 3-28) in patients who sustained a head injury within 72 hours reflects brain electrical activity that corresponds to patients who likely have no structural brain injury visible on head CT, as found in the FDA validation study population.
- An Evaluate BrainScope Structural Injury classification (Figure 3-29) using brain electrical activity in patients who sustained a closed head injury within 72 hours, corresponds to those in whom structural brain injury could not be ruled out as found in the FDA validation study population.
  May indicate the need for further observation or evaluation, including advanced neuroimaging or CT scan.
- An Equivocal BrainScope Structural Injury Classification (Figure 3-30) in patients who sustained a head injury within 72 hours reflects brain electrical activity that corresponds to patients who likely have no structural brain injury visible on head CT and are close to the positive classification cutoff, as found in the FDA validation study population.

Tap CLOSE when finished reviewing the results to return to the Information Hub.
After a Structural Injury Classifier assessment has been completed, the Structural Injury Classifier section of the Information Hub will display the results of the test (Figure 3-31). Tap VIEW below the SIC result to return to the SIC Summary Screen.

From the Information Hub, the user can proceed with other available assessments.

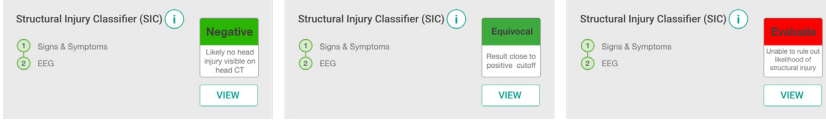


Figure 3-31: Structural Injury Classifier section of the Information Hub

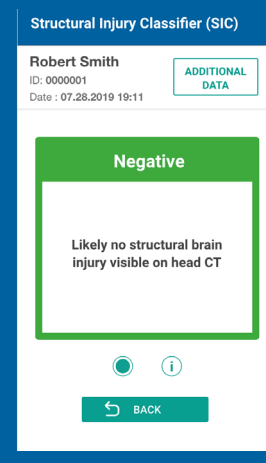


Figure 3-28: Negative Results

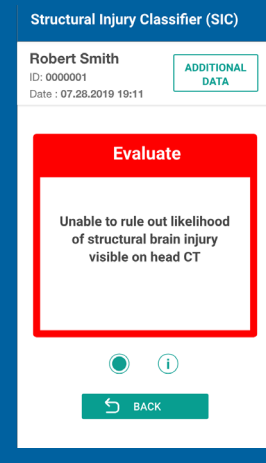


Figure 3-29: Evaluate Results

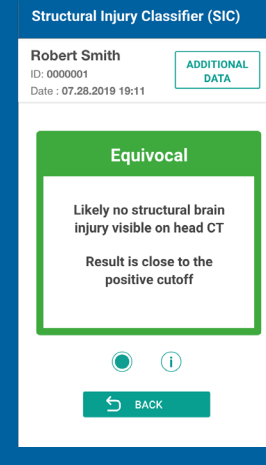


Figure 3-30: Equivocal Results

Brain Function Index Assessment

The Brain Function Index Summary summarizes the results of the Brain Function Index assessment (Figure 3-32).

NOTE:

- The Brain Function Index does not indicate the presence or absence of structural brain injury.

The Brain Function Index Summary provides the following option:

- Additional Data – provides detailed information about the recording
- For a given session only one functional EEG assessment can be executed and results computed, even when both BFI & CI are configured ON.

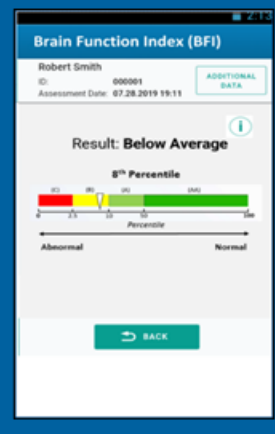
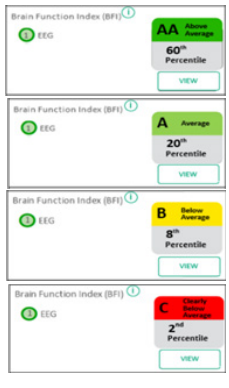


Figure 3-32:
Brain Function Index Results

See EEG View Details and EEG Data Review in Chapter 4 for detailed instructions.
After a Brain Function Index assessment has been completed, the Brain Function Index section of the
Information Hub screen (See Section 3.4.1 Information Hub) will display the results of the test.



Above Average (AA) – patient's BFI result is equal to or above the 50th percentile to the 100th percentile.

Average (A) – patient's BFI result is equal to or above the 10th percentile to the 50th percentile.

Below Average (B) – patient's BFI results is equal to or above the 2.5th percentile to the 10th percentile.

Clearly Below Average (C) – patient's BFI is equal to or above the 0th percentile to the 2.5th percentile.

The BrainScope's BFI provides an indication of functional brain impairment following a head injury. The index is a composite measure which includes features associated in the scientific literature with functional brain impairment reflecting the physiological changes associated with mTBI.

The BFI obtained in a patient is presented as a percentile of a non-injured normal population. Thus, addressing the question of how likely is this value to occur in a non-injured individual. The lower the percentile score the less the brain function of the patient resembles that of the non-injured population. More specifically, if the patient's score falls below the 10th percentile, it indicates that it is highly unlikely that the score would be obtained in a non-injured individual and is shown as "below average." When the score falls below the 2.5 percentile (more than 2 standard deviations away from the mean of the non-injured population), it is statistically very unlikely that it would occur in an uninjured individual and is shown as "clearly below average."

The BFI provides information not contained in the Structural Injury Classifier alone. The BFI is associated with brain function impairment. As an adjunct to standard clinical assessment, the BFI provides an objective measure of EEG brain function related to expected normal values.

Concussion Index Assessment

The Concussion Index Summary summarizes the results of the CI assessment (Figure 3-33).

NOTE:

- The Concussion Index does not indicate the presence or absence of structural brain injury.
- When BFI and CI are configured ON for ages 18-25, to access the Concussion Index (CI) tap on 'MORE OPTIONS' within the Information Hub.
- For a given session only one functional EEG assessment can be executed and results computed, when BFI & CI are both configured ON.

The Concussion Index Summary provides the following option:

- Additional Data – provides detailed information about the recording

See EEG View Details and EEG Data Review in Chapter 4 for detailed instructions.

After a Concussion Index assessment has been completed, the Concussion Index section of the Information Hub screen (See Section 3.4.1 Information Hub) will display the results of the test.

Figure 3-33: CI Summary Results

The Concussion Index provides a multimodal measure to aid in the evaluation of concussion. Changes in CI can be interpreted reliably. The output result of the CI assessment is a unitless, whole-number index from 0-100. Based on the CI value, patients being assessed for an injury will receive a result of either CI Negative or CI Positive. For baseline assessments of uninjured patients, patients will receive a CI value but will not receive a CI Positive / CI Negative classification. The CI values and corresponding classifications are to be used in conjunction with other clinical assessments and should not be used in isolation. The CI Information Messages appear when INFORMATION is selected on each of the Concussion Index Summary screens.

- Baseline – (0≤CI≤100) A baseline CI establishes a patient-specific reference point to aid in evaluation of change. Baseline CIs will vary by patient and are not intended to provide a CI Positive / CI Negative categorization for noninjured patients.
- CI Negative – (70<CI≤100) Patients with a CI greater than 70 are CI Negative. A CI Negative result indicates a negative screen for concussion to be assessed in conjunction with neurological/clinical evaluation.
- CI Positive – (0≤CI≤70) Patients with a CI less than or equal to 70 are CI Positive. A CI Positive result indicates a positive screen for concussion and the need for additional neurological/clinical evaluation.

3.7 Patient Session Closure

To exit the current patient session, select mechanical MENU button to see a list of navigational options or select the mechanical BACK button on the handheld to return to the Main Menu Screen (Figure 2-8).

CHAPTER 4: The Patient Database

The Patient Database stores patient information and all test results performed on the BrainScope handheld. This chapter describes the procedures to access the following:

- Returning Patient list
  - Patient demographics, session information, and injury information (review and edit)
- Previous sessions and assessment results
  - Detailed results (data review) for EEG

Instructions on how to access previous assessment results and review details for Standard Clinical Assessment tests can be found in their respective appendices.

4.1 The Returning Patient List

The Returning Patient List (Figure 4-1) provides access to all stored information on patients that have been entered into the BrainScope handheld.

To access the Returning Patient List:

1. Tap RETURNING PATIENT on the Main Menu Screen.
   - The Returning Patient List will populate a list of patients in the database sorted by the time of the last patient entry, with the latest patient entry at the top.
2. Tap on the row of patient name/ID number that you want to view. The list can be sorted on Patient name (a-z or z-a) or Session date (oldest to newest, newest to oldest), by tapping the arrow in the heading label. You can also search (on patients last name) by tapping the search icon near the back button.

   CAUTION: Pay close attention to patient identifiers (ID, DOB, Name) to ensure that the correct patient is selected.

3. The device will display the Patient History screen for the selected patient, which lists all previous sessions recorded for that patient.
4. The Patient History screen supports for the following actions:
   - New Session – Start a new session (See Section 3.4.2 for instructions).
   - Review - review detailed results on assessments performed during past sessions (See Section 4.2, 4.3 and 4.4 for instructions).
   - Resume - resume testing for the patient's most recent session (See Section 3.4.1 BrainScope Information Hub for instructions). Note: the Resume option is only available for 24 hours after the session is created.
   - Delete Patient - tap DELETE PATIENT to permanently delete the patient's data from the handheld.

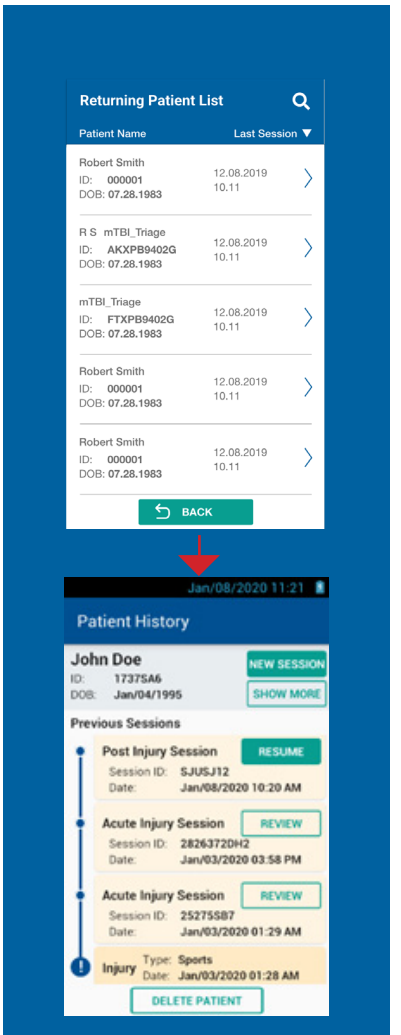


Figure 4-1: Returning Patient List and Patient History Screens

4.2 Patients added through mTBI Triage workflow

A returning patient previously created through the mTBI workflow will have incomplete information that needs to be completed before assessments can be carried out.

In the patient list (Figure 4.1), mTBI Triage patients can be identified by the label mTBI Triage in the name of the patient.

Before starting a new session on a mTBI Triage patient, all patient details will need to be completed by the operator logged in. Operator will be prompted (Figure 4-4) to enter required information. Once complete, Patient history can be accessed as per section 4.1.

4.3 Patient Information - Review

Once patient information has been entered, you can go back to review the information at any time from the Information Hub.

Patient Information Detailed Results can be accessed by tapping REVIEW next to the patient summary while in the Information Hub (Figure 4-2).

Patient Information Detailed Results (Figure 4-3) will display the summary of patient signs and symptoms information, as well as details about the injury event (if applicable) that were gathered during Patient Information, Session, and Injury Entry (See Section 3.4.3 Patient Information, Session, and Injury Entry for more information).

NOTE: While reviewing patient information, the screen header will contain "Review" to inform the operator that they are currently in review mode.

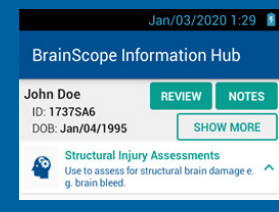


Figure 4-2: Access to review and edit stored Patient Information

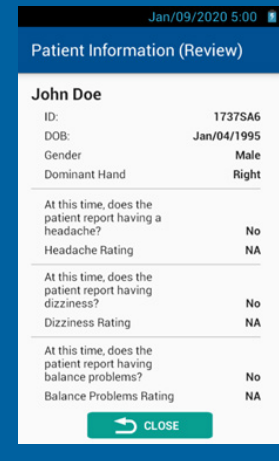


Figure 4-3: Patient Information Detailed Results Example

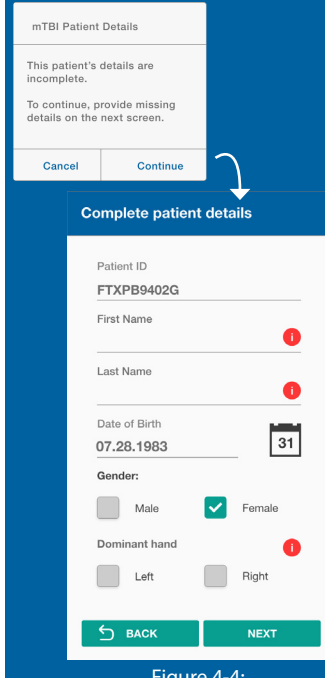


Figure 4-4: Complete mTBI patient details

4.4 EEG Results

Detailed results for the EEG tests that have been conducted for the current session are stored in the patient database and can be accessed from the Information Hub.

4.4.1 Structural Injury Classifier Detailed Results

To access the Structural Injury Classifier Detailed Results, result tap VIEW (Figure 4-4) from the Information Hub.

The Structural Injury Classifier Result – Summary Screen (Figure 4-5) displays the SIC result and contains the option to view Additional Data, which provides detailed information about the recording and playback of the EEG Data session.

Tap BACK to return to the Information Hub.

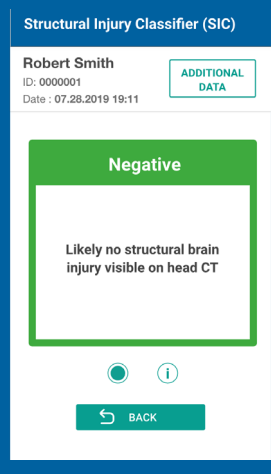


Figure 4-5: Summary of Structural Injury Classifier

4.4.2 Brain Function Index Detailed Results

To access Brain Function Index Detailed Test Results,tap VIEW "Brain Function Index" result (Figure 4-6) from the Information Hub.

The Brain Function Index Result - Summary Screen (Figure 4-7) displays the BFI result and contains the option to view Additional Data, which provides detailed information about the recording and playback of the EEG Data session.

Tap BACK to return to the Information Hub

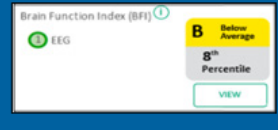


Figure 4-6: BFI Result Area from Information Hub

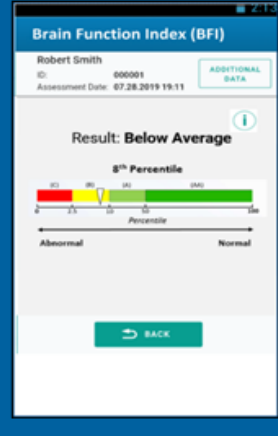


Figure 4-7: Summary of Brain Function Index

4.4.3 Concussion Index Detailed Results

To access Concussion Index Detailed Test Results, tap VIEW in the Concussion Index result (Figure 4-8) from the Information Hub.

The Concussion Index Result - Summary Screen (Figure 4-9) displays the CI result and contains the option to view Additional Data, which provides detailed information about the recording and playback of the EEG Data session

Tap CLOSE to return to the Information Hub.

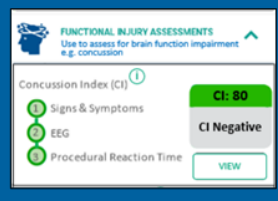


Figure 4-8:
CI Results Area from Information Hub

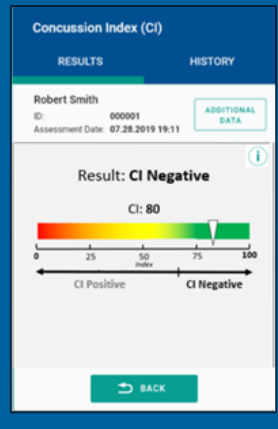


Figure 4-9:
Summary of Concussion Index

4.4.4 EEG Details

BrainScope extracts various quantitative features from the EEG in the traditional EEG frequency bands. Computed raw EEG features such as monopolar and bipolar relative power are available for review. When ADDITIONAL DATA is available on an EEG results screen, you can view EEG measures extracted from the patient's EEG recording. Note that these are not specific to the classification algorithms.

Choose the feature from the on-screen list by taping the name of the feature. A sample of each of the tables and graphs are provided below (Figure 4-10 and 4-11).

Figure 4-10:Examples of Spectral Plot Data and EEG Tables of Measures for Mono-polar To view more data on each screen tap the + and - buttons in the top right corner. (Available on the Spectral Plot Data Screen only)

Figure 4-11:
Examples of EEG Tables of
Measures for Bi-polar

4.4.5 EEG Data Review

The EEG Data Review function allows the operator to playback the EEG waveforms of the test that was chosen.

From any of the EEG detailed results screens tap ADDITIONAL DATA and then DATA REVIEW in the message box to navigate to Data Review.

Data Review provides the following options:

- Back – returns to the previous screen
- Round Timer Counter – displays the Playback Control Menu (Figure 4-15)

Data Review will automatically begin playback of the recorded EEG. Seven (7) raw EEG waveforms will be displayed relative to linked ears (Figure 4-14)

Tapping ROUND TIMER COUNTER will display EEG recording timer in Minutes and Seconds (MIN:SEC). The horizontal blue EEG Progress Bar will progress when clean epochs are detected, completely filling at 48 clean epochs.

At the bottom of the screen, Artifact Indicators for eye movement, muscle tension, electrical noise, and other artifacts will illuminate when the corresponding artifact is detected.

To access Playback Controls, tap ROUND TIMER COUNTER and the Playback Control Menu screen will appear (Figure 4-15).

The Playback Control Menu provides the following options:

- PLAY – when selected, the screen will begin playback of the selected recording
- PLAY FROM START – when selected, the screen will begin playback of the selected recording from the beginning
- DISMISS – when selected, the Playback Control Menu will close and return the user to the Data Review.

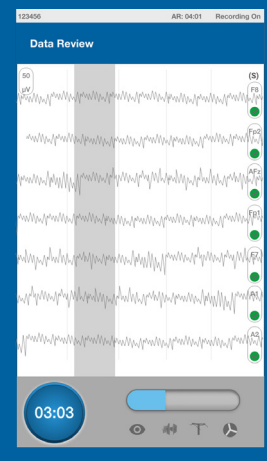


Figure 4-12: EEG Data Review

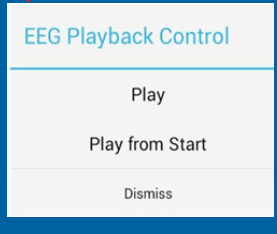


Figure 4-13: EEG Playback Control

4.4.6 New EEG

To start a new EEG from the EEG detailed result screens, tap NEW EEG (this option is only available for the Data Quality Failure and Insufficient Data results screens). The handheld will navigate to Headset Placement Instructions, where testing can begin. (Refer to Section 3.5 for detailed instructions).

4.5 Data Transfer and Networking

Use the USB-A to Micro-B USB Cable (40-1000-013) to connect the device to a computer running Windows 7 or Windows 10. The BrainScope device will appear on the PC as an MTP (media transfer protocol) device.

Host laptop or PC requirements:

- Operating System: Windows 7 or Windows 10
- Supports USB 2.0 MTP protocol
- No additional USB drivers are necessary beyond those that are standard in the Operating Systems above.

CAUTION:

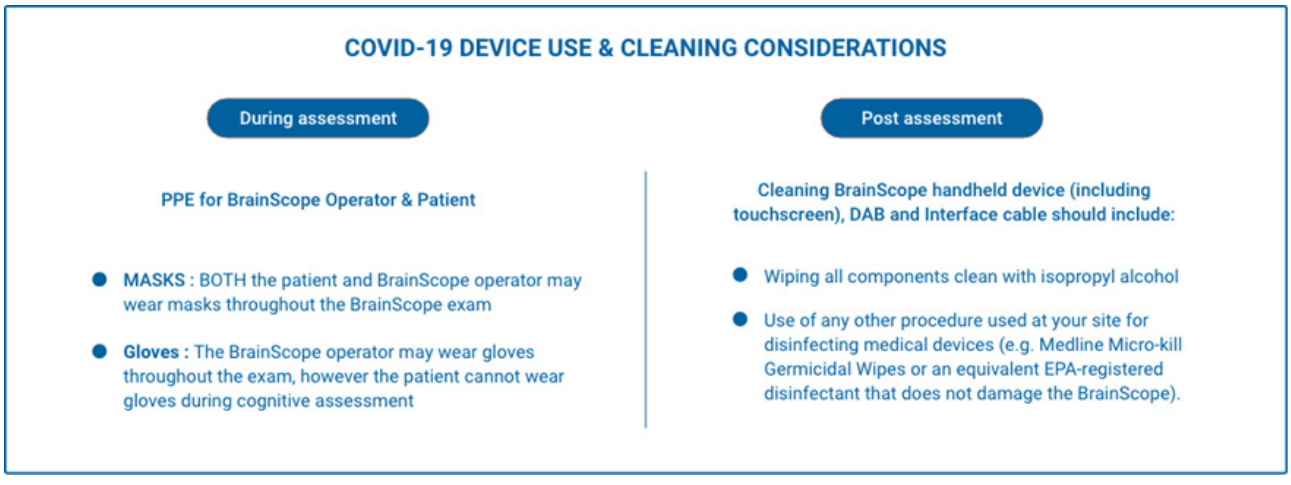
- Only Windows 7 and Windows 10 operating systems are supported. All other operating systems are not supported and may result in data transfer failure.

- Connection of BrainScope to third-party equipment for the purposes of data transfer could result in previously unidentified risks to patients, operators, or third parties. The Organization utilizing BrainScope should identify, analyze, evaluate, and control these risks. In addition, changes to the third-party equipment could introduce new risks that require additional analysis.

*Organization is accountable for the use and maintenance of BrainScope.

CHAPTER 5: Maintenance

5.1 Cleaning the BrainScope Device



WARNING

- Follow the current local regulations governing biohazard waste to safely handle the system components.
- Electrode Headsets are single use only.
- Disconnect the handheld from the AC power source before cleaning. After cleaning, do not connect to AC power source until the handheld is thoroughly dry.
- Avoid exposing Charger to excess moisture, as this can lead to an electrical shock or fire hazard.
- Turn off the handheld before cleaning. Pay particular attention around controls, connectors, and panel edges.
- Do not use abrasives.

To clean the handheld:

- Apply mild detergent and warm water or a glass cleaner to a soft cloth and gently wipe the touch screen.
- Gently wipe the handheld with a soft cloth or sponge dampened with a non-abrasive, hospital disinfectant (e.g. Medline Micro-Kill Germicidal Wipes or an equivalent EPA-registered disinfectant) or mild detergent and water.

To clean the patient interface cable and DAB Module:

- Visually inspect the patient interface cable for damage. DO NOT use if damage is apparent.
- Wipe the cable clean with a mild detergent and water or isopropyl alcohol.
- Dry the cable with a lint-free towel. If available, use medical-grade compressed air.

CAUTION

- DO NOT allow moisture in any seams, openings or electrical connectors.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified. Failure to comply may result in product damage.
- DO NOT use an aerosol spray directly on the touch screen and DO NOT scratch the touch screen.
- If the handheld is exposed to biohazard substances, clean the handheld with 10:1 water/ bleach solution. However, repeated cleaning with a bleach solution can degrade the plastic case.
- The handheld MUST NOT be immersed in liquids.

To clean the charging kit:

- The charging kit requires cleaning only if soiling is observed. If cleaning is required, wipe the exterior surfaces with a cloth dampened with isopropyl alcohol.
- Before cleaning, ensure the USB-A Charger is unplugged from AC power source.

5.2 General Maintenance

There are no user-serviceable parts contained within the BrainScope EEG Acquisition Unit, patient interface, or the charging kit. DO NOT attempt to open or service these units.

Contact BrainScope Technical Support for any issues. Opening the instrument, patient interface cable, or charging kit will void the warranty and may adversely impact handheld performance and safety.

5.3 Preventative Maintenance

Periodic factory maintenance is not required but intermittent battery replacement may be needed. Contact BrainScope Technical Support.

5.4 Software Update

BrainScope will notify customers when software updates are available for the BrainScope device. All software updates shall be performed by BrainScope personnel. If you encounter software related issues, please contact BrainScope Technical Support (See Section 5.5).

5.5 Technical Support

Contact us at:

BrainScope Company, Inc.
7648 Standish Place
Rockville, MD 20855
USA

Phone: 1-855-9-BRAIN-1 (927-2461)
Email: CustomerCare@BrainScope.com

www.BrainScope.com

5.6 Product Life

The BrainScope EEG Acquisition Unit product life is expected to be 5 years with battery replacement expected every 2 years, depending on use. The headset shelf life is 24 months* from date of manufacture. The battery is intended to be replaced only by the manufacturer. A special tool and knowledge of the handheld's assembly is required for its removal.

NOTE:* Maximum headset shelf life of 24 months can be achieved when product is stored in temperatures equal to or under 25°C or 77°F within intact and undamaged packaging.

5.7 Service - Returning a Device

Delete all patient data such as protected health information (PHI) from the device prior to sending the device back to BrainScope for servicing unless specifically instructed otherwise.

CHAPTER 6: Troubleshooting

6.1 Impedance

Message	Meaning	Corrective Action(s)
Unacceptable Impedance Values	Impedance values are higher than acceptable range.	• Press the electrode(s) firmly in place to ensure adhesion to the patient's skin. • If unacceptable impedance value remains, lift electrode using tab and apply a small dab gel on skin under electrode (See Section 3.5.1). Replace the electrode and apply firm pressure to ensure adhesion to the patient's skin.
Impedance Values Indicate OFF	Headset connector not connected.	• Keep straight and push the headset connector all the way into the DAB.

NOTE: If gel is not available, refer to section 3.5 in the user manual for skin preparation via exfoliation.

6.2 Handheld

Message	Corrective Action(s)
Handheld Not Responding to User Commands	• Push the power button and hold for more than 10 seconds. • The handheld will re-boot automatically. If the handheld does not respond to a 10 second push of the power button, connect the device to its charger and push the power button and hold for more than 60 seconds. The handheld will reboot automatically.
Incorrect Date and Time	• When the BrainScope battery is fully drained, the BrainScope 's clock will be reset to January 11, 2014. • To correct the problem: 1. Connect the charger and recharge the battery for at least 2 hours with the handheld powered off. 2. Then disconnect the charger and power on the handheld. • The clock should be set correctly after the application starts up and the EEG data connection to the DAB is established. • The handheld will not be able to get the correct date and time from the DAB while the charger is connected. • Check the time in the status bar at the upper right corner of the screen. • If the handheld's date is not correct, power off and then power back on with the charger disconnected to re-synchronize the handheld's clock with the DAB.

Message	Corrective Action(s)
Incorrect Date and Time (Cont.)	• Daylight Savings Time is handled automatically by BrainScope, but the software may not immediately apply the automatic change to or from Daylight Savings Time. Restart BrainScope to force it to apply the change. Occasionally, multiple restarts may be necessary for the clock to be adjusted correctly. • If the Date/Time is still incorrect, follow the instructions in Section 2.5.5 System Settings - Date and Time to set the clock using GPS. Make sure the unit is outdoors with a clear view of the sky and that it is not connected to a charger when setting the clock using GPS. The clocks on both the handheld and DAB will be updated to the correct time.
Battery Depletion	• If BrainScope shuts down because the battery is fully depleted (see section 2.2), recharge the handheld for a minimum of 4 hours. • If the handheld does not turn on when the power button is pressed after battery depletion, press and hold the power button for 30 seconds, then release. The handheld should reboot. • If the handheld does not respond by rebooting, connect the charger. Then press and hold the power button for 60 seconds, then release. The handheld should reboot. • After the handheld reboots, if the battery level is still low, power off the handheld and connect the charger.

6.3 EEG Data

Message	Meaning	Corrective Action(s)
EEG Data Connection Failed	The handheld has lost USB communication with the DAB for more than 30 seconds. The spinning circle indicates that the handheld is attempting to re-establish communication with the DAB.	• When the connection is re-established, the EEG Data Connection Successful message will display. Tap OK to dismiss. • If the connection is not re-established in 30 seconds, the handheld will power off in 60 seconds. • Tap CANCEL to dismiss the message. Tap POWER OFF NOW to power down the handheld.

Message	Meaning	Corrective Action(s)
Insufficient Data Collected	A sufficient amount of artifact-free EEG data has not been collected in 10 minutes. Therefore, results cannot be calculated.	• If you wish to start a new EEG session, tap NEW EEG in the center of the Insufficient Data Result screen. • The same headset can be used for up to 3 EEG sessions. • Follow artifact Troubleshooting instructions to reduce artifacts

WARNING!
Standard clinical assessment of the patient should proceed in the event that insufficient clean (artifact-free) EEG data is collected.

6.4 Other Operational Problems

There are no user-serviceable parts contained within the BrainScope handheld, DAB, or the charging kit.

DO NOT attempt to open or service these units.

For a complete list of known software issues, refer to the software release notes provided by BrainScope.

Contact BrainScope Technical Support for any technical issues. See Section 5.5 for more information

6.5 Device Reset

The device can be reset back to the original factory settings.

⚠ CAUTION: Resetting the device will remove ALL data from the handheld. Consider backing up data before performing a reset.

1. Select ADDITIONAL OPTIONS on the Login screen to display the RESET DEVICE trigger. Alternatively, reset device from the SETTINGS menu.

2. Tap on RESET DEVICE (Figure 6-1).

3. A warning message will inform the user of the data loss associated with resetting the device (Figure 6-2). To proceed with the reset, the device requires entry of the Device Activation Code, which can be provided by BrainScope.

4. Once the code is successfully entered and the user provides a final confirmation that they would like to reset the device, the device will proceed with the reset.

5. The handheld will restart during the reset process and will navigate to the Device Activation screen once the reset is complete (See Section 3.3).

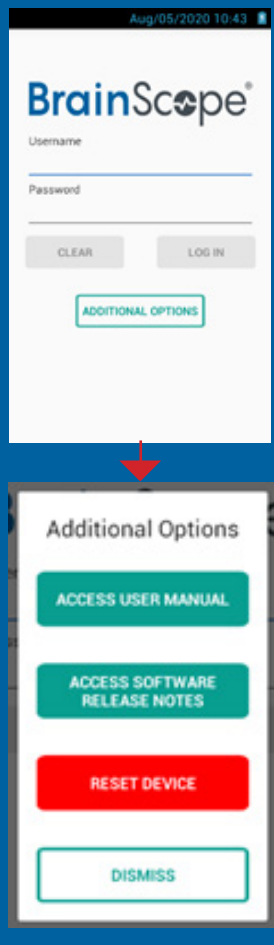


Figure 6-1:
Reset Button Access
from Login Screen

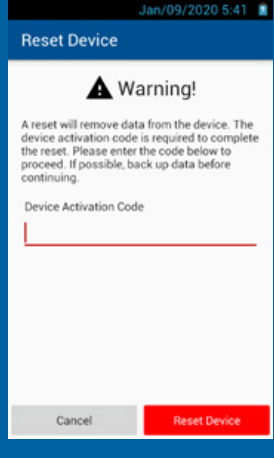


Figure 6-2:
Reset Warning Message

CHAPTER 7: Regulatory Standards

BrainScope is designed and developed in accordance with the following:

Electrical Safety Standards

BASE

- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance
- IEC 61000-3-2:2018 - Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current < 16A per phase)
- IEC 61000-3-3:2013+A2:2021 - Electromagnetic compatibility (EMC) - Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current < 16A per phase and not subject to conditional connection
- CAN/CSA-C22.2 No. 60601-1-2:2016 (R2021), Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance
- AIM 7351731 Rev. 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

COLLATERAL

- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
- CAN/CSA-C22.2 No. 60601-1-2:2016 (R2021), Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014, fourth edition, 2014-02, with Canadian deviations)

PARTICULAR

- IEC 80601-2-26:2019 – Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

APPLICABLE RULES

Federal Register CFR 47, Part 15, subpart B

- Radiated Emissions, Part 15.109(b), Class A
- Conducted Emissions, Part 15.107(b), Class A

BrainScope is intended for continuous operation, is internally powered and has a protective classification of Type BF. Refer to section 9.5 for additional details.

BrainScope RF emissions are compliant with Group I, Class A.
The standards listed above cover the Base, Collateral (EMC) and Particular (EEG specific) standards. Performance standards are not listed.

Disposable Electrode Standard

- ANSI/AAMI EC12:2000/(R)2010 Disposable ECG Electrodes

Biocompatibility

- ANSI/AAMI/ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-5:2009/(R) 2014 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ANSI/AAMI/ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization

BrainScope is intended for contact duration less than 24 hours (level A) and evaluated for Cytotoxicity, Sensitization and Irritation.

Environmental Standards

- MIL-STD-810G, Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests

Ingress Protection

- IEC 60529 (2004) Degree of Protection Provided by Enclosures

Packaging Performance Standards

- ASTM D4169 – 09, Standard Practice for Performance Testing of Shipping Containers and Systems

The BrainScope packaging is designed for Distribution Cycle 13 and meets the requirements of Assurance Level I. BrainScope is designed and manufactured in accordance with an ISO 13485 certified quality assurance system.

CHAPTER 8: BrainScope Contact Information

BrainScope Company, Inc.
7648 Standish Place
Rockville, MD 20855
USA

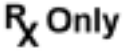
Phone: 1-855-9-BRAIN-1 (927-2461)
Email: CustomerCare@BrainScope.com

www.BrainScope.com

CHAPTER 9: Specifications

9.1 Labeling Symbols

9.2 This section contains various international symbols which may appear on BrainScope and/or system components and the Electrode Headset

Symbol	Description
	Warning!
	Caution
	Note
	Stand-by/Power
	DC Current
	Type BF Applied Part
	Alternating Current
	DO NOT Dispose in Fire
	DO NOT Recycle
	Prescription Use
REF	Reference Number
SN	Serial Number
PN	Part Number
MD	Medical Device

Symbol	Description
LOT	Lot Number
	DO NOT Reuse
	Polyvinyl Chloride Free
	Storage/Operational Temperature Limit
	Use-by Date
	Read Usage Instructions
	Upper Limit of Temperature
	Manufacturing Date
	Non Sterile
	MR Unsafe
	Information
IPNN	Ingress Protection N1N2 = Rating

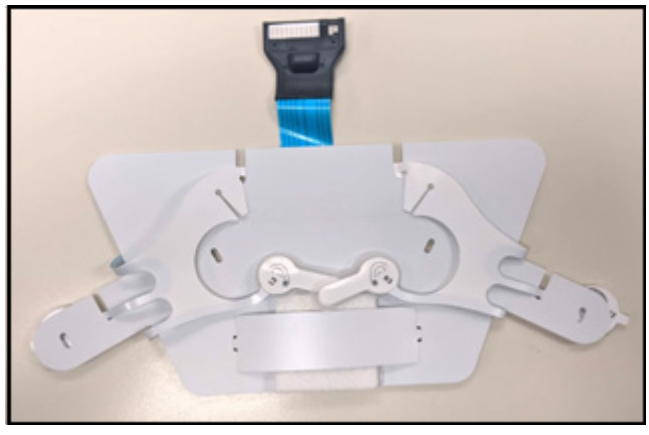
9.3 BrainScope Parts

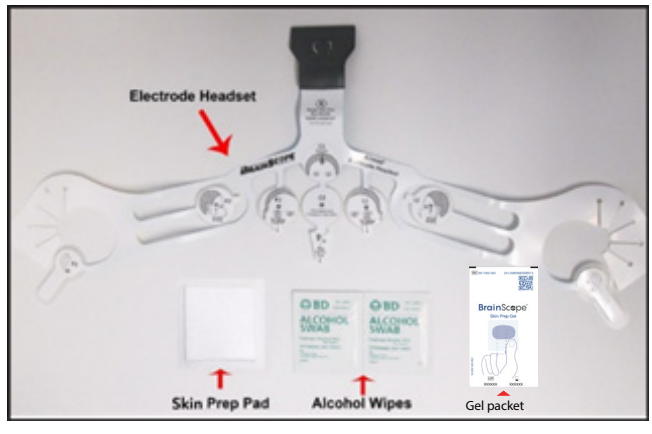
Item
BrainScope Kit (500 Series); SKU: BSO-3001
EEG Acquisition Unit (Handheld and DAB)
USB-A Charger
USB-A to Micro-B USB 3 ft cable(s)
Electrode Gel, 5 gram packet
Electrode Headset (Part Number: 99-1403-202); SKU: AH-1001

WARNING!

- The BrainScope handheld will only work properly when used with the Electrode Headset.
- Explosion Hazard: DO NOT use BrainScope in a flammable atmosphere or where concentrations of flammable anesthetics may occur.

The Electrode Headset is not included as part of the packaged system. It is obtained separately from BrainScope. The user should obtain only Electrode Headsets for use with the BrainScope EEG Acquisition Unit.





9.4 Technical Specifications

BrainScope EEG Acquisition Unit Components Physical Dimensions	
Size (nominal)	Handheld: 86 mm (3.4") x 165mm (6.5") x 27 mm (1.1") DAB: 135 mm (5.31") x 127 mm (5.00") x 49 mm (1.93") Handheld to DAB cable: 1.20 m (47.24")
Weight (nominal)	Handheld: 0.385 kg (0.84 lb) DAB: 0.206 kg (0.45 lb)
BrainScope EEG Acquisition Unit Components Operational Environment	
Ingress Protection	IP54 with DAB Jacket plug inserted
Temperature	-10°C to 55°C (-14°F to 130°F)
Altitude	4000 Meters
Humidity	5% to 95% RH
BrainScope EEG Acquisition Unit Components Transportation and Storage Environment	
Temperature	-20°C to 60°C (-4°F to 140°F)
Humidity	5% to 95% RH
Electrode Headset Operational Environment	
Temperature	0°C to 38°C (32°F to 100°F)
Electrode Headset Storage Environment	
Temperature	Upper limit of 25°C (77°F)
Shelf Life	24 months[1]
Digital Signal Characteristics	
ADC Resolution	24 bits
Raw Data Sampling Rate	1 kHz and 100 Hz data streams
Measurement Bandwidth	1 kHz data: DC to 300 Hz 100 Hz data: 0.67 Hz to 43 Hz
Storage Capacity	
EEG Data	Minimum 150 raw EEG data recordings and 500 processed results
Total Capacity	Maximum 32 GB
Amplifier	
Data Channels	7
Common Mode Rejection Ratio (CMRR)	< -100dB
System Noise[2]	< 0.4 microvolt RMS in 0.67 Hz to 43 Hz bandwidth
Impedance Measurement	

[1] Maximum headset shelf life can be achieved when product is stored in temperatures equal to or under 25°C or 77°F.
[2] Noise contribution by amplifier hardware only. Additional noise may be contributed by the electrode headset.

Artifact Detection and Rejection	
Automatic detection of 8 types of artifact or abnormal electrical activity	Eye Movement: • Horizontal/Lateral Eye Movement (HEM/LEM) • Vertical Eye Movement (VEM) Muscle Activity (EMG) High External Noise (ENH) Other Artifacts: • Patient/Cable Movement (PCM) • Impulse (IMP) • Significantly Low Amplitude Signal (SLAS) • Atypical Electrical Activity Pattern (AEAP)
Display/Touch Screen	
Type	High contrast, digital, graphic color, multi-point capacitive
Resolution	WVGA (1280px x 720px)
Size	5" diagonal
Battery	
Chemistry	Lithium-ion
Nominal Voltage	3.8 V
Nominal Capacity	4800 mAh
Run-Time	320 minutes assuming equal EEG and non-EEG assessment use. Run-time will vary based on usage.
Shelf life	At least 70% of original full capacity after 2 years of active use (total of 500 cycles, – based on heavy usage of 250 recharge cycles per year)
Safety Considerations	The battery pack is equipped with a protection circuit to prevent excessive charge and discharge currents.
Charging	Full recharge in less than 8 hours with device off
Electrical	
Input Voltage	5 V DC from wall converter
Current Consumption	2 A maximum during charging
Patient Connections	All patient probes and electrodes are Type BF Applied Parts
IEC 60601-1 Classifications	Internally powered, hand-held, body-worn
Radios	Wireless WAN, WiFi 802.11a/b/g/n, Bluetooth 4.1, GPS, NFC

9.5 Protective Classification

BrainScope is intended for continuous operation and has protective classification of internally powered equipment with a Type BF applied part (per IEC 60601-1) ordinary equipment, not suitable for use in the presence of flammable anesthetics. The BrainScope Charger is for charging the handheld. An internal battery powers the handheld.

NOTE: The handheld should never be used for any patient assessment while BrainScope is connected to an external power source.

9.6 Environment

BrainScope Components Shipping and Storage

Protect the BrainScope from sudden temperature changes that can cause condensation within the instrument.

To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the device to equilibrate in the unopened shipping container before unpacking. Before use, wipe down all visible condensation and allow the system to equilibrate to room temperature.

The BrainScope EEG Acquisition Unit complies with established electromagnetic compatibility (EMC) standards for medical devices.

The BrainScope DAB jacket includes a rubber plug that must be inserted into the headset/charging port in order to meet the specified IP54 rating. Ingress protection is not guaranteed when this plug is not in place. Keep BrainScope away from water and other fluids, do not use in wet conditions, and routinely inspect system components for possible exposure to liquid.

9.7 Power Requirements and System Grounding

Use only the BrainScope USB-A Charger and USB-A to Micro-B USB cable packaged with the BrainScope Kit.

WARNING!
The BrainScope USB-A Charger is for charging purpose only. The handheld is intended to be operated from the internal battery. The handheld should never be used for any patient assessment while BrainScope is connected to an external power source.

Isolation from the Supply Mains

A plug and socket are suitable means of equipment isolation from the supply mains. Unplugging the AC plug ensures removal of all external power. The equipment is internally powered and is connected to the mains via plug only during battery charging.

9.8 Electromagnetic Compatibility (EMC)

NOTE:

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

- Changes or modifications not expressly approved by BrainScope could void the user's authority to operate the equipment.

- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

BrainScope is designed to be compliant with the EMC standard IEC 60601-1-2. As required by that standard, the following tables are provided for guidance related to the operation of the system with respect to the electromagnetic environment.

Guidance and Manufacturer's Declaration — Electromagnetic Emissions		
The BrainScope Company, Inc. model Ahead 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainScope Company, Inc. model Ahead 500 should as-sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF emissions CISPR 11	Group I	The BrainScope Company, Inc. model Ahead 500 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 BrainScope Company, Inc. model Ahead 500 is suitable for use in all establishments other than do-mestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warn-ing is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equip-ment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BrainScope Company, Inc. model Ahead 500 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The BrainScope Company, Inc. model Ahead 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainScope Company, Inc. model Ahead 500 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 610004-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line ±2 kV line(s) to earth	±1 kV line(s) to line ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BrainScope Company, Inc. model Ahead 500 requires con-tinued operation during power mains interrup-tions, it is recommended that the BrainScope Company, Inc. model Ahead 500 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnet-ic fields should be at levels characteristic of a typical location in a typical com-mercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The BrainScope Company, Inc. model Ahead 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainScope Company, Inc. model Ahead 500 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the BrainScope Company, Inc. model Ahead 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/10] √P 80 MHz to 800 MHz d = [7/10] √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recom-mended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. 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 BrainScope Company, Inc. model Ahead 500 is used exceeds the applicable RF compliance level above, the BrainScope Company, Inc. model Ahead 500 should be observed to verify normal operation. If abnormal performance is observed, addi-tional measures may be necessary, such as re-orienting or relocating the BrainScope Company, Inc. model Ahead 500.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity							
The BrainScope Company, Inc. model Ahead 500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainScope Company, Inc. model Ahead 500 should assure that it is used in such an environment.							
Immunity Test	IEC 60601 Test Level			Compliance Level			Electromagnetic Environment— Guidance
IMMUNITY to prox-imity fields from RF wireless communica-tions equipment	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	Portable and mobile RF communi-cations equipment should be used no closer to any part of the BrainScope Company, Inc. model Ahead 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Inter-ference may occur in the vicinity of equipment marked with the follow-ing symbol:
	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
		2.1kHz	65 A/m		2.1kHz	65 A/m	
		50kHz	7.5 A/m		50kHz	7.5 A/m	
		CW	8 A/m		CW	8 A/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the BrainScope Company, Inc. model Ahead 500.				
The BrainScope Company, Inc. model Ahead 500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BrainScope Company, Inc. model Ahead 500can help prevent elec-tromagnetic interference by maintaining a minimum distance be-tween portable and mobile RF communications equipment (transmitters) and the BrainScope Company, Inc. model Ahead 500 as recommended below, according to the maximum output power of the communica-tions equipment.				
Rated maximum output pow-er of trans-mitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz d = [3.5/3] √P	800 MHz to 2.7 GHz d = [7/3] √P	710, 745, 780, 5240, 5500, 5785 MHz d = [6/9] √P	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

BrainScope is supplied with the following cables and charging accessories:

BrainScope P/N	Cable/Accessory Type	Specifications
40-1000-012 Manufacturer: Phihong USA Corporation Manufacturer P/N: PSA10F-050Q, PSA10F-050QR	USB-A Charger	DC Output Voltage: 5+/- 0.25V Min. Load: 0A Max Load: 2A AC Input Voltage Rating: 100 VAC – 240 VAC AC Input Frequency: 50 Hz – 60 Hz AC Input Current: 0.3A RMS max @ 120 VAC 0.15A RMS max @ 240 VAC Output Power: 10W continuous Standby Power: <150mW at 230VAC
40-1000-013 Manufacturer: StarTech Manufacturer P/N: UUS-BHAUB1	Micro USB Cable, USB-A to micro-B	Connector Plating: Nickel Cable Jacket Type: PVC Cable Shield Type: Aluminum-Mylar Foil with Braid Connector A: 1 – USB A (4 pin) Male Connector B: 1 – USB Micro-B (5 pin) Male Color: Black Wire Gauge: 28 AWG or 24/30 AWG Cable Length: 3 ft (0.3 m) Product Weight: 0.6 oz (17 g)

WARNING!
The use of accessories, transducers and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity.

NOTE: In order to satisfy the electromagnetic emissions and immunity requirements, BrainScope must be used with the following accessories included in the International Charging Kit:

- USB-A Charger (PSA10F-050Q, PSA10F-050QR)
- USB-A to Micro-B USB 1ft Cable (40-1000-013)
- International Charging Clips.

Warranty Information

For details on BrainScope's product warranties, please contact BrainScope Customer Support, which can be reached at CustomerCare@brainscope.com or at 1-855-9-BRAIN-1 (1-855-927-2461).

Appendix 1: Cognitive Performance

Cognitive Performance Overview

BrainScope includes a configurable battery of 5 computerized neurocognitive tests to assess patients' cognitive performance. These tests are conducted by the patient on the BrainScope handheld device. The assessment produces results in comparison to a normative population and the operator can also select to compare against data from a previous session for that patient, if available on the device. Additional details regarding the assessment results are provided below.

Prior to starting the test, inform the patient of the following:

- "There are no grades for this test and you cannot pass or fail it, but I would like for you to try as hard as you can."
- "You need to read the instructions carefully before starting each section. If you do not understand the instructions or have any questions during the test, please tell me."

The full description of the Normative Data can be found at the end of this section.

Conducting Cognitive Performance Tests

Start of Assessment Battery

After the patient information has been entered, the device will display the Information Hub.

Instruct the patient that the BrainScope handheld will be handed to him or her and to read the instructions on the screen. The patient will follow the instructions on the screen to complete the test.

1. To perform a Cognitive Performance session, tap START on the Information Hub.

NOTE: A message will display prompting you to hand the patient the handheld, and how to cancel an assessment if needed.

- Three taps to the top right corner of the screen will trigger a dialog allowing you to either restart current assessment or cancel the assessment at this time. DO NOT dismiss this dialog by pressing hardware back button or tapping outside the dialog, doing so will result in an inaccurate assessment.

2. Hand the handheld to the patient and confirm that the handheld is positioned properly so the patient can read the instructions (Figure A1-1).

3. The Vista Cognitive Performance test will appear. Instruct the patient to read the instructions, then tap CONTINUE when ready. Tap EXIT to return to the Information Hub.

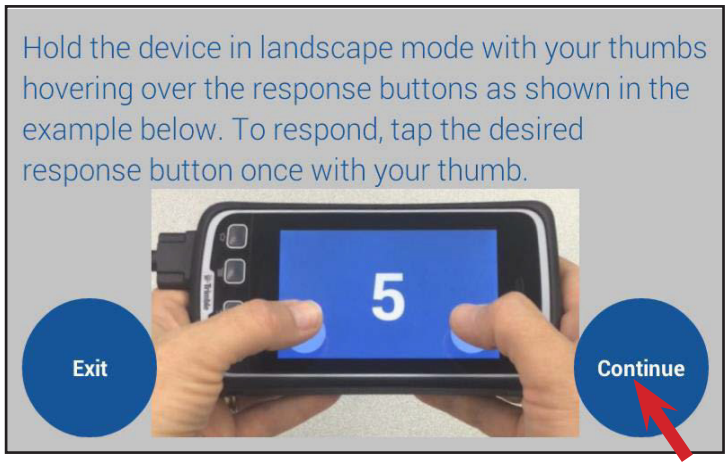


Figure A1-1: Handheld Position while performing Cognitive Performance assessment. EXIT and CONTINUE displayed in lower corners of the screen.

1. Procedural Reaction Time

The Procedural Reaction Time test measures information processing speed, visuomotor reaction time, simple decision making, and attention. The patient is presented with a number (2, 3, 4, or 5). The patient is instructed to tap one designated button for a "low" number (2 or 3) and another designated button for a "high" number (4 or 5).

1. The handheld will instruct the patient on how to perform the Procedural Reaction Time test (Figure A1-2). The operator should monitor the patient to be sure that the patient is reading and understanding the instructions given.
2. Before moving to the next screen ask the patient if they understand the instructions.

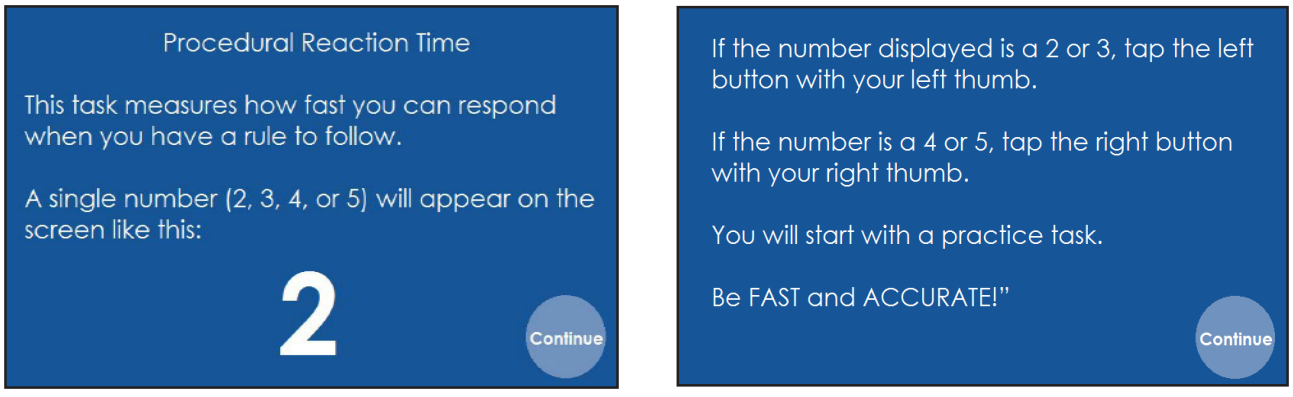


Figure A1-2:
Procedural Reaction Time Instructions

3. After being presented with a number (2, 3, 4, or 5), the patient is instructed to tap one designated button for a "low" number (2 or 3) and another designated button for a "high" number (4 or 5). The patient should respond as quickly as possible to different sets of stimuli based on simple rules.

4. Once a number appears on the screen, the patient will tap the left button if he/she sees a 2 or 3 and the right button if he/she sees a 4 or 5. In this example, the LEFT button is the correct answer. (Figure A1-3)

After the test is complete, the handheld will navigate to the next configured cognitive performance test or to the test complete screen (Figure A1-12) if applicable.

2. Simple Reaction Time

Figure A1-3:
Example of Stimulus (2) and Response Button (denoted by a red arrow)

The Simple Reaction Time test measures visuomotor processing speed, simple motor speed, and attention. The patient is presented with a symbol (*). The patient is instructed to tap one designated button as soon as they see the symbol appear on the screen.

1. If the Simple Reaction Time test is configured on the device, the handheld will instruct the patient on how to perform the Simple Reaction Time test (Figure A1-4). The operator should monitor the patient to be sure that the patient is reading and understanding the instructions given.
2. Before moving to the next screen ask the patient if they understand the instructions.

Figure A1-4:
Simple Reaction Time Instructions

3. After being presented with a symbol (*), the patient is instructed to tap a designated button. The patient should respond as quickly as possible. See the example screen below (Figure A1-5).

After the test is complete, the handheld will navigate to the next configured cognitive performance test or to the test complete screen (Figure A1-12) if applicable.

3. Match To Sample

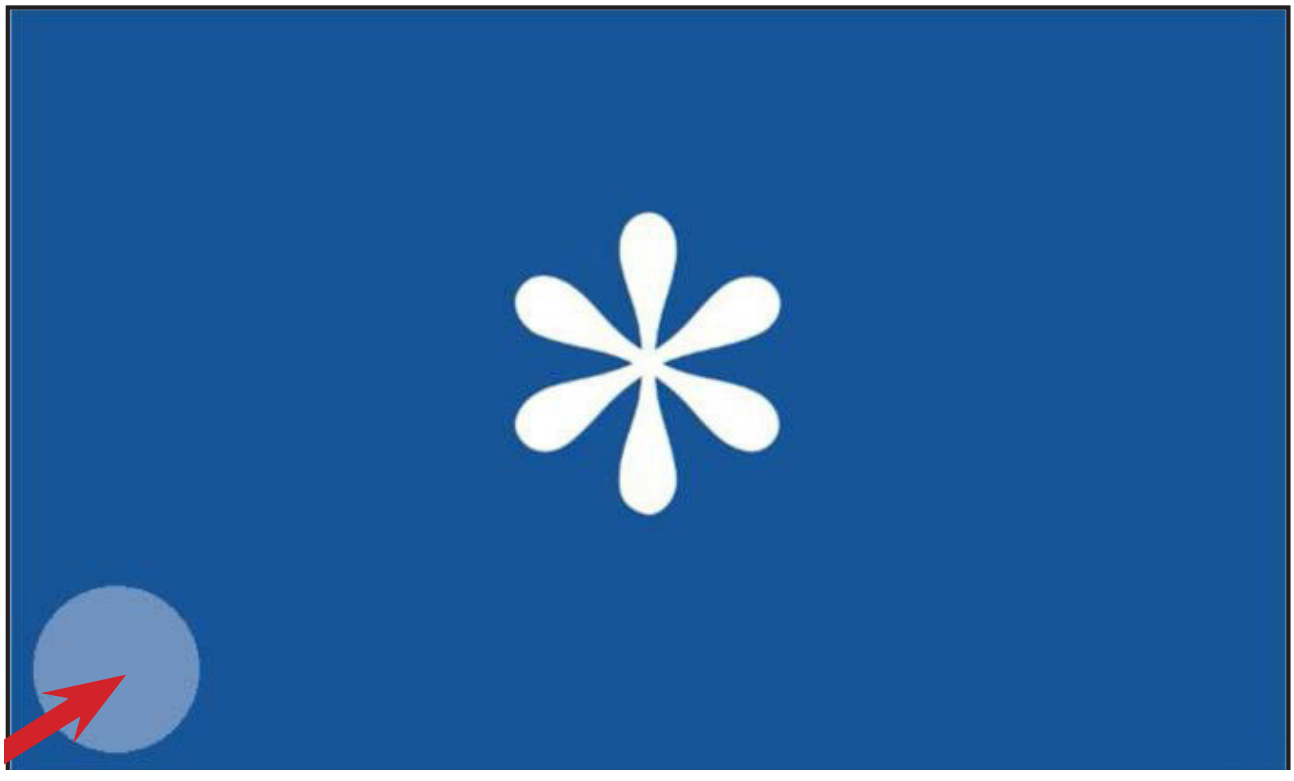


Figure A1-5:
Example of Stimulus (*) and Response Button (denoted by a red arrow)

The Match To Sample test measures visual-spatial processing, working memory, and visual short-term recognition memory. During this test the patient views a pattern produced by eight shaded cells in a 4x4 sample grid. The sample is then removed and two comparison patterns are displayed side by side. The patient is to tap a designated button to select the grid that matches the sample.

The patient will be presented with a 4x4 visual pattern (Figure A1-6).
Instruct the patient to read the instructions, then tap the CONTINUE button when ready. The patient must

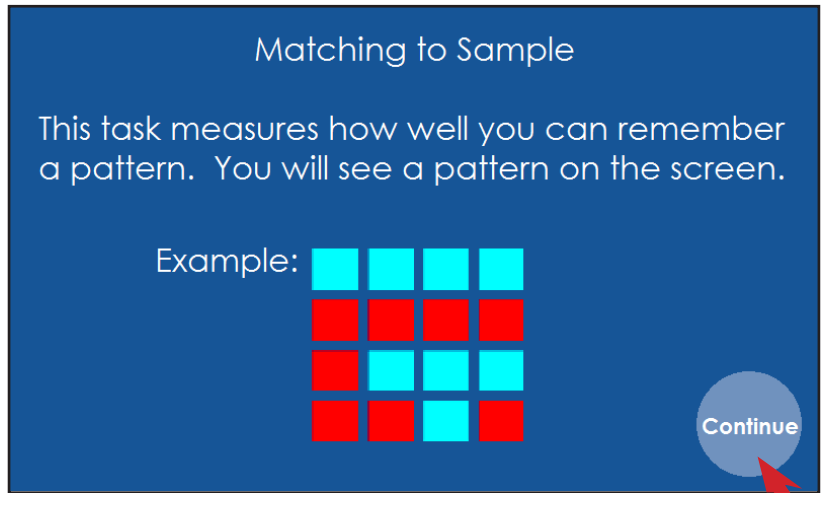


Figure A1-6: Match to Sample Instructions

attempt to memorize the pattern so he/she can remember it later. They should look carefully at the pattern because it will go away (Figure A1-7).
Two comparison patterns are presented side-by-side during the test. Pick the pattern that matches the

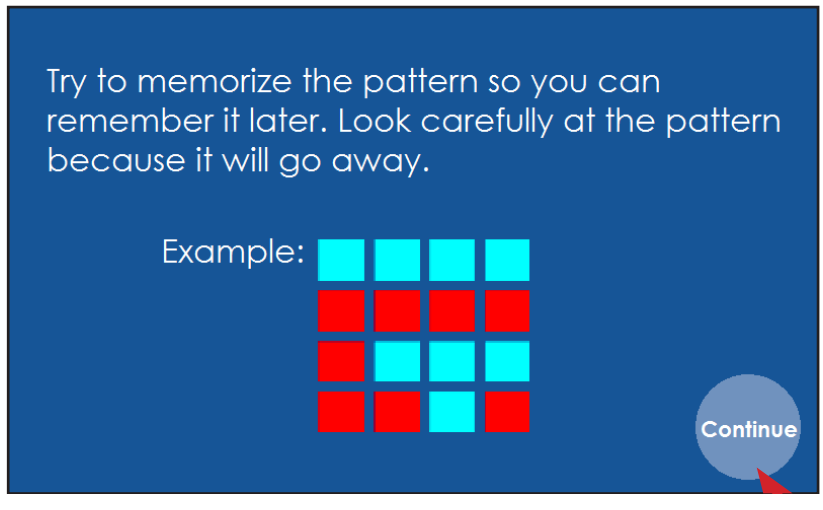


Figure A1-7: Match to Sample Pattern

one that was just memorized by tapping either the right or left button next to the comparison pattern that matches the sample pattern (Figure A1-8).
The application will have the patient conduct a practice test prior to the actual test beginning. The patient

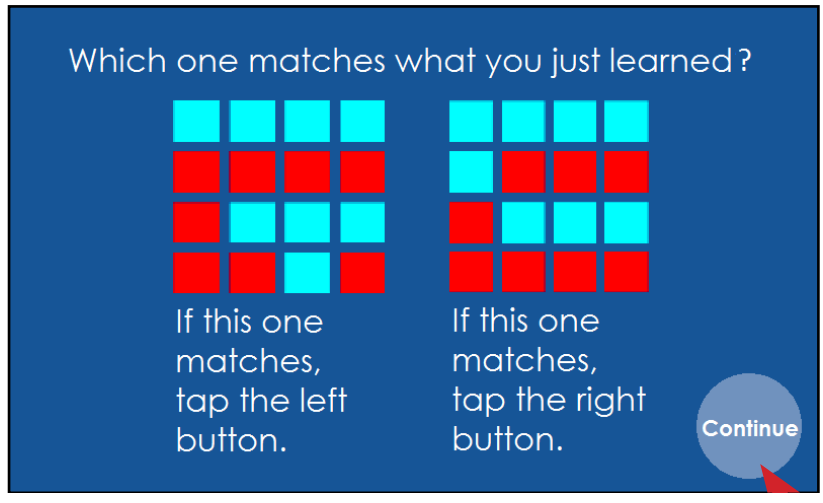


Figure A1-8: Match to Pattern Comparison

should follow the on screen instructions to complete the test (Figure A1-9).
After the test is complete, the handheld will navigate to the next configured cognitive performance test or to

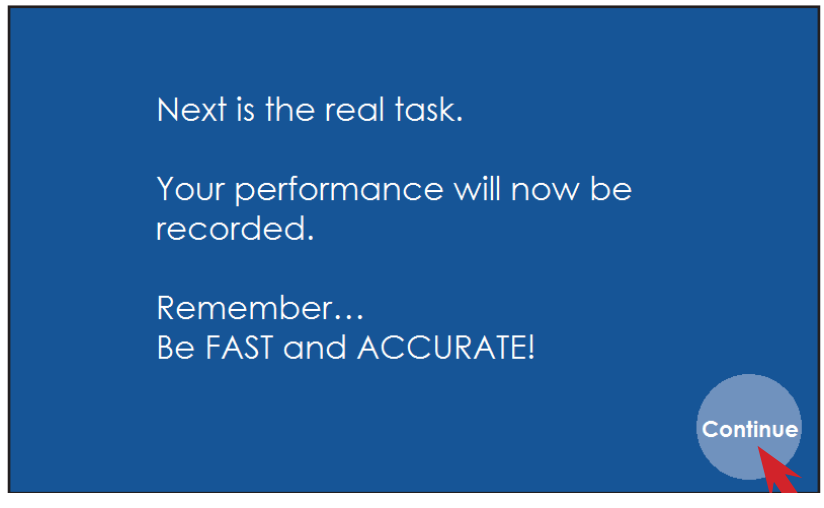


Figure A1-9: Start test

the test complete screen (Figure A1-12) if applicable.

4. Go/No Go

The Go/No Go test measures sustained attention, reaction time, and response control, specifically response inhibition. The patient is presented with one of two characters (either "X" or "O"). The patient is instructed to tap a designated button as soon as they see the "X" character appear on the screen. The patient is instructed to not tap the button if they are presented the "O" character

1. If the Go/No Go test is configured on the device, the handheld will instruct the patient on how to

perform the Go/No Go test (Figure A1-10). The operator should monitor the patient to be sure that the patient is reading and understanding the instructions given.

2. Before moving to the next screen ask the patient if they understand the instructions.

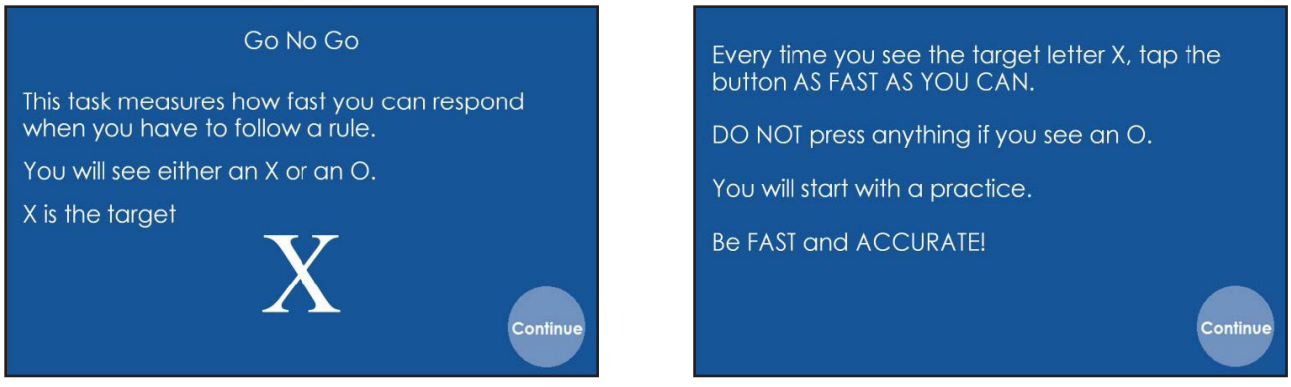


Figure A1-10: Go/No Go Instructions

3. After being presented with one of two characters ("X" or "O"), the patient is instructed to tap a designated button if the "X" character is presented. The patient should respond as quickly as possible. See the example screen below (Figure A1-11).

After the test is complete, the handheld will navigate to the next configured cognitive performance test or to

Figure A1-11:
Example of "X" Character to React to

the test complete screen (Figure A1-12) if applicable.

5. Simple Reaction Time Repeated

The Simple Reaction Time Repeated test is a repeat of the Simple Reaction Time test. Results of the Simple Reaction Time Repeated test are used to measure the effect of fatigue on performance as well as an index of visuomotor processing speed and attention. The instructions to conduct this test are identical to those provided for the Simple Reaction Time Test.
After the test is complete, the handheld will navigate to the test complete screen (Figure A1-12) if applicable.

NOTE: Simple Reaction Time Repeated is only available when all available tests are configured on.

End of Assessment Battery

After the battery of configured tests is run, the application will advance to a Test Complete screen (Figure A1-12). Tap EXIT to return to the Cognitive Performance Summary.

Cognitive Performance Summary (Comparison to Normative Data)

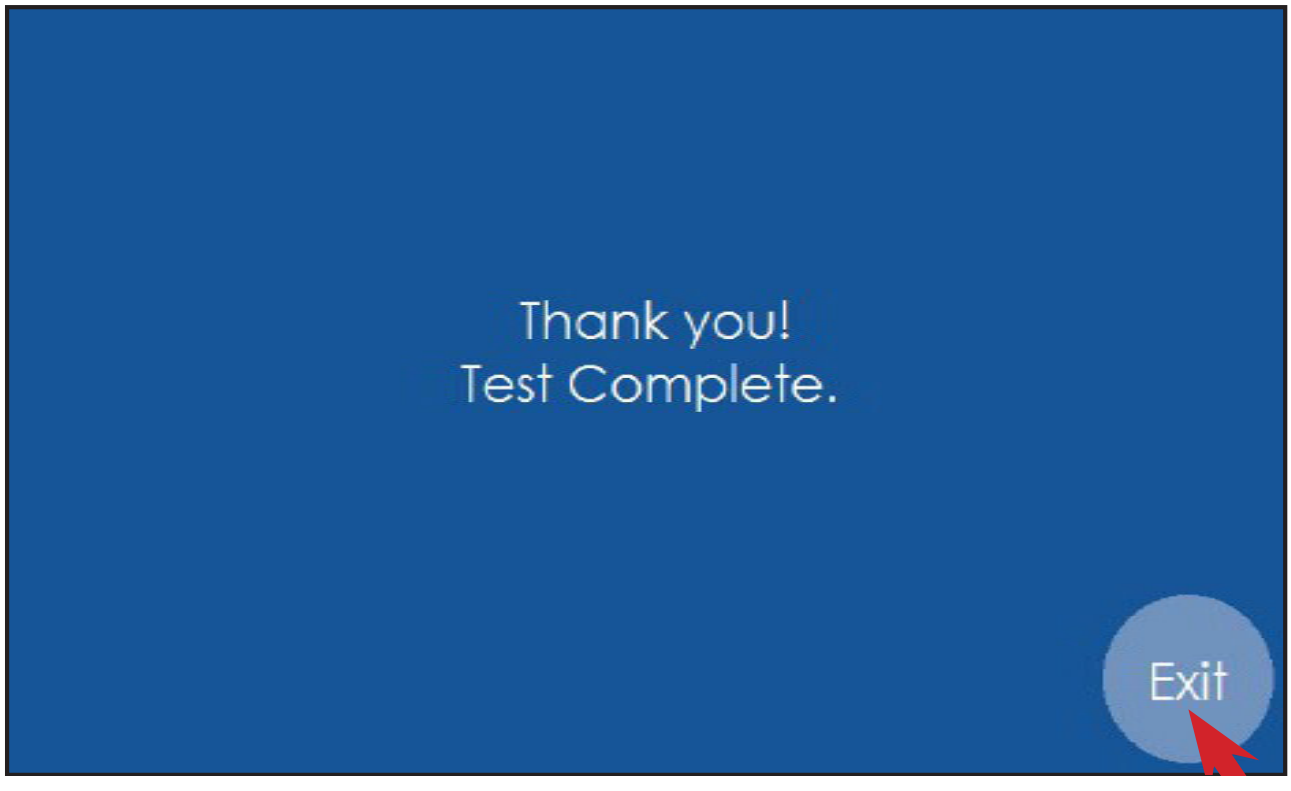


Figure A1-12: Test Complete

After a Cognitive Performance session has been completed, the Cognitive Performance Summary will display (Figure A1-13). For each test, one of three statements is displayed which represents how the patient performed in comparison to normative data. Several variables (such as Mean Reaction Time for correct responses, Percent Correct, and Throughput) are examined for each test conducted in comparison to the normative data and summarized for the operator (Figure A1-13). Tap VIEW DATA NUMBERS to review the patient's results in comparison to the normative group in the database (Figure A1-14).

The Data Numbers are displayed in six columns with a row for each variable. The first three columns are the results for the patient tested. The last three columns (shaded grey) display the results from the Normative Study for comparison.

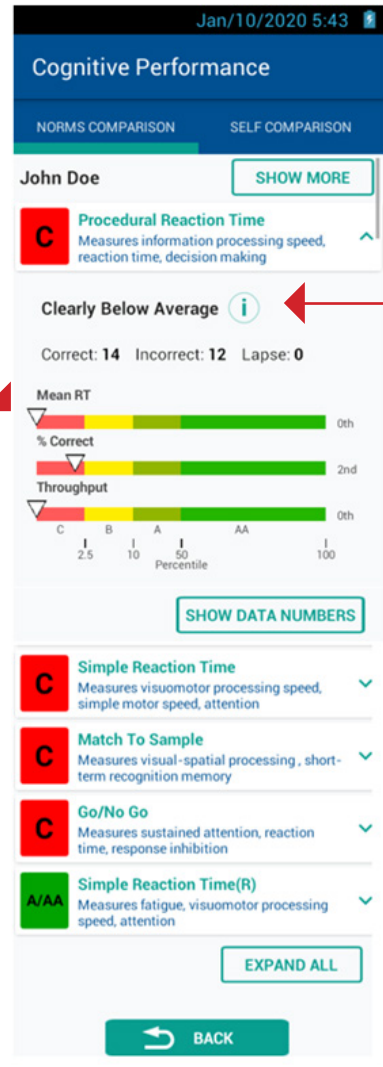
Tap REMOVE DATA NUMBERS to hide the detailed results.

Press BACK to return to the Information Hub.

The Cognitive Performance section of the Information Hub (See Section 3.4.1 Information Hub Screen) will display the results of the test using letters A/AA (for Average or Above), B (for Below Average), or C (for Clearly Below Average) (Figure A1-15).

Average or Above – All measures are greater than or equal to the 10th percentile.

Each variable scale will display an arrow indicating the patient's resulting percentile on the scale and the percentile number will be displayed on the right.



When the information button for a test is selected the following messages will appear explaining the result:

- The Cognitive Performance Average or Above Summary Information Message, if an Average or Above result was above.
- The Cognitive Performance Below Average Information Message if a Below Average result was obtained.
- The Cognitive Performance Information Message if a Clearly Below Average result was obtained.

Figure A1-13:
Cognitive Performance Summary
(Comparison to Normative Data)

Mean Reaction Time (1st Row):
- Score: Average response time for correct responses (milliseconds). Higher numbers reflect a slowing in response time, thus poorer performance.
- %ile: Percentile for Mean RT in comparison to normative data
- StdSc: Standardized score for Mean RT compared to normative data (mean = 100, SD = 15)

Percent Correct (2nd Row):
- Score: Percent of items with a correct response. Higher numbers reflect better performance.
- %ile: Percentile for Percent Correct in comparison to normative data
- StdSc: Standardized score for Percent Correct compared to normative data (mean = 100, SD = 15)

Percent Correct (2nd Row):
- Score: Percent of items with a correct response. Higher numbers reflect better performance.
- %ile: Percentile for Percent Correct in comparison to normative data
- StdSc: Standardized score for Percent Correct compared to normative data (mean = 100, SD = 15)

Throughput (3rd Row):
- Score: Number of correct responses per minute. Higher numbers reflect better performance.
- %ile: Percentile for Throughput in comparison to normative data
- StdSc: Standardized score for Throughput compared to normative data (mean = 100, SD = 15)
- Throughput is considered a measure of effectiveness or cognitive efficiency (Thorne, 2006) and is a combination of reaction time and accuracy.

Hits (3rd Row):
- Number of correct responses to target stimuli

Omissions (4th Row):
- Score: Number of trials where a response was required to target stimulus but no response was made
- %ile: Percentile for Omissions in comparison to normative data
- StdSc: Standardized score for Omissions compared to normative data (mean = 100, SD = 15)

Commisions (5th Row):
- Score: Number of incorrect responses to target stimulus
- %ile: Percentile for Commissions in comparison to normative data
- StdSc: Standardized score for Commissions compared to normative data (mean = 100, SD= 15)

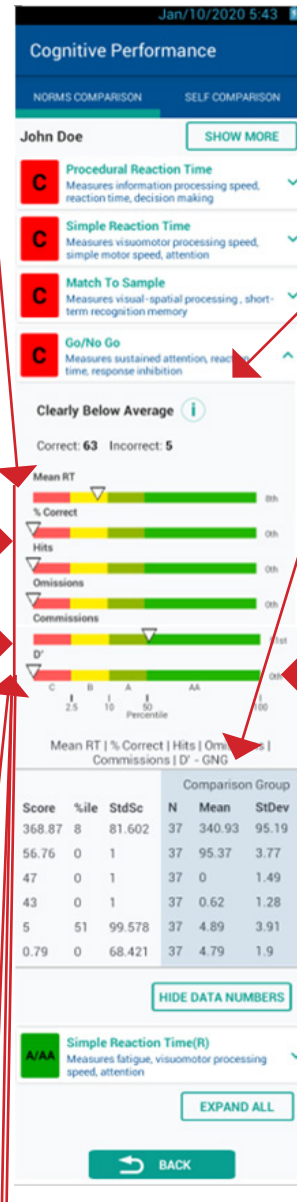
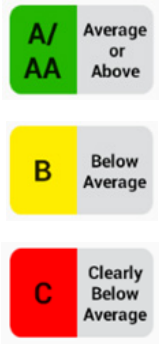


Figure A1-14:
View with Data Numbers

When either information button is selected the following messages will appear:
- The Cognitive Performance Average or Above Summary Information Message, if an Average or Above result was obtained.
- The Cognitive Performance Below Average Information Message if a Below Average result was obtained.
- The Cognitive Performance Clearly Below Average Information. Message if a Clearly Below Average result was obtained.

Normative Study for comparison:
- N: Sample size of subjects in the normative study
- Mean: Mean of the data result
- StDev: Standard deviation

D' (6th Row):
- Score: D prime (D') from Signal Detection Theory. Seperation between the means of the signal and the noise distributions. Reported in standard deviation units.
- %ile: Percentile for D' in comparison to normative data
- StdSc: Standardized score for D' compared to normative data (mean = 100, SD = 15)



Below Average – One or two measures are less than the 10th percentile AND no measures are less than the 2.5th percentile.

Clearly Below Average – The Mean Reaction Time and Percent Correct measures are both less than the 10th percentile OR at least one measure is less than the 2.5th percentile.

Cognitive Performance Detailed Results

Figure A1-15:
Cognitive Performance results from the Information Hub.

To access the Cognitive Performance Detailed Results screen, tap any Cognitive Performance test result (Figure A1-16) from the Information Hub screen.

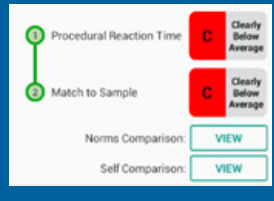


Figure A1-16: Cognitive Performance results area from the Information Hub

Norms Comparison Tab (Comparison to Normative Data)

Cognitive Performance Norms Comparison - Summary (Figure A1-17) contains the following options:

- Expand/Collapse Test Details
- Show/Hide Data Numbers

Tap one of the test headers or click EXPAND ALL to display the detailed test results. Tap SHOW DATA NUMBERS to navigate to the Cognitive Performance Norms Comparison- Summary (with data numbers)(Figure A1-17).

For details on the data numbers see Figure A1-14.

Tap HIDE DATA NUMBERS to return to the Cognitive Performance Current Test - Summary (without data numbers) screen (Figure A1-17).

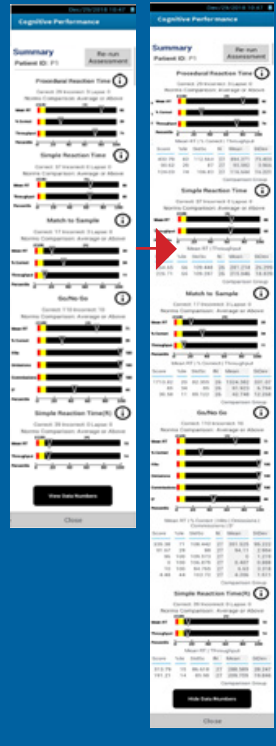


Figure A1-17: Summary of Cognitive Performance Results (with and without data numbers)

Press BACK to return to the Information Hub.

Self Comparison Tab (Comparison to previous patient session)

BrainScope also allows comparisons against data from a previous session for that patient, if available on the device. This calculation between two Cognitive Performance sessions is referred to as the Reliable Change Index (RCI). The BrainScope operator has the ability to compare the current session's cognitive performance results to the results of a prior session, if available on the device, and compute an RCI value for each of the Cognitive Performance tests conducted. The RCI value is associated with a description based on the value and sign of the RCI.

When comparing the current session to a reference session available on the device, the description provides information on the statistical significance of the result when considering the change between the two sessions. These descriptions include:

- An RCI of greater than +1.64: "Significant Increase"
- An RCI of less than -1.64: "Significant Decrease"
- An RCI of greater than or equal to -1.64 and less than or equal to +1.64: "No Significant Change"

To calculate self comparison RCI results, select the SELF COMPARISON tab from the Cognitive Performance Norms Comparison - Summary screen or the VIEW button in the Cognitive Performance Assessment section in the Information Hub that corresponds to Self Comparison.

Tap SELECT on the Cognitive Performance Self Comparison tab to select a Reference Session from a list of prior sessions for that patient (Figure A1-18). The current Cognitive Performance results will be compared to the result of the selected Reference Session.

Once a Reference Session has been selected, the RCI results and change descriptions will be displayed (Figure A1-19 displays example test results).

Press BACK to return to the Information Hub.

NOTE: The RCI results for the selected reference session will be included in the Patient PDF report.

RCI Calculations for Cognitive Performance Assessment

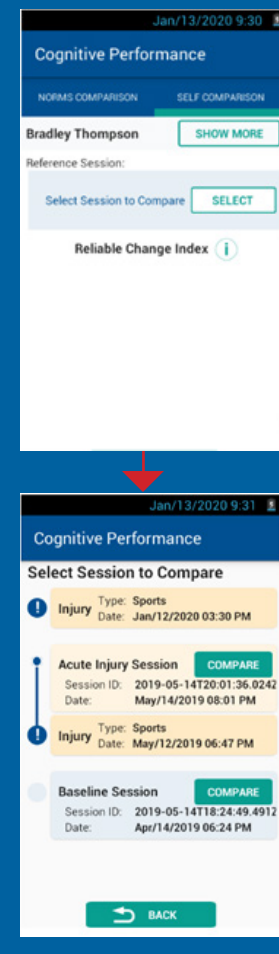


Figure A1-18: Self Comparison Tab

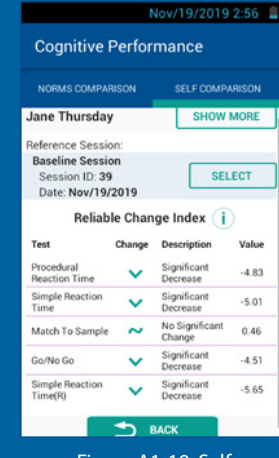


Figure A1-19: Self Comparison Results

A reliable change index may be used for self-comparisons of neurocognitive tests (i.e. comparison of an individual's performance at one time point to that same individual's performance at another time point). The RCI is intended to establish whether a statistically significant change in performance has occurred.

NOTE: A statistically reliable change does not guarantee a clinically meaningful change.

The RCI for each of the neurocognitive tests on BrainScope will be computed using the same formula as is used in the ANAM Test System (510(k) number K150154). Implementation according to the same equation is described below (Figure A1-19).

BrainScope uses the following equation to calculate RCI1,[2]:
The absolute value of the RCI (|RCI|) will be compared to a threshold value of 1.64. If |RCI|>1.64 for a

Equation 1 $$RCI = \frac{(Y_2 - Y_1) - X_{normchg}}{\sqrt{(s_{x_1}^2 + s_{x_2}^2)(1 - r_{xx})}} = \frac{(Y_2 - Y_1) - X_{normchg}}{s_{diff}}$$

Where:
Y_2 = raw score of test taker at Time 2,
Y_1 = raw score of test taker at Time 1,
$X_{normchg}$ = prac = average change observed in the control group,
s^2_{X1} = variance of raw scores of control group at Time 1,
s^2_{X2} = variance of raw scores of control group at Time 2,
r_{xx} = test-retest reliability (which is computed as an Intra Class Correlation coefficient),
$(Y_2 - Y_1) - X_{normchg}$ = absolute change from Time 1 to Time 2,
s_{diff} = standard error of measurement[1]

Figure A1-20: RCI Equation

given set of test results for an individual, then the change in test performance shall be deemed statistically significant.

For all tests except Go/No Go, RCI will be calculated using throughput values for Y1 and Y2. For Go/No Go, RCI will be calculated using commission errors as the values for Y1 and Y2.

For throughput, which measures a rate of correct responses per unit of time, a negative RCI (with Y1 assumed to be a baseline measurement) indicates a change in the direction of more abnormality (the throughput decreases with decrease in performance). For commission error in the Go/No Go test, which measures the number of times a subject responds to stimuli when no response was warranted, a negative RCI would be associated with greater normality (commission errors decrease with improved performance).

For consistent usability, RCI values are displayed so that positive RCI values are always associated with normality and negative RCI values are associated with abnormality. Consequently, the RCI values displayed for the tests using throughput will be the same as the value computed by the equation above, whereas the RCI values displayed for tests using commission error will be the additive inverse of the equation above.

Normative Data for Cognitive Performance Tests

The normative data was developed from a community sample obtained from the US population. The sample was stratified by age and sex. Recruitment sites were identified to maximize the representativeness of the target population and included the following geographic regions: Colorado, Texas, Ohio, Virginia, and Oklahoma.

All participants were administered the test battery on the BrainScope handheld computer. Tests administered included the Procedural Reaction Time test, Match to Sample test, Simple Reaction Time test, Go/No-Go test, and Simple Reaction Time Repeated test. All testing was conducted by trained test administrators. The normative dataset is available upon request.

[1] Maassen GH, Bossema ER, Brand N, Reliable change assessment with practice effects in sport concussion research: a comment on Hinton-Bayre, British Journal Sport Med., 2006, 829-833.

[2] Roebuck-Spencer, TM, Vincent AS, Schlegel, RE, Gilliland K, Evidence for Added Value of Baseline Testing in Computer-Based Cognitive Assessment, Journal of Athletic Training, 2013, 48(4):499-505.

Appendix 2: PECARN Decision Rule

PECARN Decision Rule Overview

The PECARN Pediatric Head Injury Decision Rule is a well-validated clinical decision aid that allows physicians to safely rule out the presence of clinically important traumatic brain injuries, including those that would require neurosurgical intervention among pediatric head injury patients who meet its criteria without the need for CT imaging. The Pediatric Emergency Care Applied Research Network (PECARN) consortium produced the largest study to date aiming to derive and validate clinical prediction rules to identify children with very low risk of Clinically Important TBI (ciTBI) following blunt head trauma who would not require imaging.

The original PECARN trial1 included 42,412 children < 18 years old presenting to 1 of 25 North American PECARN-affiliated emergency departments with 33,785 in derivation cohort (8,502 < 2 years old) and 8,627 in the validation cohort (2,216 <2years old). PECARN has now been externally validated in a separate study2.

BrainScope implements the decision rule from literature for pediatric age patients from 2 through 17 years of age, which is shown in Figure A2-1 as algorithm B. The PECARN assessment is indicated for patients with GCS scores of 14 or greater, and within 24 hours of head trauma.

[1]Kuppermann N, Holmes JF, Dayan PS, Hoyle JD Jr, Atabaki SM, Holubkov R, Nadel FM, Monroe D, Stanley RM, Borgialli DA, Badawy MK, Schunk JE, Quayle KS, Mahajan P, Lichenstein R, Lillis KA, Tunik MG, Jacobs ES, Callahan JM, Gorelick MH, Glass TF, Lee LK, Bachman MC, Cooper A, Powell EC, Gerardi MJ, Melville KA, Muizelaar JP, Wisner DH, Zuspan SJ, Dean JM, Wootton-Gorges SL; Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. Lancet. 2009 Oct 3;374(9696):1160- 70. doi: 10.1016/S0140-6736(09)61558-0. Epub 2009 Sep 14.

[2]Schonfeld D1, Bressan S, Da Dalt L, Henien MN, Winnett JA, Nigrovic LE. Pediatric Emergency Care Applied Research Network head injury clinical prediction rules are reliable in practice. Arch Dis Child. 2014 May;99(5):427-31. doi: 10.1136/archdischild-2013-305004. Epub 2014 Jan 15.

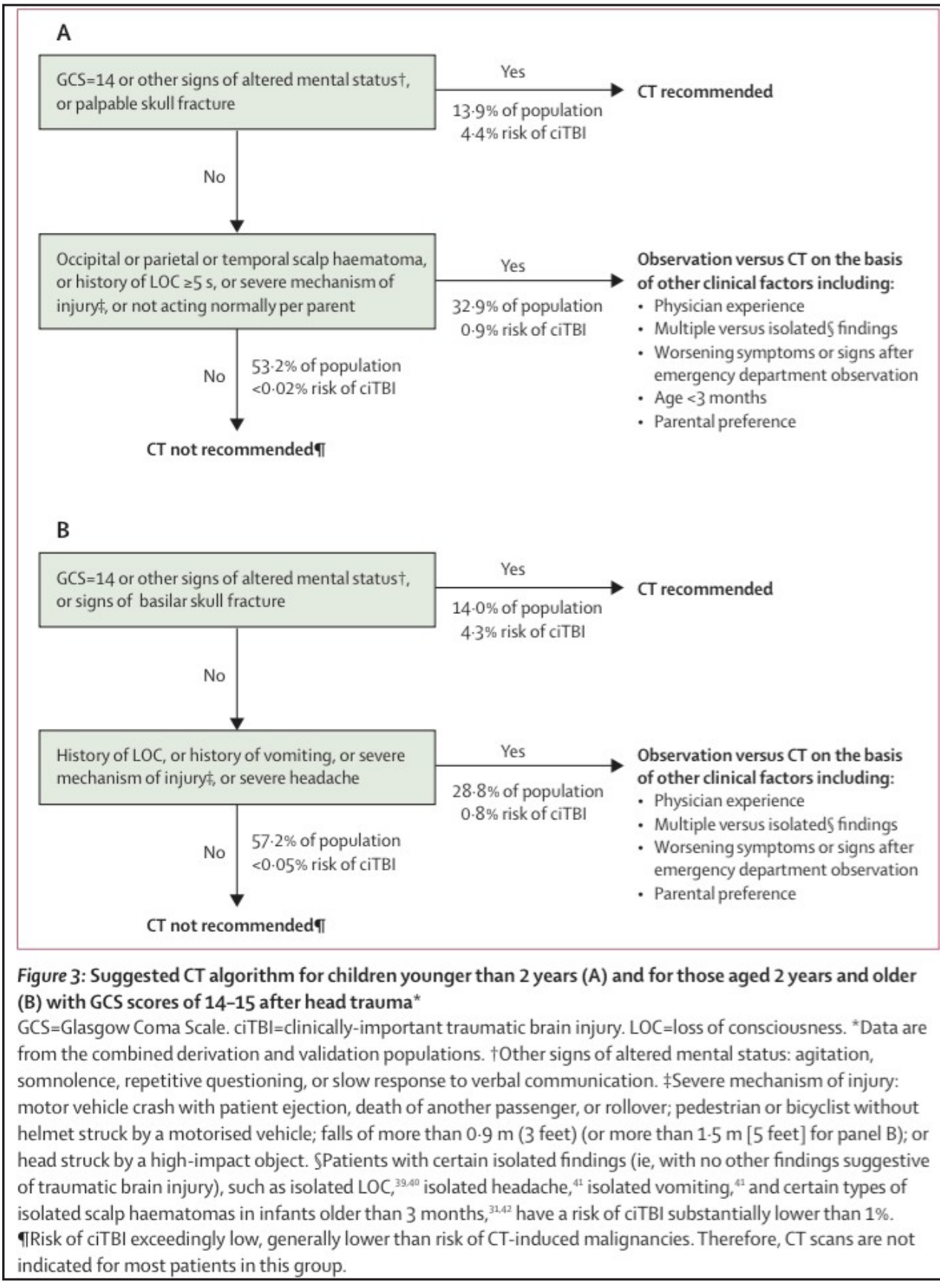


Figure 3*: Suggested CT algorithm for children younger than 2 years (A) and for those aged 2 years and older (B) with GCS scores of 14–15 after head trauma

GCS=Glasgow Coma Scale. ciTBI=clinically-important traumatic brain injury. LOC=loss of consciousness. *Data are from the combined derivation and validation populations. †Other signs of altered mental status: agitation, somnolence, repetitive questioning, or slow response to verbal communication. ‡Severe mechanism of injury: motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorised vehicle; falls of more than 0·9 m (3 feet) (or more than 1·5 m [5 feet] for panel B); or head struck by a high-impact object. §Patients with certain isolated findings (ie, with no other findings suggestive of traumatic brain injury), such as isolated LOC,[39,40] isolated headache,[41] isolated vomiting,[41] and certain types of isolated scalp haematomas in infants older than 3 months,[31,42] have a risk of ciTBI substantially lower than 1%. ¶Risk of ciTBI exceedingly low, generally lower than risk of CT-induced malignancies. Therefore, CT scans are not indicated for most patients in this group.

Figure A2-1: PECARN Decision Rule1

Conducting the PECARN Decision Rule Assessment

When configured on, the PECARN Decision rule assessment will be available for pediatric patients in appropriate age range at the top of the Information Hub screen to assess whether or not a CT scan is recommended per the rule (Figure A2-2).

After clicking the START button for the PECARN DECISION RULE, a device provides a
brief reminder of the appropriate age population and the paper where the rule was initially published will display (Figure A2-3).

When proceeding through the rule, the screen first provides prompts regarding altered mental status, GCS (Glasgow Coma Scale) score, and basilar skull fracture (Figure A2-4). If any signs of altered mental status (including a GCS score below 15) or basilar skull fracture are noted, the device provides the PECARN Decision Rule result of "CT Recommended."

If no signs of altered mental status or basilar skull fracture are noted, the device proceeds to prompts regarding severe mechanisms of injury, loss of consciousness, severe headache, and vomiting (Figure A2-5).

If none of the symptoms are present, the device provides the PECARN Decision Rule result of "CT not recommended". If any of the symptoms are present, the device presents a PECARN Decision Rule result of
"Observation versus CT on the basis of other clinical factors" with verbiage from the original PECARN Decision Rule publication.

Figure A2-6 displays the three possible results of the PECARN assessment.

In each of the three result cases, the operator may confirm the result to save it or select the "Previous" button to return to the assessment and adjust answers as necessary. Once results are confirmed, they may not be edited and they are displayed on the Hub (Figure (A2-7). The operator may select REVIEW to review the data entered.

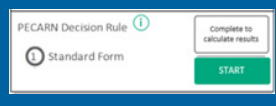


Figure A2-2:
PECARN Start from Hub

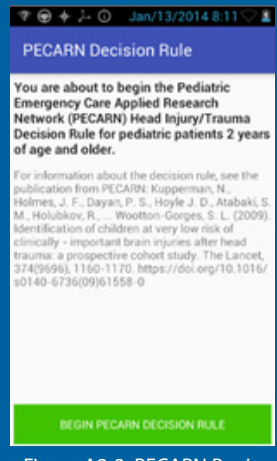


Figure A2-3: PECARN Begin

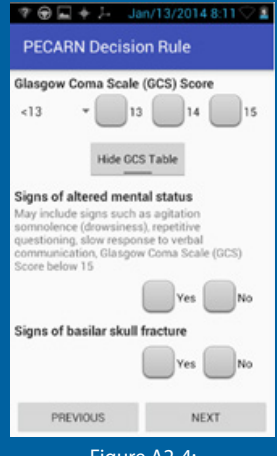


Figure A2-4:
Altered Mental Status, GCS Score, Basilar Skull Fracture

Figure A2-5: Severe mechanisms of injury, loss of consciousness, severe headache, and vomiting

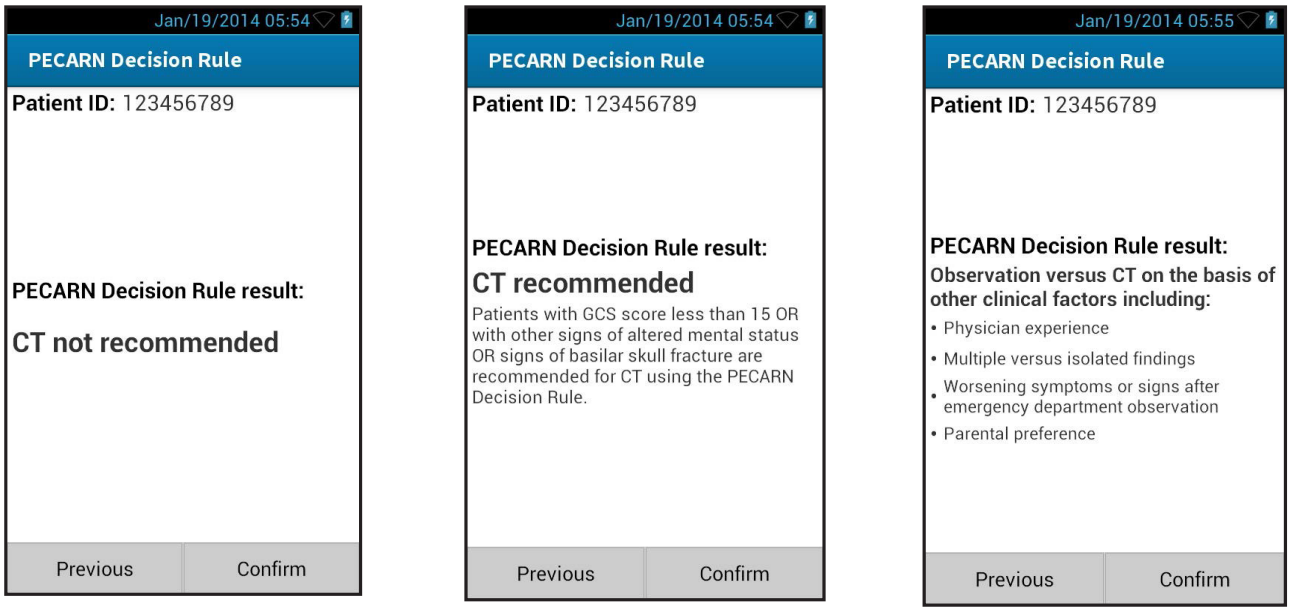


Figure A2-6:
PECARN Assessment Results Screens

Figure A2-7:
PECARN Assessment Results in
Information Hub

Appendix 3: Patient Session PDF Report

BrainScope®

Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM
Assessment Operator: XXXXXX
Device SN: XXXXXX

BrainScope® Patient Session Report

SESSION INFORMATION

Patient ID:	Session Type:	Injury Date:
Name:	Session Date:	Injury Type:
Date of Birth:	Session ID:	
Gender:	Session Status:	
Dominant Hand:	Assessment Operator:	

SIGNS & SYMPTOMS

At time of injury...
Loss of Consciousness:
Witnessed:
Duration:
At time of assessment...
GCS Score:
Headache:
Rating:
Dizziness:
Rating:
Balance:
Rating:
At any time since injury...
Disoriented:
Retrograde Amnesia:
Altered Mental Status:

ASSESSMENT SUMMARY

Structural Injury Assessments	
Structural Injury Classifier (SIC)	**Negative** Likely no structural brain injury visible on head CT
PECARN Decision Rule	**CT Not Recommended**
Functional Injury Assessments	
Concussion Index (CI)	**CI: 80** **CI Negative**
Brain Function Index (BFI)	**20th Percentile** **Average** **A**
Cognitive Performance	
• Procedural Reaction Time	**Average or Above** **A/AA**
• Simple Reaction Time	**Average or Above** **A/AA**
• Match to Sample	**Below Average** **B**
• Go/No Go	**Clearly Below Average** **C**
• Simple Reaction Time (R)	**Below Average** **B**
Near Point Convergence (NPC)	**M1: 5cm** **M2: 7cm** **M3: 4cm** **Avg: 5.3cm**
SCAT5	**See Page X**
MACE 2	**See Page X**

SESSION NOTES

BrainScope Patient Session Report
Page 1 of 33

Assessment: Structural Injury Classifier (SIC)
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM

STRUCTURAL INJURY CLASSIFIER (SIC) RESULTS

Negative

Likely no structural brain injury visible on head CT

ASSESSMENT INFORMATION

A Negative BrainScope Structural Injury Classification in patients who sustained a head injury within 72 hours reflects brain electrical activity that corresponds to patients who likely have no structural brain injury visible on head CT, as found in the FDA validation study population.

PECARN DECISION RULE RESULTS

CT Not Recommended

Risk of clinically-important TBI (e.g. leading to death, need for neurosurgery, intubation, hospital admission associated with structural injury visible on CT) exceedingly low, generally lower than risk of CT-induced malignancies. Therefore, CT scans are not indicated for most patients in this group.

Responses:

- Patient's GCS Score: **XX**
- Does the patient exhibit any signs of...
  - Altered mental status: **XX**
  - Basilar skull fracture: **XX**
- Was the mechanism of injury severe?: **XX**
- Since the time of injury, is there history of...
  - Loss of consciousness: **XX**
  - Vomiting: **XX**
  - Severe headache: **XX**

ASSESSMENT INFORMATION

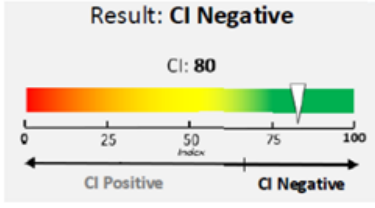
The Pediatric Emergency Care Applied Research Network (PECARN) Head Injury/Trauma Decision Rule is intended for pediatric patients who are:

- Ages 2 through 17
- Within 24 hours of head injury
- With GCS scores ≥14

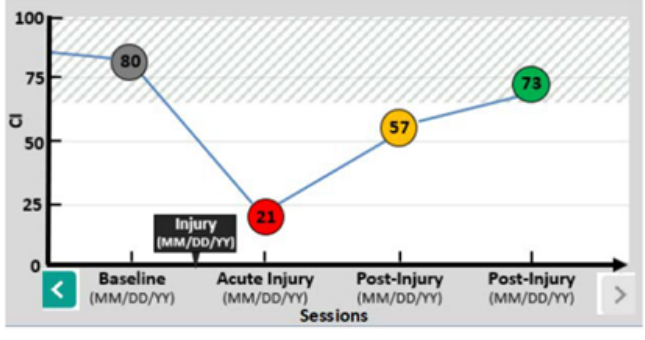
For information about the decision rule, see the publication from PECARN: *Kuppermann, N., Holmes, J. F., Dayan, P. S., Hoyle, J. D., Atabaki, S. M., Holubkov, R., ... Wootton-Gorges, S. L. (2009). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. The Lancet, 374(9696), 1160-1170. https:doi.org/10.1016/s0140-6736(09)61558-0*

CONCUSSION INDEX (CI) RESULTS

ASSESSMENT RESULTS FOR THIS SESSION



ASSESSMENT HISTORY CHART



ASSESSMENT INFORMATION

The Concussion Index (CI) provides a multimodal measure to aid in the evaluation of concussion. Changes in CI can be interpreted reliably.

Concussion Index Result	
Baseline	0<CI≤100

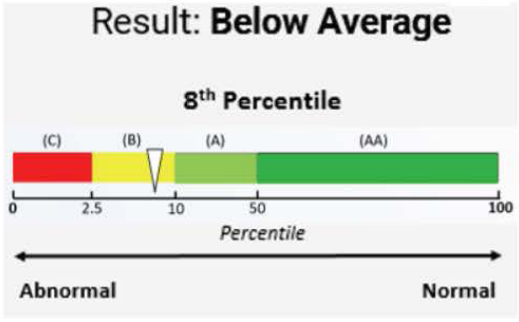
A Baseline CI establishes a patient-specific reference point to aid in the evaluation of change. Baseline CIs will vary by patient and are not intended to provide a CI Positive / CI Negative categorization for noninjured patients.

Concussion Index Result	
CI Negative	70<CI≤100
CI Positive	0≤CI≤70

For the assessment of injured patients, A CI Negative result indicates a negative screen for concussion to be assessed in conjunction with neurological/clinical evaluation. A CI Positive result indicates a positive screen for concussion and the need for additional neurological/clinical evaluation.

The shaded area in the chart from 65-100 represents CI scores consistent with the range of non-injured CI values obtained in the FDA validation study.

BRAIN FUNCTION INDEX (BFI) RESULTS



ASSESSMENT INFORMATION

The BrainScope Brain Function Index (BFI) provides a measure of brain function for the statistical evaluation of the patient's electroencephalogram (EEG). This measure does not interact with any other measures, and is stand alone. The BFI does not indicate the likelihood of the presence or absence of structural brain injury.

Statements displayed represent how the patient performed in comparison to normative data.

Brain Function Index Result	
Above Average (AA)	50≤BFI≤100
Average (A)	10≤BFI<50
Below Average (B)	2.5≤BFI<10
Clearly Below Average (C)	0≤BFI<2.5

Above Average – patient's BFI result is equal to or above the 50th percentile

Average – patient's BFI result is equal to or above the 10th percentile to the 50th percentile

Below Average – patient's BFI result is equal to or above the 2.5th percentile to the 10th percentile, significantly different from the mean of the normal distribution

Clearly Below Average – patient's BFI is below the 2.5th percentile, highly different from the mean of the normal distribution.

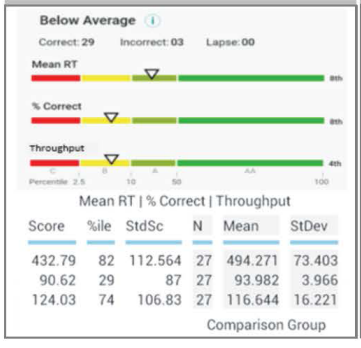
Assessment: Cognitive Performance
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM

COGNITIVE PERFORMANCE RESULTS

NORMS COMPARISON

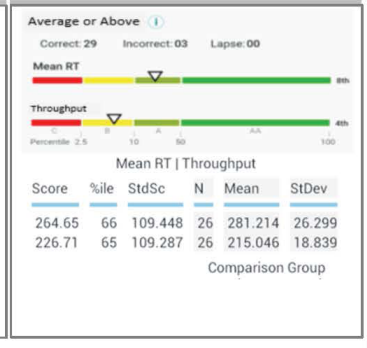
Procedural Reaction Time



Score	%ile	StdSc	N	Mean	StDev
432.79	82	112.564	27	494.271	73.403
90.62	29	87	27	93.982	3.966
124.03	74	106.83	27	116.644	16.221

Comparison Group

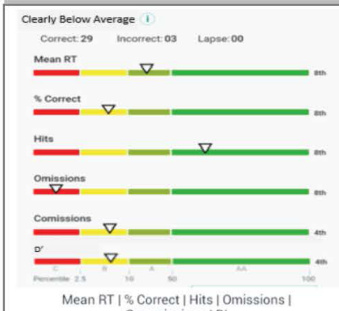
Simple Reaction Time



Score	%ile	StdSc	N	Mean	StDev
264.65	66	109.448	26	281.214	26.299
226.71	65	109.287	26	215.046	18.839

Comparison Group

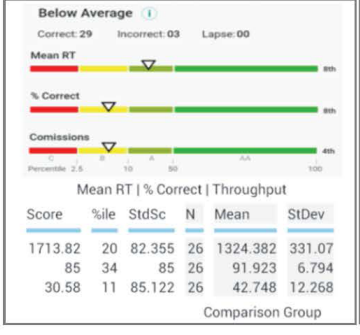
Go/No Go



Score	%ile	StdSc	N	Mean	StDev
335.38	71	108.442	27	351.525	95.222
91.67	29	88	27	94.11	2.994
96	100	109.573	27	0	1.219
0	100	106.875	27	0.407	0.888
10	100	84.765	27	6.63	3.318
4.48	44	102.72	27	4.206	1.511

Comparison Group

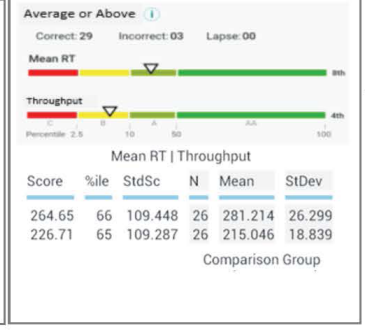
Match to Sample



Score	%ile	StdSc	N	Mean	StDev
1713.82	20	82.355	26	1324.382	331.07
85	34	85	26	91.923	6.794
30.58	11	85.122	26	42.748	12.268

Comparison Group

Simple Reaction Time (R)



Score	%ile	StdSc	N	Mean	StDev
264.65	66	109.448	26	281.214	26.299
226.71	65	109.287	26	215.046	18.839

Comparison Group

SELF COMPARISON (RELIABLE CHANGE INDEX)

Reference Session:

Baseline Session
Session ID: **XX**
Date: **XXX/X/XXXX HH:MM**

Reliable Change Index

Test	Change	Description	Value
Procedural Reaction Time	v	Significant Decrease	-7.36
Simple Reaction Time	v	Significant Decrease	-7.22
Match to Sample	~	No Significant Change	-1.32
Go/No Go	v	Significant Decrease	-2.00
Simple Reaction Time (R)	^	Significant Increase	+4.48

ASSESSMENT INFORMATION

Norms Comparison Results: For each test, one of three statements is displayed that represents how the patient performed in comparison to normative data. Several variables (such as Mean Reaction Time, Percent Correct, and Throughput) are examined in comparison to the normative data and summarized for in the results above. The three possible statements are detailed below:

Average or Above – All measures are greater than or equal to the 10th percentile

Below Average – One or two measures are less than the 10th percentile AND no measures are less than the 2.5th percentile. Excludes when Mean Reaction Time and Percent Correct measures are both less than the 10th percentile, which is an exception to the rule and is classified as "Clearly Below Average."

Clearly Below Average – The Mean Reaction Time and Percent Correct measures are both less than the 10th percentile OR at least one measure is less than the 2.5th percentile.

Self Comparison Results: The self comparison results provide a Reliable Change Index (RCI) for statistical comparison of cognitive performance results for the current session to those of a prior session to support the evaluation of change in performance over time.

Reliable Change Index Result		
Significant Increase		RCI ≥ 1.64
No Significant Change		-1.64 < RCI < 1.64
Significant Decrease		RCI ≤ -1.64

An RCI greater than or equal to 1.64 corresponds to a Significant Increase relative to the selected reference session. An RCI greater than negative 1.64 and less than positive 1.64 corresponds to No Significant Change relative to the selected reference session. An RCI less than or equal to negative 1.64 corresponds to a Significant Decrease relative to the selected reference session.

NEAR POINT CONVERGENCE (NPC) RESULTS

Trial	Distance
Measure 1	5 cm
Measure 2	7 cm
Measure 3	4 cm
Average	5.33cm

ASSESSMENT INFORMATION

The Near Point Convergence (NPC) assessment measures the ability to view a near target without double vision. The patient is seated and wearing corrective lenses (if needed). The examiner is seated front of the patient and observes their eye movement during this test. The patient focuses on a small target (approximately 14 point font size) at arm's length and slowly brings it toward the tip of their nose. The patient is instructed to stop moving the target when they see two distinct images or when the examiner observes an outward deviation of one eye. Blurring of the image is ignored. The distance in centimeters between the target and the tip of the nose is measured and recorded. This is repeated a total of 3 times with measures recorded each time.

Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
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SCAT5 RESULTS

BJSM Online First, published on April 28, 2017 as 10.1136/bjsports-2017-097506SCAT5

Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

SCAT5® SPORT CONCUSSION ASSESSMENT TOOL – 5TH EDITION
DEVELOPED BY THE CONCUSSION IN SPORT GROUP
FOR USE BY MEDICAL PROFESSIONALS ONLY

supported by Aaa Bbb

Patient details

Name: John Doe
DOB: Oct/23/1980
Address: 1234
ID number: WRK93
Examiner: Aaa Bbb
Date of Injury: Dec/12/2016 Time: 07:45 PM

WHAT IS THE SCAT5?

The SCAT5 is a standardized tool for evaluating concussions designed for use by physicians and licensed healthcare professionals[1]. The SCAT5 cannot be performed correctly in less than 10 minutes.

If you are not a physician or licensed healthcare professional, please use the Concussion Recognition Tool 5 (CRT5). The SCAT5 is to be used for evaluating athletes aged 13 years and older. For children aged 12 years or younger, please use the Child SCAT5.

Preseason SCAT5 baseline testing can be useful for interpreting post-injury test scores, but is not required for that purpose.Detailed instructions for use of the SCAT5 are provided on page 7. Please read through these instructions carefully before testing the athlete. Brief verbal instructions for each test are given in italics. The only equipment required for the tester is a watch or timer.

Recognise and Remove

A head impact by either a direct blow or indirect transmission of force can be associated with a serious and potentially fatal brain injury. If there are significant concerns, including any of the red flags listed in Box 1, then activation of emergency procedures and urgent transport to the nearest hospital should be arranged.

Key points

- Any athlete with suspected concussion should be REMOVED FROM PLAY, medically assessed and monitored for deterioration. No athlete diagnosed with concussion should be returned to play on the day of injury.
- If an athlete is suspected of having a concussion and medical personnel are not immediately available, the athlete should be referred to a medical facility for urgent assessment.
- Athletes with suspected concussion should not drink alcohol, use recreational drugs and should not drive a motor vehicle until cleared to do so by a medical professional.
- Concussion signs and symptoms evolve over time and it is important to consider repeat evaluation in the assessment of concussion.
- The diagnosis of a concussion is a clinical judgment, made by a medical professional. The SCAT5 should NOT be used by itself to make, or exclude, the diagnosis of concussion. An athlete may have a concussion even if their SCAT5 is "normal".

Remember:

- The basic principles of first aid (danger, response, airway, breathing, circulation) should be followed.
- Do not attempt to move the athlete (other than that required for airway management) unless trained to do so.
- Assessment for a spinal cord injury is a critical part of the initial on-field assessment.
- Do not remove a helmet or any other equipment unless trained to do so safely.

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM

Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

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IMMEDIATE OR ON-FIELD ASSESSMENT

The following elements should be assessed for all athletes who are suspected of having a concussion prior to proceeding to the neurocognitive assessment and ideally should be done on-field after the first first aid / emergency care priorities are completed.

If any of the "Red Flags" or observable signs are noted after a direct or indirect blow to the head, the athlete should be immediately and safely removed from participation and evaluated by a physician or licensed healthcare professional.

Consideration of transportation to a medical facility should be at the discretion of the physician or licensed healthcare professional.

The GCS is important as a standard measure for all patients and can be done serially if necessary in the event of deterioration in conscious state. The Maddocks questions and cervical spine exam are critical steps of the immediate assessment; however, these do not need to be done serially.

Name: John Doe
DOB: Oct/23/1980
Address: 1234
ID number: WRK93
Examiner: Aaa Bbb
Date: Oct/22/2017

STEP 1: RED FLAGS

RED FLAGS:

- Neck pain or tenderness
- Double vision
- Weakness or tingling/ burning in arms or legs
- Severe or increasing headache
- Seizure or convulsion
- Loss of consciousness
- Deteriorating conscious state
- Vomiting
- Increasingly restless, agitated or combative

STEP 2: OBSERVABLE SIGNS

Witnessed ☐ Observed on Video ✖

Lying motionless on the playing surface	(Y)	N
Balance / gait difficulties / motor incoordination: stumbling, slow / laboured movements	Y	(N)
Disorientation or confusion, or an inability to respond appropriately to questions	Y	(N)
Blank or vacant look	Y	(N)
Facial injury after head trauma	Y	(N)

STEP 3: MEMORY ASSESSMENT MADDOCKS QUESTIONS[2]

"I am going to ask you a few questions, please listen carefully and give your best effort. First, tell me what happened?"

Description

Mark Y for correct answer / N for incorrect

What venue are we at today?	Y	(N)
Which half is it now?	Y	(N)
Who scored last in this match?	(Y)	N
What team did you play last week / game?	(Y)	N
Did your team win the last game?	(Y)	N

Note: Appropriate sport-specific questions may be substituted.

STEP 4: EXAMINATION GLASGOW COMA SCALE (GCS)[3]

Time of assessment	01:45 PM		
Date of assessment	Oct/22/2017		
Best eye response (E)			
No eye opening	1	1	1
Eye opening in response to pain	(2)	2	2
Eye opening to speech	3	3	3
Eyes opening spontaneously	4	4	4
Best verbal response (V)			
No verbal response	1	1	1
Incomprehensible sounds	2	2	2
Inappropriate words	(3)	3	3
Confused	4	4	4
Oriented	5	5	5
Best motor response (M)			
No motor response	1	1	1
Extension to pain	2	2	2
Abnormal flexion to pain	3	3	3
Flexion / Withdrawal to pain	4	4	4
Localizes to pain	(5)	5	5
Obeys commands	6	6	6
Glasgow Coma score (E + V + M)	10		

CERVICAL SPINE ASSESSMENT

Does the athlete report that their neck is pain free at rest?	Y	(N)
If there is NO neck pain at rest, does the athlete have a full range of ACTIVE pain free movement?	Y	(N)
Is the limb strength and sensation normal?	(Y)	N

In a patient who is not lucid or fully conscious, a cervical spine injury should be assumed until proven otherwise.

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
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Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

OFFICE OR OFF-FIELD ASSESSMENT

Please note that the neurocognitive assessment should be done in a distraction-free environment with the athlete in a resting state.

STEP 1: ATHLETE BACKGROUND

Sport / team / school: team

Date / time of injury: Dec/12/2016 07:45 PM

Years of education completed: 6

Age: 36

Gender: (M) F / Other

Dominant hand: [left] / neither / right

How many diagnosed concussions has the athlete had in the past?: 3

When was the most recent concussion?: 08/13/2008

How long was the recovery (time to being cleared to play) from the most recent concussion?: 3 (days)

Has the athlete ever been:

Hospitalized for a head injury?	(Yes)	No
Diagnosed / treated for headache disorder or migraines?	(Yes)	No
Diagnosed with a learning disability / dyslexia?	(Yes)	No
Diagnosed with ADD / ADHD?	(Yes)	No
Diagnosed with depression, anxiety or other psychiatric disorder?	(Yes)	No

Current medications? If yes, please list:

medication

Name: John Doe
DOB: Oct/23/1980
Address: 764 s st
ID number: WRK93
Examiner: Aaa Bbb
Date: Oct/22/2017

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STEP 2: SYMPTOM EVALUATION

The athlete should be given the symptom form and asked to read this instruction paragraph out loud then complete the symptom scale. For the baseline assessment, the athlete should rate his/her symptoms based on how he/she typically feels and for the post injury assessment the athlete should rate their symptoms at this point in time.

Please Check: ☐ **Baseline** ☒ **Post-Injury**

Please hand the form to the athlete

	none	mild		moderate		severe	
Headache	0	1	(2)	3	4	5	6
"Pressure in head"	0	1	(2)	3	4	5	6
Neck Pain	0	1	(2)	3	4	5	6
Nausea or vomiting	0	1	(2)	3	4	5	6
Dizziness	0	1	(2)	3	4	5	6
Blurred vision	0	1	(2)	3	4	5	6
Balance problems	0	1	2	(3)	4	5	6
Sensitivity to light	0	1	2	(3)	4	5	6
Sensitivity to noise	0	1	2	(3)	4	5	6
Feeling slowed down	0	1	2	(3)	4	5	6
Feeling like "in a fog"	0	1	2	(3)	4	5	6
"Don't feel right"	0	1	2	(3)	4	5	6
Difficulty concentrating	0	1	2	3	(4)	5	6
Difficulty remembering	0	1	2	3	(4)	5	6
Fatigue or low energy	0	1	2	3	(4)	5	6
Confusion	0	1	2	3	(4)	5	6
Drowsiness	0	1	2	3	(4)	5	6
More emotional	0	1	2	3	(4)	5	6
Irritability	0	(1)	2	3	4	5	6
Sadness	0	(1)	2	3	4	5	6
Nervous or Anxious	0	(1)	2	3	4	5	6
Trouble falling asleep (if applicable)	0	(1)	2	3	4	5	6

Total number of symptoms:	22 of 22
Symptom severity score:	58 of 132
Do your symptoms get worse with physical activity?	(Y) N
Do your symptoms get worse with mental activity?	Y (N)
If 100% is feeling perfectly normal, what percent of normal do you feel?	30

If not 100%, why?

Reason

Please hand form back to examiner

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

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STEP 3: COGNITIVE SCREENING

Standardised Assessment of Concussion (SAC)[4]

Name: John Doe
DOB: Oct/23/1980
Address: 764 s st
ID number: WRK93
Examiner: Aaa Bbb
Date: Oct/22/2017

ORIENTATION

What month is it?	0	(1)
What is the date today?	0	(1)
What is the day of the week?	0	(1)
What year is it?	0	(1)
What time is it right now? (within 1 hour)	0	(1)
Orientation score	5	of 5

IMMEDIATE MEMORY

The Immediate Memory component can be completed using the traditional 5-word per trial list or optionally using 10-words per trial to minimise any ceiling effect. All 3 trials must be administered irrespective of the number correct on the first trial. Administer at the rate of one word per second.

Please choose EITHER the 5 or 10 word list groups and circle the specific word list chosen for this test.

I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order. For Trials 2 & 3: I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before.

List	Alternate 5 word lists					Score (of 5) Trial 1	Trial 2	Trial 3
A	Finger	Penny	Blanket	Lemon	Insect			
B	Candle	Paper	Sugar	Sandwich	Wagon			
C	Baby	Monkey	Perfume	Sunset	Iron			
D	Elbow	Apple	Carpet	Saddle	Bubble			
E	Jacket	Arrow	Pepper	Cotton	Movie			
F	Dollar	Honey	Mirror	Saddle	Anchor			
					Immediate Memory Score			of 15
					Time that last trial was completed			

List	Alternate 10 word lists					Score (of 10) Trial 1	Trial 2	Trial 3
G	Finger / Candle	Penny / Paper	Blanket / Sugar	Lemon / Sandwich	Insect / Wagon			
(H)	Baby / Elbow	Monkey / Apple	Perfume / Carpet	Sunset / Saddle	Iron / Bubble	8	6	5
I	Jacket / Dollar	Arrow / Honey	Pepper / Mirror	Cotton / Saddle	Movie / Anchor			
					Immediate Memory Score	19		of 30
					Time that last trial was completed	01:49		

CONCENTRATION

DIGITS BACKWARDS

Please circle the Digit list chosen (A, B, C, D, E, F). Administer at the rate of one digit per second reading DOWN the selected column.

I am going to read a string of numbers and when I am done, you repeat them back to me in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7.

Concentration Number Lists (circle one)

List A	List B	List C			
4-9-3	5-2-6	1-4-2	Y	(N)	(0)
6-2-9	4-1-5	6-5-8	Y	(N)	1
3-8-1-4	1-7-9-5	6-8-3-1	Y	(N)	(0)
3-2-7-9	4-9-6-8	3-4-8-1	Y	(N)	1
6-2-9-7-1	4-8-5-2-7	4-9-1-5-3	Y	(N)	0
1-5-2-8-6	6-1-8-4-3	6-8-2-5-1	(Y)	N	(1)
7-1-8-4-6-2	8-3-1-9-6-4	3-7-6-5-1-9	(Y)	N	0
5-3-9-1-4-8	7-2-4-8-5-6	9-2-6-5-1-4	Y	N	(1)
List D	**List E**	**List F**			
7-8-2	3-8-2	2-7-1	Y	N	0
9-2-6	5-1-8	4-7-9	Y	N	1
4-1-8-3	2-7-9-3	1-6-8-3	Y	N	0
9-7-2-3	2-1-6-9	3-9-2-4	Y	N	1
1-7-9-2-6	4-1-8-6-9	2-4-7-5-8	Y	N	0
4-1-7-5-2	9-4-1-7-5	8-3-9-6-4	Y	N	1
2-6-4-8-1-7	6-9-7-3-8-2	5-8-6-2-4-9	Y	N	0
8-4-1-9-3-5	4-2-7-9-3-8	3-1-7-8-2-6	Y	N	1
		Digits Score:	2		of 4

MONTHS IN REVERSE ORDER

Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November. Go ahead.

Dec - Nov - Oct - Sept - Aug - Jul - Jun - May - Apr - Mar - Feb - Jan		(0) 1
Months Score	1	of 1
Concentration Total Score (Digits + Months)	3	of 5

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
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STEP 4: NEUROLOGICAL SCREEN

See the instruction sheet (page 7) for details of test administration and scoring of the tests.

Can the patient read aloud (e.g. symptom check-list) and follow instructions without difficulty?	(Y)	N
Does the patient have a full range of pain-free PASSIVE cervical spine movement?	(Y)	N
Without moving their head or neck, can the patient look side-to-side and up-and-down without double vision?	(Y)	N
Can the patient perform the finger nose coordination test normally?	(Y)	N
Can the patient perform tandem gait normally?	Y	(N)

BALANCE EXAMINATION

Modified Balance Error Scoring System (mBESS) testing[5]

Which foot was tested (i.e. which is the non-dominant foot): ☐ Left ☒ Right

Testing surface (hard floor, field, etc.): hard floor

Footwear (shoes, barefoot, braces, tape, etc.): braces

Condition	Errors	
Double leg stance	7	of 10
Single leg stance (non-dominant foot)	5	of 10
Tandem stance (non-dominant foot at the back)	4	of 10
Total Errors	16	of 30

Name: John Doe
DOB: Oct/23/1980
Address: 764 s st
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Date: Oct/22/2017

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STEP 5: DELAYED RECALL:

The delayed recall should be performed after 5 minutes have elapsed since the end of the Immediate Recall section. Score 1 pt. for each correct response.

Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order.

Time Started: 01:51 PM

Please record each word correctly recalled. Total score equals number of words recalled.

Baby Monkey Perfume Bubble

Total number of words recalled accurately: of 5 or 4 of 10

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STEP 6: DECISION

Domain	Date & time of assessment: Oct/22/2017 01:52 PM		
Symptom number (of 22)	22		
Symptom severity score (of 132)	58		
Orientation (of 5)	5		
Immediate memory	19 of 15 of 30	of 15 of 30	of 15 of 30
Concentration (of 5)	3		
Neuro exam	Normal / Abnormal	Normal / Abnormal	Normal / Abnormal
Balance errors (of 30)	16		
Delayed Recall	4 of 5 of 10	of 5 of 10	of 5 of 10

Date and time of injury: Dec/12/2016 07:45 PM

If the athlete is known to you prior to their injury, are they different from their usual self?
☐ Yes ☐ No ☐ Unsure ☒ Not Applicable
(If different, describe why in the clinical notes section)

Concussion Diagnosed?
☐ Yes ☐ No ☐ Unsure ☒ Not Applicable

If re-testing, has the athlete improved?
☒ Yes ☐ No ☐ Unsure ☐ Not Applicable

I am a physician or licensed healthcare professional and I have personally administered or supervised the administration of this SCAT5.

Signature: sig
Name: name
Title: title
Registration number (if applicable): 25689
Date: Oct/22/2017

SCORING ON THE SCAT5 SHOULD NOT BE USED AS A STAND-ALONE METHOD TO DIAGNOSE CONCUSSION, MEASURE RECOVERY OR MAKE DECISIONS ABOUT AN ATHLETE'S READINESS TO RETURN TO COMPETITION AFTER CONCUSSION.

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Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

CLINICAL NOTES:

Notes

Name: John Doe
DOB: Oct/23/1980
Address: 764 s st
ID number: WRK93
Examiner: Aaa Bbb
Date: Oct/22/2017

CONCUSSION INJURY ADVICE

(To be given to the person monitoring the concussed athlete)

This patient has received an injury to the head. A careful medical examination has been carried out and no sign of any serious complications has been found. Recovery time is variable across individuals and the patient will need monitoring for a further period by a responsible adult. Your treating physician will provide guidance as to this timeframe.

If you notice any change in behaviour, vomiting, worsening headache, double vision or excessive drowsiness, please telephone your doctor or the nearest hospital emergency department immediately.

Other important points:

Initial rest: Limit physical activity to routine daily activities (avoid exercise, training, sports) and limit activities such as school, work, and screen time to a level that does not worsen symptoms.

1) Avoid alcohol

2) Avoid prescription or non-prescription drugs without medical supervision. Specifically:

   a) Avoid sleeping tablets

   b) Do not use aspirin, anti-inflammatory medication or stronger pain medications such as narcotics

3) Do not drive until cleared by a healthcare professional.

4) Return to play/sport requires clearance by a healthcare professional.

Clinic phone number: 3567425894

Patient's name: John Doe

Date / time of injury: Dec/12/2016 07:45 PM

Date / time of medical review: Oct/22/2017 01:52 PM

Healthcare Provider: provider

details

Contact details or stamp

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM
Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM

Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

INSTRUCTIONS

Words in *Italics* throughout the SCAT5 are the instructions given to the athlete by the clinician

Symptom Scale

The time frame for symptoms should be based on the type of test being administered. At baseline it is advantageous to assess how an athlete "typically" feels whereas during the acute/post-acute stage it is best to ask how the athlete feels at the time of testing.

The symptom scale should be completed by the athlete, not by the examiner. In situations where the symptom scale is being completed after exercise, it should be done in a resting state, generally by approximating his/her resting heart rate.

For total number of symptoms, maximum possible is 22 except immediately post injury, if sleep item is omitted, which then creates a maximum of 21.

For Symptom severity score, add all scores in table, maximum possible is 22 x 6 = 132, except immediately post injury if sleep item is omitted, which then creates a maximum of 21x6=126.

Immediate Memory

The Immediate Memory component can be completed using the traditional 5-word per trial list or, optionally, using 10-words per trial. The literature suggests that the Immediate Memory has a notable ceiling effect when a 5-word list is used. In settings where this ceiling is prominent, the examiner may wish to make the task more difficult by incorporating two 5–word groups for a total of 10 words per trial. In this case, the maximum score per trial is 10 with a total trial maximum of 30.

Choose one of the word lists (either 5 or 10). Then perform 3 trials of immediate memory using this list.

Complete all 3 trials regardless of score on previous trials.

"I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order." The words must be read at a rate of one word per second.

Trials 2 & 3 MUST be completed regardless of score on trial 1 & 2.

Trials 2 & 3:

"I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Score 1 pt. for each correct response. Total score equals sum across all 3 trials. Do NOT inform the athlete that delayed recall will be tested.

Concentration

Digits backward

Choose one column of digits from lists A, B, C, D, E or F and administer those digits as follows:

Say: *"I am going to read a string of numbers and when I am done, you repeat them back to me in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7."*

Begin with first 3 digit string.

If correct, circle "Y" for correct and go to next string length. If incorrect, circle "N" for the first string length and read trial 2 in the same string length. One point possible for each string length. Stop after incorrect on both trials (2 N's) in a string length. The digits should be read at the rate of one per second.

Months in reverse order

"Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November ... Go ahead"

1 pt. for entire sequence correct

Delayed Recall

The delayed recall should be performed after 5 minutes have elapsed since the end of the Immediate Recall section.

"Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order."

Score 1 pt. for each correct response

Modified Balance Error Scoring System (mBESS)[5] testing

This balance testing is based on a modified version of the Balance Error Scoring System (BESS)[5]. A timing device is required for this testing.

Each of 20-second trial/stance is scored by counting the number of errors. The examiner will begin counting errors only after the athlete has assumed the proper start position. The modified BESS is calculated by adding one error point for each error during the three 20-second tests. The maximum number of errors for any single condition is 10. If the athlete commits multiple errors simultaneously, only one error is recorded but the athlete should quickly return to the testing position, and counting should resume once the athlete is set. Athletes that are unable to maintain the testing procedure for a minimum of five seconds at the start are assigned the highest possible score, ten, for that testing condition.

OPTION: For further assessment, the same 3 stances can be performed on a surface of medium density foam (e.g., approximately 50cm x 40cm x 6cm).

Balance testing – types of errors

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hip into > 30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position > 5 sec

"I am now going to test your balance. Please take your shoes off (if applicable), roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of three twenty second tests with different stances."

(a) Double leg stance:

"The first stance is standing with your feet together with your hands on your hips and with your eyes closed. You should try to maintain stability in that position for 20 seconds. I will be counting the number of times you move out of this position. I will start timing when you are set and have closed your eyes."

(b) Single leg stance:

"If you were to kick a ball, which foot would you use? [This will be the dominant foot] *Now stand on your non-dominant foot. The dominant leg should be held in approximately 90 degrees of hip flexion and 45 degrees of knee flexion. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."*

(c) Tandem stance:

"Now stand heel-to-toe with your non-dominant foot in back. Your weight should be evenly distributed across both feet. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Tandem Gait

Participants are instructed to stand with their feet together behind a starting line (the test is best done with footwear removed). Then, they walk in a forward direction as quickly and as accurately as possible along a 38mm wide (sports tape), 3 metre line with an alternate foot heel-to-toe gait ensuring that they approximate their heel and toe on each step. Once they cross the end of the 3m line, they turn 180 degrees and return to the starting point using the same gait. Athletes fail the test if they step off the line, have a separation between their heel and toe, or if they touch or grab the examiner or an object.

Finger to Nose

"I am going to test your coordination now. Please sit comfortably on the chair with your eyes open and your arm (either right or left) outstretched (shoulder flexed to 90 degrees and elbow and fingers extended), pointing in front of you. When I give a start signal, I would like you to perform five successive finger to nose repetitions using your index finger to touch the tip of the nose, and then return to the starting position, as quickly and as accurately as possible."

References

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3. Jennett, B., Bond, M. Assessment of outcome after severe brain damage: a practical scale. Lancet 1975; I: 480-484
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5. Guskiewicz KM. Assessment of postural stability following sport-related concussion. Current Sports Medicine Reports. 2003; 2: 24-30

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Assessment: SCAT5
Assessment Date: MMM/DD/YYYY HH:MM

Patient ID: 12345678901
Generated: MMM/DD/YYYY HH:MM

Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

CONCUSSION INFORMATION

Any athlete suspected of having a concussion should be removed from play and seek medical evaluation.

Signs to watch for

Problems could arise over the first 24-48 hours. The athlete should not be left alone and must go to a hospital at once if they experience:

- Worsening headache
- Drowsiness or inability to be awakened
- Inability to recognize people or places
- Repeated vomiting
- Unusual behaviour or confusion or irritable
- Seizures (arms and legs jerk uncontrollably)
- Weakness or numbness in arms or legs
- Unsteadiness on their feet.
- Slurred speech

Consult your physician or licensed healthcare professional after a suspected concussion. Remember, it is better to be safe.

Rest & Rehabilitation

After a concussion, the athlete should have physical rest and relative cognitive rest for a few days to allow their symptoms to improve. In most cases, after no more than a few days of rest, the athlete should gradually increase their daily activity level as long as their symptoms do not worsen. Once the athlete is able to complete their usual daily activities without concussion-related symptoms, the second step of the return to play/sport progression can be started. The athlete should not return to play/sport until their concussion-related symptoms have resolved and the athlete has successfully returned to full school/learning activities.

When returning to play/sport, the athlete should follow a stepwise, **medically managed exercise progression, with increasing amounts of exercise.** For example:

Graduated Return to Sport Strategy

Exercise step	Functional exercise at each step	Goal of each step
1. Symptom-limited activity	Daily activities that do not provoke symptoms.	Gradual reintroduction of work/school activities.
2. Light aerobic exercise	Walking or stationary cycling at slow to medium pace. No resistance training.	Increase heart rate.
3. Sport-specific exercise	Running or skating drills. No head impact activities.	Add movement.
4. Non-contact training drills	Harder training drills, e.g., passing drills. May start progressive resistance training.	Exercise, coordination, and increased thinking.
5. Full contact practice	Following medical clearance, participate in normal training activities.	Restore confidence and assess functional skills by coaching staff.
6. Return to play/sport	Normal game play.	

In this example, it would be typical to have 24 hours (or longer) for each step of the progression. If any symptoms worsen while exercising, the athlete should go back to the previous step. Resistance training should be added only in the later stages (Stage 3 or 4 at the earliest).

Written clearance should be provided by a healthcare professional before return to play/sport as directed by local laws and regulations.

Graduated Return to School Strategy

Concussion may affect the ability to learn at school. The athlete may need to miss a few days of school after a concussion. When going back to school, some athletes may need to go back gradually and may need to have some changes made to their schedule so that concussion symptoms do not get worse. If a particular activity makes symptoms worse, then the athlete should stop that activity and rest until symptoms get better. To make sure that the athlete can get back to school without problems, it is important that the healthcare provider, parents, caregivers and teachers talk to each other so that everyone knows what the plan is for the athlete to go back to school.

Note: If mental activity does not cause any symptoms, the athlete may be able to skip step 2 and return to school part-time before doing school activities at home first.

Mental Activity	Activity at each step	Goal of each step
1. Daily activities that do not give the athlete symptoms	Typical activities that the athlete does during the day as long as they do not increase symptoms (e.g. reading, texting, screen time). Start with 5-15 minutes at a time and gradually build up.	Gradual return to typical activities.
2. School activities	Homework, reading or other cognitive activities outside of the classroom.	Increase tolerance to cognitive work.
3. Return to school part-time	Gradual introduction of school-work. May need to start with a partial school day or with increased breaks during the day.	Increase academic activities.
4. Return to school full-time	Gradually progress school activities until a full day can be tolerated.	Return to full academic activities and catch up on missed work.

If the athlete continues to have symptoms with mental activity, some other accomodations that can help with return to school may include:

- Starting school later, only going for half days, or going only to certain classes
- More time to finish assignments/tests
- Quiet room to finish assignments/tests
- Not going to noisy areas like the cafeteria, assembly halls, sporting events, music class, shop class, etc.
- Taking lots of breaks during class, homework, tests
- No more than one exam/day
- Shorter assignments
- Repetition/memory cues
- Use of a student helper/tutor
- Reassurance from teachers that the child will be supported while getting better

The athlete should not go back to sports until they are back to school/learning, without symptoms getting significantly worse and no longer needing any changes to their schedule.

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Date and Time of Assessment: Oct/22/2017 01:45 PM, Patient ID: WRK93

BJSM

Sport concussion assessment tool - 5th edition

Br J Sports Med published online April 26, 2017

Notes

MACE 2 RESULTS

MACE 2
Military Acute Concussion Evaluation

Use MACE 2 as close to time of injury as possible.

Service Member Name: _____

DoDI/EDIPI/SSN: _____ Branch of Service & Unit: _____

Date of Injury: _____ Time of Injury: _____

Examiner: _____

Date of Evaluation: _____ Time of Evaluation: _____

Purpose: MACE 2 is a multimodal tool that assists providers in the assessment and diagnosis of concussion. The scoring, coding and steps to take after completion are found at the end of the MACE 2.

Timing: MACE 2 is most effective when used as close to the time of injury as possible. The MACE 2 may be repeated to evaluate recovery.

RED FLAGS

Evaluate for red flags in patients with Glasgow Coma Scale (GCS) 13-15.

- ❑ Deteriorating level of consciousness
- ❑ Double vision
- ❑ Increased restlessness, combative or agitated behavior
- ❑ Repeat vomiting
- ❑ Results from a structural brain injury detection device (if available)
- ❑ Seizures
- ❑ Weakness or tingling in arms or legs
- ❑ Severe or worsening headache

Defer MACE 2 if any red flags are present. Immediately consult higher level of care and consider urgent evacuation according to evacuation precedence/Tactical Combat Casualty Care (TCCC).

- ❑ **Negative for all red flags**
  Continue MACE 2, and observe for red flags throughout evaluation.

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MACE 2 - Military Acute Concussion Evaluation

MILITARY ACUTE CONCUSSION SCREENING

Complete this section to determine if there was an injury event AND an alteration of consciousness or memory.

1. Description of Incident

A. Record the event as described by the service member or witness.

Use open-ended questions to get as much detail as possible.

_____
_____
_____
_____

Key questions:
- ❑ Can you tell me what you remember?
- ❑ What happened?
- ❑ Who were you last with?

B. Observable Signs

At the time of injury were any of these observable signs witnessed?
Visual clues that suggest a possible concussion include:

- ❑ Lying motionless on the ground
- ❑ Slow to get up after a direct or indirect blow to the head
- ❑ Disorientation, confusion, or an inability to respond appropriately to questions
- ❑ Blank or vacant look
- ❑ Balance difficulties, stumbling, or slow labored movements
- ❑ Facial injury after head trauma
- ❑ Negative for all observable signs

C. Record the type of event.

Check all that apply:

☐ Blunt object ☐ Sports injury ☐ Gunshot wound
☐ Fall ☐ Assault ☐ Explosion/blast Estimated distance ____
☐ Fragment ☐ Motor vehicle crash ☐ Other _____

D. Was there a blow or jolt to the head?

- ❑ Did your head hit any objects?
- ❑ Did any objects strike your head?
- ❑ Did you feel a blast wave? (A blast wave that is felt striking the body or head is considered a blow to the head.)
- ❑ Did you have a head acceleration or deceleration?

☐ YES ☐ NO ☐ UNKNOWN

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MACE 2 - Military Acute Concussion Evaluation

2. Alteration of Consciousness or Memory

A. Was there alteration of consciousness (AOC)?
AOC is temporary confusion or "having your bell rung."

☐ YES ☐ NO

If yes, for how long? ____ seconds ____ minutes

☐ UNKNOWN

Key questions:
- ❑ Were you dazed, confused, or did you "see stars" immediately after the event?
- ❑ Did you feel like you were in a fog, slowed down, or "something was not right"?

B. Was there loss of consciousness (LOC)?
LOC is temporarily passing out or blacking out.

☐ YES ☐ NO

If yes, for how long? ____ seconds ____ minutes

☐ UNKNOWN

Key questions:
- ❑ Did you pass out or black out?
- ❑ Is there a period of time you cannot account for?

C. Was there any post traumatic amnesia (PTA)?
PTA is a problem remembering part or all of the injury events.

☐ YES ☐ NO

If yes, for how long? ____ seconds ____ minutes

☐ UNKNOWN

Key questions:
- ❑ Is there a period of time you cannot account for?
- ❑ What is the last thing you remember before the event?
- ❑ What is the first thing you remember after the event?

D. Was the AOC, LOC or PTA witnessed?

☐ YES ☐ NO

If yes, for how long? ____ seconds ____ minutes

☐ UNKNOWN

Tips for assessment:
- ❑ Ask witness to verify AOC, LOC or PTA and estimate duration.

3. Symptoms

Common symptoms after a concussion are listed below. For this event, check all that apply.

- ❑ Headache
- ❑ Dizziness
- ❑ Memory problems
- ❑ Balance problems
- ❑ Nausea/vomiting
- ❑ Difficulty concentrating
- ❑ Irritability
- ❑ Visual disturbances
- ❑ Ringing in the ears
- ❑ Other _____
- ❑ **Negative for all symptoms**

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MACE 2 - Military Acute Concussion Evaluation

4. History

A. During the past 12 months, were you diagnosed with a concussion, not counting this event?

☐ YES ☐ NO

If yes, how many? ____

☐ UNKNOWN

B. History of diagnosed/treated headache disorder or migraine.

☐ YES ☐ NO

C. History of depression, anxiety, or other behavioral health concerns.

☐ YES ☐ NO

CONCUSSION SCREENING RESULTS (Possible Concussion?)

Was there a blow or jolt to the head (1D)
AND
ANY alteration of consciousness or memory? (2A,2B,2C,or 2D)

YES (to both) ⬇

POSITIVE CONCUSSION SCREEN:
1. **Continue** MACE 2.
2. Complete evaluation before prescribing rest.
3. Communicate findings to line leadership.
4. Document and code findings in electronic health record (EHR).

NO (to either or both) ⬇

NEGATIVE CONCUSSION SCREEN:
1. **Stop** MACE 2.
2. Initiate 24 hour-rest period, if deployed. During rest, avoid activities that worsen symptoms. Follow up with the service member after rest period per concussion management tool (CMT).
3. Communicate findings to line leadership.
4. Document and code findings in electronic health record (EHR).

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MACE 2 - Military Acute Concussion Evaluation

COGNITIVE EXAM

5. Orientation

Score one point for each correct response.

Ask This Question	Incorrect	Correct
"What month is this?"	0	1
"What is the date or day of the month?"	0	1
"What day of the week is it?"	0	1
"What year is it?"	0	1
"What time do you think it is?"	0	1
Correct response must be within one hour of actual time.		

ORIENTATION TOTAL SCORE ____/5

6. Immediate Memory

Choose one list (A-F below) and use that list for the remainder of the MACE 2.

Read the script for each trial and then read all five words. Circle the response for each word for each trial. Repeat the trial three times, even if the service member scores perfectly on any of the trials.

Trial 1 script: Read the script exactly as written.

- *"I am going to test your memory. I will read you a list of words and when I am done, repeat back to me as many words as you can remember, in any order."*

Trials 2 and 3 script: Read the script exactly as written.

- *"I am going to repeat that list again. Repeat back to me as many words as you can remember, in any order, even if you said them before."*

	Trial 1		Trial 2		Trial 3	
List A	Incorrect	Correct	Incorrect	Correct	Incorrect	Correct
Jacket	0	1	0	1	0	1
Arrow	0	1	0	1	0	1
Pepper	0	1	0	1	0	1
Cotton	0	1	0	1	0	1
Movie	0	1	0	1	0	1

IMMEDIATE MEMORY TOTAL SCORE ____/15

Immediate Memory Alternate Word Lists

List B	List C	List D	List E	List F
Dollar	Finger	Baby	Candle	Elbow
Honey	Penny	Monkey	Paper	Apple
Mirror	Blanket	Perfume	Sugar	Carpet
Saddle	Lemon	Sunset	Sandwich	Saddle
Anchor	Insect	Iron	Wagon	Bubble

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MACE 2 - Military Acute Concussion Evaluation

NEUROLOGICAL EXAM

7. Speech Fluency

☐ Normal
☐ Abnormal

- Speech should be fluid and effortless
  – no pauses or unnatural breaks.
  – Stuttering or struggling to speak is abnormal.

8. Word Finding

☐ Normal
☐ Abnormal

- Assess difficulties with word finding:
  – Difficulty in coming up with the name of an object or grasping to find words is abnormal.

9. Grip Strength

☐ Normal
☐ Abnormal

- Assess grip strength. Grip strength should be strong and equal bilaterally.
  – Unequal or weak grip strength is abnormal.

10. Pronator Drift

☐ Normal
☐ Abnormal

- Direct service member to stand with eyes closed and arms extended forward, parallel to the ground with palms up. Assess for five to 10 seconds:
  – Any arm or palm drift is abnormal.

11. Single Leg Stance

☐ Normal
☐ Abnormal

- Remove shoes if possible. Have service member stand on one leg, arms across chest, hands touching shoulders, eyes open initially. Once service member is balanced, have them close their eyes and time for 15 seconds how long they can maintain their balance. Repeat test with opposite leg.
  – Loss of balance on either leg before eight seconds is abnormal.

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MACE 2 - Military Acute Concussion Evaluation

NEUROLOGICAL EXAM - Continued

12. Tandem Gait

☐ Normal
☐ Abnormal

❑ Remove shoes if possible. Have service member take six steps one foot in front of the other, heel-to-toe, with arms at side
- Stumbling or shifting feet is abnormal.

13. Pupil Response

☐ Normal
☐ Abnormal

❑ Pupils should be round, equal in size and briskly constrict to a direct, bright light.
- Unequal pupil size, dilation or constriction delay is abnormal.

14. Eye Tracking

☐ Normal
☐ Abnormal

❑ Both eyes should smoothly track your finger side-to-side and up and down.
- Unequal, irregular or delayed eye tracking is abnormal.

NEUROLOGICAL EXAM RESULTS (Questions 7-14)

☐ All Normal ☐ Any Abnormal

COGNITIVE EXAM

15. Concentration

A. Reverse Digits

Read the script and begin the trial by reading the first string of numbers in Trial 1.

Circle the response for each string.

- If correct on string length of Trial 1, proceed to the next longer string length in the same column.
- If incorrect on string length of Trial 1, move to the same string length of Trial 2.
- If incorrect on both string lengths in Trials 1 and 2, **STOP** and record score as zero for that string length. Record total score as sum of previous correct trials.

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MACE 2 - Military Acute Concussion Evaluation

COGNITIVE EXAM - Continued

15. Concentration - Continued

A. Reverse Digits

Script: Read the script exactly as written.

- *"I am going to read you a string of numbers. When I am finished, repeat them back to me backward. That is, in reverse order of how I read them to you. For example, if I said 7 - 1 - 9, then you would say 9 - 1 - 7."*

List A			
Trial 1	**Trial 2** (if Trial 1 is incorrect)	**Incorrect**	**Correct**
4-9-3	6-2-9	0	1
3-8-1-4	3-2-7-9	0	1
6-2-9-7-1	1-5-2-8-5	0	1
7-1-8-4-6-3	5-3-9-1-4-8	0	1

REVERSE DIGITS SCORE (16A) ____/4

Concentration Alternate Number Lists

Note: Use the same list (A-F) that was used in Question 6.

List B	
Trial 1	**Trial 2**
5-2-6	4-1-5
1-7-9-5	4-9-6-8
4-8-5-2-7	6-1-8-4-3
8-3-1-9-6-4	7-2-7-8-5-6

List C	
Trial 1	**Trial 2**
1-4-2	6-5-8
6-8-3-1	3-4-8-1
4-9-1-5-3	6-8-2-5-1
3-7-6-5-1-9	9-2-6-5-1-4

List D	
Trial 1	**Trial 2**
7-8-2	9-2-6
4-1-8-3	9-7-2-3
1-7-9-2-6	4-1-7-5-2
2-6-4-8-1-7	8-4-1-9-3-5

List E	
Trial 1	**Trial 2**
3-8-2	5-1-8
2-7-9-3	2-1-6-9
4-1-8-6-9	9-4-1-7-5
6-9-7-3-8-2	4-2-7-9-3-8

List F	
Trial 1	**Trial 2**
2-7-1	4-7-9
1-6-8-3	3-9-2-4
2-4-7-5-8	8-3-9-6-4
5-8-6-2-4-9	3-1-7-8-2-6

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MACE 2 - Military Acute Concussion Evaluation

COGNITIVE EXAM - Continued

15. Concentration - Continued

B. Months in Reverse Order

Script: Read the script exactly as written.

- *"Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say: December, November…Go ahead."*

Correct Response:

Dec – Nov – Oct – Sep – Aug – Jul – Jun – May – Apr – Mar – Feb – Jan

	Incorrect	Correct
ALL months in reverse order	0	1

MONTHS IN REVERSE ORDER (16B) ___/1

CONCENTRATION TOTAL SCORE ___/5
Sum of scores:
15A (0-4 points) and 15B (0 or 1 point)

16. Delayed Recall

Read the script and circle the response for each word. Do NOT repeat the word list.
Note: Use the same list (A-F) that was used in Question 6.

Script: Read the script exactly as written.

- *"Do you remember that list of words I read a few minutes earlier? I want you to tell me as many words from that list as you can remember. You can say them in any order."*

List A	Incorrect	Correct
Jacket	0	1
Arrow	0	1
Pepper	0	1
Cotton	0	1
Movie	0	1

DELAYED RECALL TOTAL SCORE ___/5

Delayed Recall Alternate Word Lists

List B	List C	List D	List E	List F
Dollar	Finger	Baby	Candle	Elbow
Honey	Penny	Monkey	Paper	Apple
Mirror	Blanket	Perfume	Sugar	Carpet
Saddle	Lemon	Sunset	Sandwich	Saddle
Anchor	Insect	Iron	Wagon	Bubble

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MACE 2 - Military Acute Concussion Evaluation

17. Vestibular/Ocular-Motor Screening (VOMS) for Concussion Instructions

VOMS Contraindication: Unstable Cervical Spine.

Consider defering VOMS if patient is overtly symptomatic or a trained provider unavailable. VOMS should be completed before return to duty. Use comment section for any provider-observed difficulty with specific VOMS tasks.

A. **Baseline symptoms.** Record headache, dizziness, nausea and fogginess (HDNF), on zero to 10 scale prior to screening.

B. **Smooth pursuits**. Service member and examiner are seated. Hold fingertip three feet from patient. Service member focuses on fingertip target as examiner moves fingertip smoothly horizontally one and a half feet right and left of midline at rate requiring two seconds to go fully from left to right and right to left. Perform twice. Repeat in vertical direction one and a half feet above and one and a half feet below midline up and down, moving eyes two seconds fully up and two seconds down. Perform twice. Record HDNF on a zero to 10 scale.

C. **Saccades**. Service member and examiner are seated.

1) **Horizontal saccades:** Hold two fingertips horizontally at a distance of three feet from service member, and one and a half feet left and right of midline so service member gazes 30 degrees left and right. Service member moves eyes as quickly as possible from point to point. Perform 10 times. Record HDNF on a zero to 10 scale.

2) **Vertical saccades:** Repeat with two fingertips vertically three feet from service member, and one and a half feet above and below midline so service member gazes 30 degrees upward and downward. Service member moves eyes as quickly as possible from point to point. Perform 10 times. Record HDNF on a zero to 10 scale.

D. **Convergence**. Service member and provider are seated facing each other. Service member focuses on font target (page 14) at arm's length and slowly brings toward tip of nose. Service member stops target when two distinct images seen or when outward deviation of eye observed. Repeat and measure three times. Record centimeters between target and tip of nose for each trial. A near point of convergence ≥ five centimeters from the tip of the nose is considered abnormal. Record HDNF on a zero to 10 scale.

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MACE 2 - Military Acute Concussion Evaluation

17. Vestibular/Ocular-Motor Screening (VOMS) for Concussion Instructions (Continued)

E. Vestibular-ocular reflex (VOR) test. Service member and examiner are seated. Examiner holds font target (page 14) in front of service member in midline at three feet, rotation speed set with metronome.

1) **Horizontal VOR test:** Service member rotates head horizontally focusing on target at 20 degrees to each side. Rotation = 180 beats per minute (bpm). Perform 10 times. Record: HDNF 10 seconds after test.

2) **Vertical VOR test:** Repeat test moving head vertically 20 degrees up and down at 180 bpm. Perform 10 times. Record HDNF 10 seconds after test.

F .Visual motion sensitivity (VMS) test. Service member stands with feet shoulder width apart, facing a busy area. Examiner stands next to and slightly behind service member. Service member outstretches arm. Focusing on their thumb, the service member rotates head,eyes and trunk as unit 80 degrees right and left. Rotation = 50 bpm. Perform five times. Record HDNF on a zero to 10 scale.

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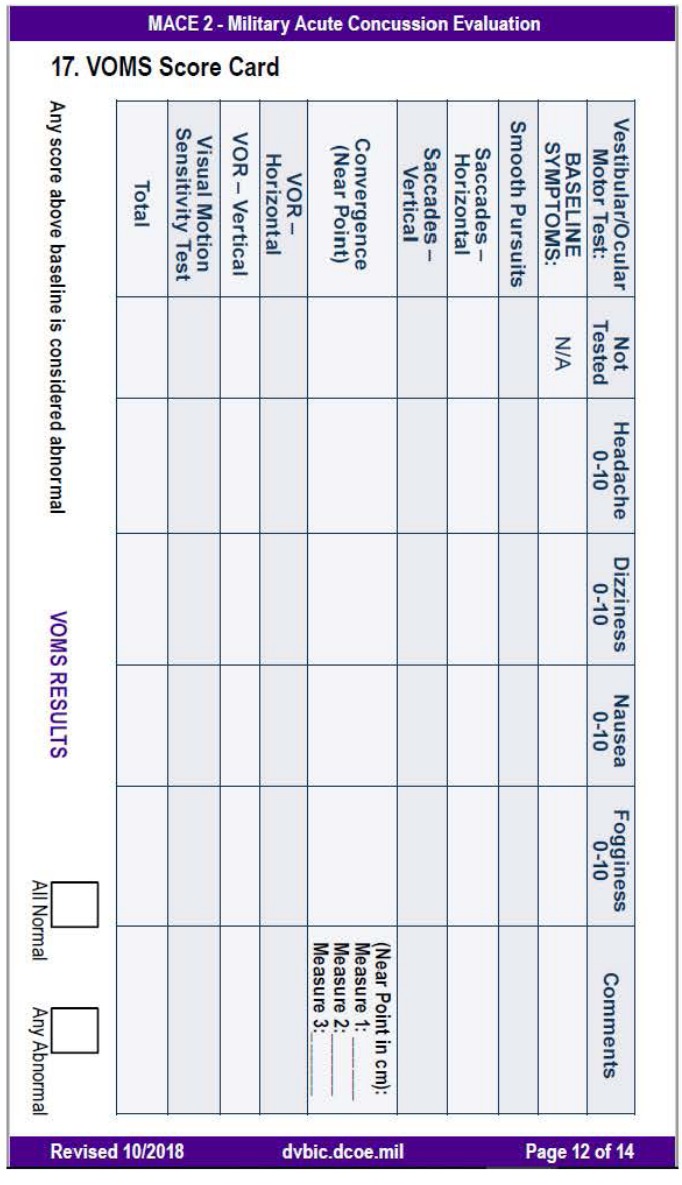

MACE 2 - Military Acute Concussion Evaluation

17. VOMS Score Card

Vestibular/Ocular Motor Test: BASELINE SYMPTOMS:	Not Tested N/A	Headache 0-10	Dizziness 0-10	Nausea 0-10	Fogginess 0-10	Comments
Smooth Pursuits						
Saccades – Horizontal						
Saccades – Vertical						
Convergence (Near Point)						(Near Point in cm): Measure 1: ____ Measure 2: ____ Measure 3: ____
VOR – Horizontal						
VOR – Vertical						
Visual Motion Sensitivity Test						
Total						

Any score above baseline is considered abnormal

VOMS RESULTS

All Normal ☐ Any Abnormal ☐

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MACE 2 - Military Acute Concussion Evaluation

EXAM SUMMARY

Record the data for correct MACE 2 documentation.

Cognitive Summary

Orientation Total Score - Q5	/5
Immediate Memory Total Score (all 3 trials) **- Q6**	/15
Concentration Total Score (Sections A and B) **- Q15**	/5
Delayed Recall Total Score - Q16	/5
COGNITIVE RESULTS ≤ 25 is abnormal	/30

NEUROLOGICAL RESULTS (Q 7-14)	☐ Abnormal (+)	☐ Normal (-)
SYMPTOM RESULTS (Q 3)	☐ 1 or more symptoms (+)	☐ No symptoms (-)
HISTORY RESULTS (Q 4A-4C)	☐ Positive (+)	☐ Negative (-)
VOMS RESULTS (Q 17) ☐ Abnormal (+)	☐ Normal (-)	☐ Deferred
MACE 2 RESULTS	☐ Positive (+)	☐ Negative (-)

AFTER COMPLETING MACE 2:

- ☐ Document MACE 2 results in the EHR with coding instructions.
- ☐ Initiate 24-hour rest.
- ☐ Refer to concussion management tool for the management recommendations based on MACE 2 results.
- ☐ After 24-hour rest period, evaluate for initiation into the Progressive Return to Activity (PRA) following the guidance of the PRA Clinical Recommendation.

Refer to Progressive Return to Activity Clinical Tool at dvbic.dcoe.mil/files/resources/2013_PRA_PCM_CST_FINAL.pdf

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MACE 2 - Military Acute Concussion Evaluation

VOMS Equipment Sample 14 point font: **A**

Centimeter Ruler

0 cm

5 cm

15 cm

TBI CODING INSTRUCTIONS

Initial TBI screening code*: Z13.850
TBI coding sequence:

1. **Primary TBI diagnostic code: S06. E L S E****
2. **Primary symptom code,** if applicable: (e.g., H53.2 - diplopia)
3. **Deployment status code,** if applicable:*** (e.g., Z56.82 for deployed or Z91.82 for history of military deployment)
4. **TBI external cause of morbidity code:** (For example, Y36.290A (A- use for initial visit) for war operations involving other explosions and fragments, military personnel, initial encounter)
5. Place of occurrence code, if applicable
6. **Activity code,** if applicable
7. **Personal History of TBI code:** if applicable Z87.820

* MACE 2
** Etiology, Location, Severity, Encounter
*** Deployment code must fall within the first four codes when applicable

For more information, see DVBIC ICD-10 Coding Guidance Tool.

References available at https://dvbic.dcoe.mil/material/military-acute-concussion-evaluation-2-mace-2-reference-list.

We are authorized to collect the information on this form and any supporting documentation, including social security numbers, under the Patient Protection and Affordable Care Act (Public Law No. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Public Law No. 111-152), and the Social Security Act.

THIS TOOL MAY BE COPIED FOR CLINICAL USE.

PUID 4901
Released: February 2012 | Revised October 2018
by Defense and Veterans Brain Injury Center.
This product is reviewed annually and is current until superseded.

Revised 10/2018 **dvbic.dcoe.mil** **Page 14 of 14**

Note: Page printing and scaling may impact the accuracy of the printed VOMS equipment (sample font and centimeter ruler).

Appendix 4: Sports Concussion Assessment Tool – 5th Edition (SCAT5)

The SCAT5 is a standardized tool for evaluating concussions designed for use by physicians and licensed healthcare professionals. The SCAT5 cannot be performed correctly in less than 10 minutes.
If you are not a physician or licensed healthcare professional, please use the Concussion Recognition Tool 5 (CRT5). The SCAT5 is to be used for evaluating athletes aged 13 years and older. For children aged 12 years or younger, please use the Child SCAT5.
Preseason SCAT5 baseline testing can be useful for interpreting post-injury test scores, but is not required for that purpose. Detailed instructions for use of the SCAT5 are provided on the following pages. Please read through these instructions carefully before testing the athlete. Brief verbal instructions for each test are given in italics. The only equipment required for the tester is a watch or timer.

Recognize and Remove

A head impact by either a direct blow or indirect transmission of force can be associated with a serious and potentially fatal brain injury. If there are significant concerns, including any of the red flags listed, then activation of emergency procedures and urgent transport to the nearest hospital should be arranged.

Key points

- Any athlete with suspected concussion should be REMOVED FROM PLAY, medically assessed and monitored for deterioration. No athlete diagnosed with concussion should be returned to play on the day of injury.
- If an athlete is suspected of having a concussion and medical personnel are not immediately available, the athlete should be referred to a medical facility for urgent assessment.
- Athletes with suspected concussion should not drink alcohol, use recreational drugs and should not drive a motor vehicle until cleared to do so by a medical professional.
- Concussion signs and symptoms evolve over time and it is important to consider repeat evaluation in the assessment of concussion.
- The diagnosis of a concussion is a clinical judgment, made by a medical professional. The SCAT5 should NOT be used by itself to make, or exclude, the diagnosis of concussion. An athlete may have a concussion even if their SCAT5 is "normal".

Remember

- The basic principles of first aid (danger, response, airway, breathing, circulation) should be followed.
- Do not attempt to move the athlete (other than that required for airway management) unless trained to do so.
- Assessment for a spinal cord injury is a critical part of the initial on field assessment.
- Do not remove a helmet or any other equipment unless trained to do so safely.

INSTRUCTIONS

Words in *Italics* throughout the SCAT5 are the instructions given to the athlete by the clinician

Symptom Scale

The time frame for symptoms should be based on the type of test being administered. At baseline it is advantageous to assess how an athlete "typically" feels whereas during the acute/post-acute stage it is best to ask how the athlete feels at the time of testing.

The symptom scale should be completed by the athlete, not by the examiner. In situations where the symptom scale is being completed after exercise, it should be done in a resting state, generally by approximating his/her resting heart rate.

For total number of symptoms, maximum possible is 22 except immediately post injury, if sleep item is omitted, which then creates a maximum of 21.

For Symptom severity score, add all scores in table, maximum possible is 22 x 6 = 132, except immediately post injury if sleep item is omitted, which then creates a maximum of 21x6=126.

Immediate Memory

The Immediate Memory component can be completed using the traditional 5-word per trial list or, optionally, using 10-words per trial. The literature suggests that the Immediate Memory has a notable ceiling effect when a 5-word list is used. In settings where this ceiling is prominent, the examiner may wish to make the task more difficult by incorporating two 5–word groups for a total of 10 words per trial. In this case, the maximum score per trial is 10 with a total trial maximum of 30.

Choose one of the word lists (either 5 or 10). Then perform 3 trials of immediate memory using this list.

Complete all 3 trials regardless of score on previous trials.

"I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order." The words must be read at a rate of one word per second.

Trials 2 & 3 MUST be completed regardless of score on trial 1 & 2.

Trials 2 & 3:

"I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Score 1 pt. for each correct response. Total score equals sum across all 3 trials. Do NOT inform the athlete that delayed recall will be tested.

Concentration

Digits backward

Choose one column of digits from lists A, B, C, D, E or F and administer those digits as follows:

Say: *"I am going to read a string of numbers and when I am done, you repeat them back to me in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7."*

Begin with first 3 digit string.

If correct, circle "Y" for correct and go to next string length. If incorrect, circle "N" for the first string length and read trial 2 in the same string length. One point possible for each string length. Stop after incorrect on both trials (2 N's) in a string length. The digits should be read at the rate of one per second.

Months in reverse order

"Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November ... Go ahead"

1 pt. for entire sequence correct

Delayed Recall

The delayed recall should be performed after 5 minutes have elapsed since the end of the Immediate Recall section.

"Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order."

Score 1 pt. for each correct response

Modified Balance Error Scoring System (mBESS)[5] testing

This balance testing is based on a modified version of the Balance Error Scoring System (BESS)[5]. A timing device is required for this testing.

Each of 20-second trial/stance is scored by counting the number of errors. The examiner will begin counting errors only after the athlete has assumed the proper start position. The modified BESS is calculated by adding one error point for each error during the three 20-second tests. The maximum number of errors for any single condition is 10. If the athlete commits multiple errors simultaneously, only one error is recorded but the athlete should quickly return to the testing position, and counting should resume once the athlete is set. Athletes that are unable to maintain the testing procedure for a minimum of five seconds at the start are assigned the highest possible score, ten, for that testing condition.

OPTION: For further assessment, the same 3 stances can be performed on a surface of medium density foam (e.g., approximately 50cm x 40cm x 6cm).

Balance testing – types of errors

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hip into > 30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position > 5 sec

"I am now going to test your balance. Please take your shoes off (if applicable), roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of three twenty second tests with different stances."

(a) Double leg stance:

"The first stance is standing with your feet together with your hands on your hips and with your eyes closed. You should try to maintain stability in that position for 20 seconds. I will be counting the number of times you move out of this position. I will start timing when you are set and have closed your eyes."

(b) Single leg stance:

"If you were to kick a ball, which foot would you use? [This will be the dominant foot] *Now stand on your non-dominant foot. The dominant leg should be held in approximately 30 degrees of hip flexion and 45 degrees of knee flexion. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."*

(c) Tandem stance:

"Now stand heel-to-toe with your non-dominant foot in back. Your weight should be evenly distributed across both feet. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Tandem Gait

Participants are instructed to stand with their feet together behind a starting line (the test is best done with footwear removed). Then, they walk in a forward direction as quickly and as accurately as possible along a 38mm wide (sports tape), 3 metre line with an alternate foot heel-to-toe gait ensuring that they approximate their heel and toe on each step. Once they cross the end of the 3m line, they turn 180 degrees and return to the starting point using the same gait. Athletes fail the test if they step off the line, have a separation between their heel and toe, or if they touch or grab the examiner or an object.

Finger to Nose

"I am going to test your coordination now. Please sit comfortably on the chair with your eyes open and your arm (either right or left) outstretched (shoulder flexed to 90 degrees and elbow and fingers extended), pointing in front of you. When I give a start signal, I would like you to perform five successive finger to nose repetitions using your index finger to touch the tip of the nose, and then return to the starting position, as quickly and as accurately as possible."

References

1. McCrory et al. Consensus Statement On Concussion In Sport – The 5th International Conference On Concussion In Sport Held In Berlin, October 2016. British Journal of Sports Medicine 2017 (available at www.bjsm.bmj.com)
2. Maddocks, DL; Dicker, GD; Saling, MM. The assessment of orientation following concussion in athletes. Clinical Journal of Sport Medicine 1995; 5: 32-33
3. Jennett, B., Bond, M. Assessment of outcome after severe brain damage: a practical scale. Lancet 1975; i: 480-484
4. McCrea M. Standardized mental status testing of acute concussion. Clinical Journal of Sport Medicine. 2001; 11: 176-181
5. Guskiewicz KM. Assessment of postural stability following sport-related concussion. Current Sports Medicine Reports. 2003; 2: 24-30

CONCUSSION INFORMATION

Any athlete suspected of having a concussion should be removed from play and seek medical evaluation.

Signs to watch for

Problems could arise over the first 24-48 hours. The athlete should not be left alone and must go to a hospital at once if they experience:

- Worsening headache
- Drowsiness or inability to be awakened
- Inability to recognize people or places
- Repeated vomiting
- Unusual behaviour or confusion or irritable
- Seizures (arms and legs jerk uncontrollably)
- Weakness or numbness in arms or legs
- Unsteadiness on their feet.
- Slurred speech

Consult your physician or licensed healthcare professional after a suspected concussion. Remember, it is better to be safe.

Rest & Rehabilitation

After a concussion, the athlete should have physical rest and relative cognitive rest for a few days to allow their symptoms to improve. In most cases, after no more than a few days of rest, the athlete should gradually increase their daily activity level as long as their symptoms do not worsen. Once the athlete is able to complete their usual daily activities without concussion-related symptoms, the second step of the return to play/sport progression can be started. The athlete should not return to play/sport until their concussion-related symptoms have resolved and the athlete has successfully returned to full school/learning activities.

When returning to play/sport, the athlete should follow a stepwise, **medically managed exercise progression, with increasing amounts of exercise.** For example:

Graduated Return to Sport Strategy

Exercise step	Functional exercise at each step	Goal of each step
1. Symptom-limited activity	Daily activities that do not provoke symptoms.	Gradual reintroduction of work/school activities.
2. Light aerobic exercise	Walking or stationary cycling at slow to medium pace. No resistance training.	Increase heart rate.
3. Sport-specific exercise	Running or skating drills. No head impact activities.	Add movement.
4. Non-contact training drills	Harder training drills, e.g., passing drills. May start progressive resistance training.	Exercise, coordination, and increased thinking.
5. Full contact practice	Following medical clearance, participate in normal training activities.	Restore confidence and assess functional skills by coaching staff.
6. Return to play/sport	Normal game play.	

In this example, it would be typical to have 24 hours (or longer) for each step of the progression. If any symptoms worsen while exercising, the athlete should go back to the previous step. Resistance training should be added only in the later stages (Stage 3 or 4 at the earliest).

Written clearance should be provided by a healthcare professional before return to play/sport as directed by local laws and regulations.

Graduated Return to School Strategy

Concussion may affect the ability to learn at school. The athlete may need to miss a few days of school after a concussion. When going back to school, some athletes may need to go back gradually and may need to have some changes made to their schedule so that concussion symptoms do not get worse. If a particular activity makes symptoms worse, then the athlete should stop that activity and rest until symptoms get better. To make sure that the athlete can get back to school without problems, it is important that the healthcare provider, parents, caregivers and teachers talk to each other so that everyone knows what the plan is for the athlete to go back to school.

Note: If mental activity does not cause any symptoms, the athlete may be able to skip step 2 and return to school part-time before doing school activities at home first.

Mental Activity	Activity at each step	Goal of each step
1. Daily activities that do not give the athlete symptoms	Typical activities that the athlete does during the day as long as they do not increase symptoms (e.g. reading, texting, screen time). Start with 5-15 minutes at a time and gradually build up.	Gradual return to typical activities.
2. School activities	Homework, reading or other cognitive activities outside of the classroom.	Increase tolerance to cognitive work.
3. Return to school part-time	Gradual introduction of school-work. May need to start with a partial school day or with increased breaks during the day.	Increase academic activities.
4. Return to school full-time	Gradually progress school activities until a full day can be tolerated.	Return to full academic activities and catch up on missed work.

If the athlete continues to have symptoms with mental activity, some other accomodations that can help with return to school may include:

- Starting school later, only going for half days, or going only to certain classes
- More time to finish assignments/tests
- Quiet room to finish assignments/tests
- Not going to noisy areas like the cafeteria, assembly halls, sporting events, music class, shop class, etc.
- Taking lots of breaks during class, homework, tests
- No more than one exam/day
- Shorter assignments
- Repetition/memory cues
- Use of a student helper/tutor
- Reassurance from teachers that the child will be supported while getting better

The athlete should not go back to sports until they are back to school/learning, without symptoms getting significantly worse and no longer needing any changes to their schedule.

Appendix 4 SCAT 5 Decision Rule

There are two versions of the SCAT5 available with BrainScope:

- Immediate or On-Field Assessment
- Office or Off-Field Assessment

The SCAT5 Office or Off-Field Assessment test sequence, will be available after the SCAT5 Immediate or On-Field Assessment test sequence.

For Immediate or On-Field Assessment see Figure A20-1; for Sideline and Office or Off-Field Assessment see Figure A20-2.

Figure A20-1 appears when the operator has not completed the Immediate or On-Field Assessment and the version in Figure A20-2 appears when the operator has completed the Immediate or On-Field Assessment.

To begin the SCAT5 from the Information Hub, tap START (Figure A20-1 or A20-2) next to the appropriate assessment and the handheld will navigate to SCAT5 Start (Figure A20-3 or A20-4).

NOTE: Scoring on the SCAT5 should not be used as a stand-alone method to diagnose concussion, measure recovery or make decisions about an athlete's readiness to return to competition after concussion. Since signs and symptoms may evolve over time, it is important to consider repeat evaluation in the acute assessment of concussion.

The "Date of Injury" field on the SCAT5 Immediate Assessment Start screen (Figure A20-3) will be populated with the date of injury entered in Patient Information. The "Date" field on the SCAT5 Office Assessment Start screen (Figure A20-4) will be populated with the current date.

The "Name", "DOB", and "ID Number" fields on both start screens will be pre-populated for the current session. The "Examiner" field is pre-populated, but editable.

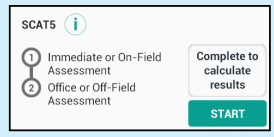


Figure A20-1: Start SCAT5

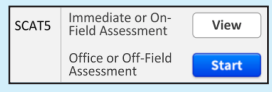


Figure A20-2: Start SCAT5 After Immediate Assessment

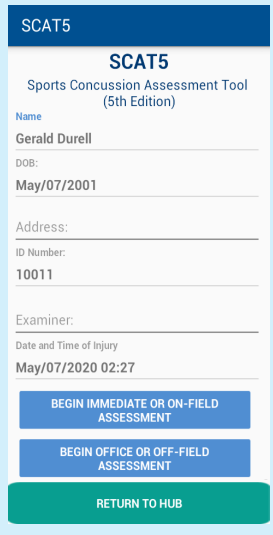


Figure A20-3:Start SCAT5-Immediate Assessment

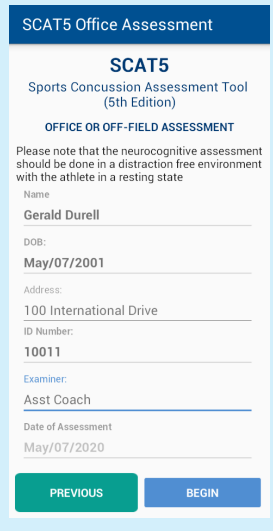


Figure A20-4: Start SCAT5 - Office Assessment

SCAT5 - Immediate or On-Field Assessment

Tap START from the SCAT5 Immediate Assessment Start screen to navigate to a screen with the following instructions:

> "The following elements should be assessed for all athletes who are suspected of having a concussion prior to proceeding to the neurocognitive assessment and ideally should be done on field after the first first aid / emergency care priorities are completed.
>
> If any of the "Red Flags" or observable signs are noted after a direct or indirect blow to the head, the athlete should be immediately and safely removed from participation and evaluated by a physician or licensed healthcare professional.
>
> Consideration of transportation to a medical facility should be at the discretion of the physician or licensed healthcare professional.
>
> The GCS is important as a standard measure for all patients and can be done serially if necessary in the event of deterioration in conscious state. The Maddocks questions and cervical spine exam are critical steps of the immediate assessment; however, these do not need to be done serially."

Tap NEXT to navigate to the SCAT5 Immediate Assessment Red Flags (Figure A20-5)

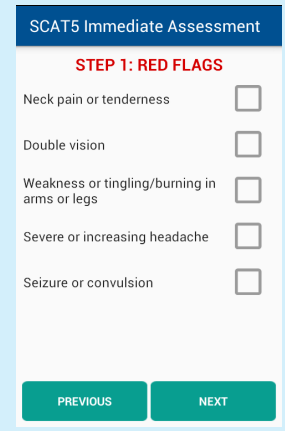


Figure A20-5: Immediate Assessment Red Flags

Red Flags:

- Neck pain or tenderness
- Double vision
- Weakness or tingling/burning in arms or legs
- Severe or increasing headache
- Seizure or convulsion
- Loss of consciousness
- Deteriorating conscious state
- Vomiting
- Increasingly restless, agitated or combative

Tap NEXT to navigate to SCAT5 Observable Signs 1 and 2 (Figure A20-6).

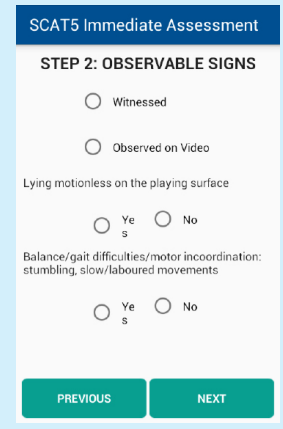


Figure A20-6: Immediate Assessment Observable Signs

The SCAT5 Observable Signs 1 and 2 screens contain a series of questions to identify the potential signs of a concussion. The questions will cover the following signs:

- Lying motionless on the playing surface
- Balance / gait difficulties / motor incoordination: stumbling, slow / laboured movements

- Disorientation or confusion, or an inability to respond appropriately to questions
- Blank or vacant look
- Facial injury after head trauma

Tap NEXT to navigate to SCAT5 Immediate Assessment Maddocks.

The SCAT5 Immediate Assessment Maddocks - Memory Assessment (1) (Figure A20-7) will provide a text box to record the patient's memory of the event. The following instructions will be provided to read to the patient:

> "I am going to ask you a few questions, please listen carefully and give your best effort. First, tell me what happened?"

Record the response in the text box using the onscreen keyboard.

Tap NEXT to navigate to SCAT5 Immediate Assessment Maddocks - Memory Assessment (2) (Figure A20-8).

To record the subject's response tap either INCORRECT or CORRECT to the answer they provided and move on to the next question. Repeat these steps for all questions on the SCAT5 Immediate Assessment Maddocks - Memory Assessment (2). Tap NEXT to navigate to SCAT5 Immediate Assessment GCS screen.

SCAT5 Immediate Assessment GCS (Figure A20-9) contains three drop-down menus to record responses for the following:

- Best eye response (E)
- Best verbal response (V)
- Best motor response (M)

For Best eye response (E) the following options are available to select from in the drop-down menu:

1 – No eye opening
2 – Eye opening in response to pain
3 – Eye opening to speech
4 – Eye opening spontaneously

For Best verbal response (V) the following options are available to select from in the drop-down menu:

1 – No verbal response
2 – Incomprehensible sounds
3 – Inappropriate words
4 – Confused
5 – Oriented

For Best motor response (M) the following options are available to

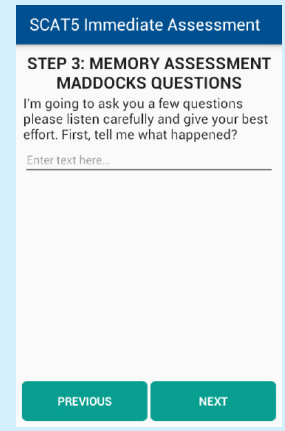


Figure A20-7: Immediate Assessment Maddocks- Memory Assessment (1)

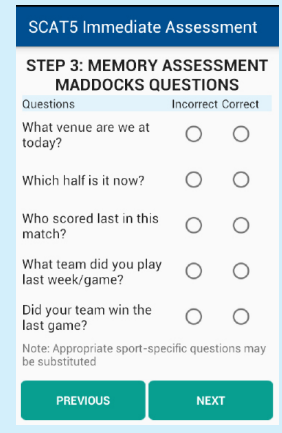


Figure A20-8: Immediate Assessment Maddocks - Memory Assessment (2)

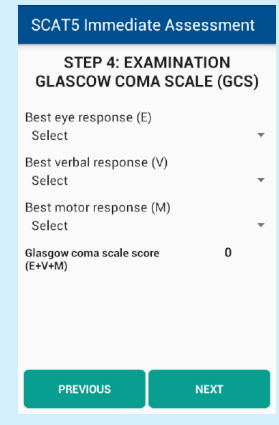


Figure A20-9: Immediate Assessment GCS

select from in the drop-down menu:

1 – No motor response
2 – Extension to pain
3 – Abnormal flexion to pain
4 – Flexion/Withdrawal to pain
5 – Localizes to pain
6 – Obeys commands

Once the options for each response have been recorded the SCAT5 Immediate Assessment GCS will display the Glasgow Coma Scale score (E+V+M) at the bottom of the screen (Figure A20-9).

Tap NEXT to navigate to the SCAT5 Immediate Assessment Cervical Spine (Figure A20-10).

To record the response tap either YES or NO and move on to the next question. Repeat these steps for all questions on the SCAT5 Immediate Assessment Cervical Spine. Tap NEXT to navigate to SCAT5 Immediate Assessment Summary (Figure A20-11).

On the SCAT5 Immediate Assessment Summary review the results and tap CONFIRM to return to the Information Hub screen. To view the SCAT5 Immediate Assessment results tap VIEW from the Information Hub (Figure A20-12).

SCAT5 - Office or Off-Field Assessment

To begin the SCAT5 Office or Off Field Assessment from the Information Hub, tap START (Figure A20-2) and the handheld will navigate to SCAT5 Office Assessment Start (Figure A20-4).

NOTE: The neurocognitive assessment should be done in a distraction-free environment with the athlete in a resting state.

Tap START from the SCAT5 Office Assessment Start screen to navigate to the SCAT5 Office Assessment Athlete Background 1 through 3 screens (Figure A20-12).

The SCAT5 Office Assessment Athlete Background 1 through 3 provide a series of questions on the subjects background. Enter information using either the onscreen keyboard or by taping the appropriate checkbox. At the end of the SCAT5 Office Assessment Athlete Background tap NEXT to navigate to the SCAT5 Office Assessment Symptoms 1 through 9 screens.
The SCAT5 Office Assessment Symptoms 1 screen (Figure A20-

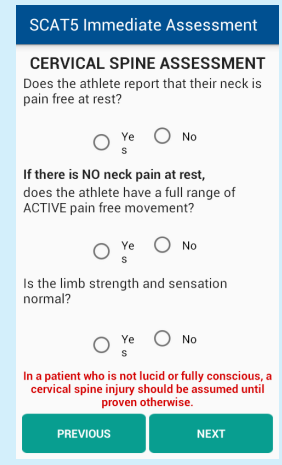


Figure A20-10: Immediate Assessment Cervical Spine

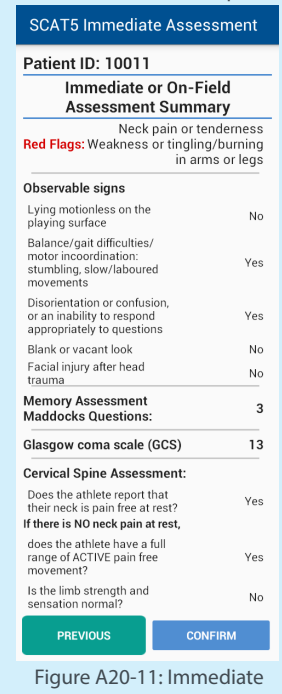


Figure A20-11: Immediate Assessment Summary

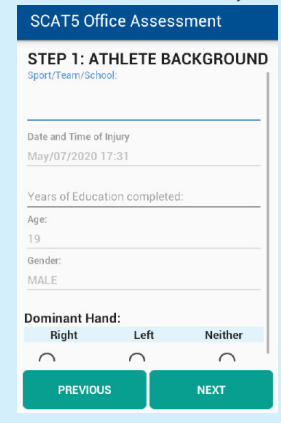


Figure A20-12: Assessment Athlete Background 1

13) provides instructions for the symptoms evaluation. Check either Baseline or Post-injury, tap NEXT and then hand the device to the subject.

The SCAT5 Office Assessment Symptoms 2 through 9 screens (Figure A20-14) shows an example of one of the screens) will run through a series of symptoms comparing the symptoms to before the accident and rating each symptom by severity on a scale of 0-6 with the following labels:

- 0 – Absent
- 1, 2 – Mild
- 3, 4 – Moderate
- 5, 6 – Severe

Once the last response has been recorded tap NEXT to advance to the SCAT5 Office Assessment Symptoms Summary (Figure A20-15).

The SCAT5 Office Assessment Symptoms Summary will display the total number of symptoms recorded and the symptom severity score.

The SCAT5 Office Assessment Symptoms Summary allows for the operator to answer two questions to record whether the symptoms get worse with physical or mental activity.

The SCAT5 Office Assessment Symptoms Summary allows for the operator to ask the subject the following:

> "If 100% is feeling perfectly normal, what percent of normal do you feel?"

If the subject replied, not 100%, ask the subject why and record it using the onscreen keyboard.

Tap NEXT to navigate to SCAT5 Office Assessment Cognitive Screening.
The SCAT5 Cognitive Evaluation includes a cognitive assessment of

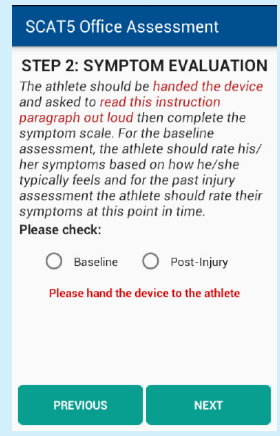


Figure A20-13: Office Assessment Symptoms 1

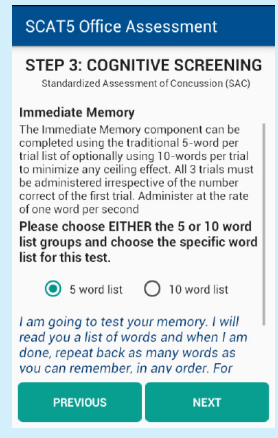


Figure A20-14: Office Assessment Symptoms 2

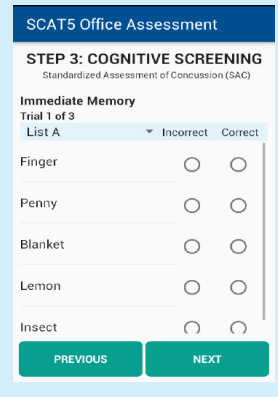


Figure A20-15: SCAT3 Office Assessment Symptoms Summary

the following areas:

- Orientation
- Immediate Memory
- Concentration

The SCAT5 Office Assessment Orientation (Figure A20-16) consists of a series of questions to determine the subject's ability to identify time accurately.

Tap NEXT to navigate to the SCAT5 Office Assessment Immediate Memory screens.

NOTE: The Immediate Memory component can be completed using the traditional 5-word per trial list or optionally using 10-words per trial to minimize any ceiling effect. All 3 trials must be administered irrespective of the number correct on the first trial. Administer at the rate of one word per second.

Please choose either the 5 or 10 word list groups.

The SCAT5 Office Assessment Immediate Memory 1 (Figure A20-17) will contain the following instructions for the operator to read to the subject:

> "I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order. For Trials 2 & 3: I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Press NEXT to navigate to the SCAT5 Office Assessment Immediate Memory 2 screen (Figure A20-18 and A20-19).

The SCAT5 Office Assessment Immediate Memory 2 contains ether a 5 word list, five pairs (ten total) of checkboxes, or a 10 word list, 10 pairs (20 total) of checkboxes, with each pair displayed next to a test word defined by the selected list.

On the SCAT5 Office Assessment Immediate Memory 2, tap SWAP to switch to a different list. The current list will be displayed next to the SWAP button; e.g. "List A", "List B" or "List C". Each time SWAP is selected, the display for the List column title shall cycle from "List A" through "List F" (5 word list) or "List H" through "List J" (10 word list), and then back to either "List A" or "List H".
The SCAT5 Office Assessment Immediate Memory 2 uses the test

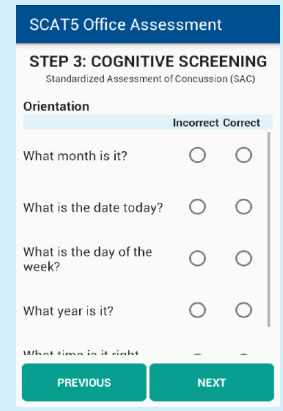


Figure A20-16: Orientation

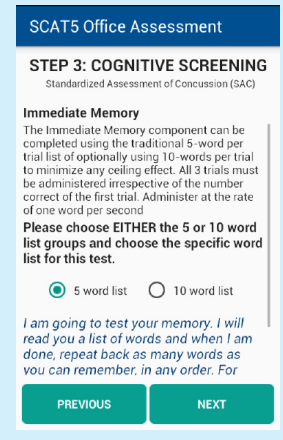


Figure A20-17: Office Assessment Immediate Memory 1

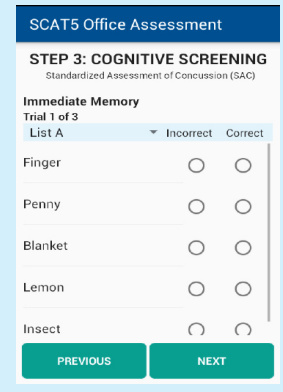


Figure A20-18: Office Assessment Immediate Memory 2 (5 word list)

words for each list as defined in the table below:
The SCAT5 Office Assessment Immediate Memory 3 navigates to

List Name	Ordered Test Words
List A	Finger, Penny, Blanket, Lemon, Insect
List B	Candle, Paper, Sugar, Sandwich, Wagon
List C	Baby, Monkey, Perfume, Sunset, Iron
List D	Elbow, Apple, Carpet, Saddle, Bubble
List E	Jacket, Arrow, Pepper, Cotton, Movie
List F	Dollar, Honey, Mirror, Saddle, Anchor
List H (10 word list)	Finger, Penny, Blank, Lemon, Insect, Candle, Paper, Sugar, Sandwich, Wagon
List I (10 word list)	Baby, Monkey, Perfume, Sunset, Iron, Elbow, Apple, Carpet, Saddle, Bubble
List J (10 word list)	Jacket, Arrow, Pepper, Cotton, Movie, Dollar, Honey, Mirror, Saddle, Anchor

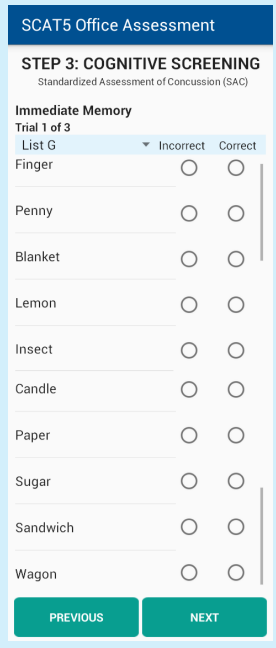


Figure A20-19:
Office Assessment Immediate Memory 2 (10 word list)

Trial 2 of 3 and SCAT5 Office Assessment Immediate Memory 4 navigates to Trial 3 of 3.

At the end of Trial 3, on both the 5 and 10 word list, a text box is available to enter Time the last trial was completed. Enter the time and tap NEXT to navigate to the SCAT5 Concentration section.

The SCAT5 Office Assessment Digits Backwards 1 (Figure A20-20) will contain the following instructions for the operator to read to the subject.

> "I am going to read a string of numbers and when I am done, you repeat them back to me in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7."

NOTE: If subject answers correctly, go to next string length. If incorrect, read trial 2. 1 pt. possible for each string length. Stop after incorrect on both trials. The digits should be read at the rate of one per second.

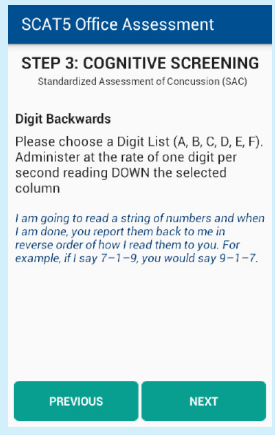


Figure A20-20:
Office Assessment Digits Backwards 1

The SCAT5 Office Assessment Digits Backwards 2 (Figure A20-21)

will contain columns for "Trial 1", "Trial 2" and the answer ("Y" or "N").

The SCAT5 Office Assessment Digits Backwards 2 uses the test numbers for each list as defined in the table below:
Tap NEXT to navigate to SCAT5 Office Assessment Months in

List	Trial 1	Trial 2
List A	4-9-3, 3-8-1-4, 6-2-9-7-1, 7-1-8-4-6-2	6-2-9, 3-2-7-9, 1-5-2-8-6, 5-3-9-1-4-8
List B	5-2-6, 1-7-9-5, 3-8-5-2-7, 8-3-1-9-6-4	4-1-5, 4-9-6-8, 6-1-8-4-3, 7-2-7-8-5-6
List C	1-4-2 6-8-3-1 4-9-1-5-3 3-7-6-5-1-9	6-5-8 3-4-8-1 6-8-2-5-1 9-2-6-5-1-4
List D	7-8-2 4-1-8-3 1-7-9-2-6 2-6-4-8-1-7	9-2-6 9-7-2-3 4-1-7-5-2 8-4-1-9-3-5
List E	3-8-2 2-7-9-3 4-1-8-6-9 6-9-7-3-8-2	5-1-8 2-1-6-9 9-4-1-7-5 4-2-7-9-3-8
List F	2-7-1 1-6-8-3 2-4-7-5-8 5-8-6-2-4-9	4-7-9 3-9-2-4 8-3-9-6-4 3-1-7-8-2-6

Reverse.

SCAT5 Office Assessment Months in Reverse (Figure A20-22) contains the following information to be read by the operator to the subject:

> "Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November. Go ahead."

Tap the checkbox with 0 for incorrect answer and 1 for correct answer. Tap NEXT to navigate to the SCAT5 Neurological Screen sections.
Neurological Screen

Figure A20-21: Office Assessment Digits Backwards 2

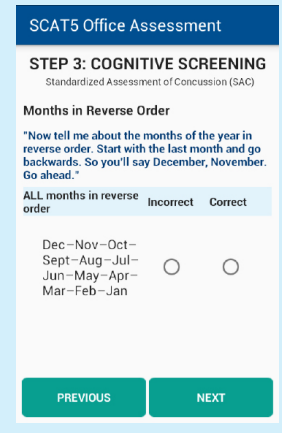


Figure A20-22: Office Assessment Months in Reverse

The SCAT5 Office Assessment Neurological Screen Questionnaire (Figure A20-23) presents a series of questions to ask the patient - reading skills, range of motion, eye movement, finger nose coordination and tandem gait performance ability. Record the results in the "Y" or "N" column. Tap NEXT to navigate to SCAT5 Office Assessment mBESS 1.

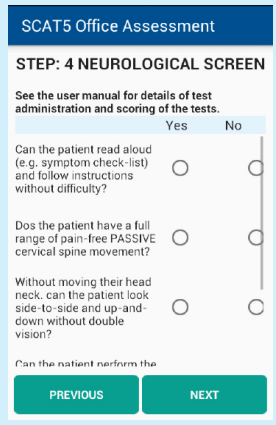


Figure A20-23: Office Assessment Neurological Screen Questionnaire

The SCAT5 Office Assessment mBESS 1 (Figure A20-24) allows for entry of the following conditions:

1. Testing foot (left or right)
2. Testing surface (hard floor, field, etc.)
3. Type of footwear

Tap NEXT to navigate to SCAT5 Office Assessment mBESS 2.

SCAT5 Office Assessment mBESS 2 displays types of errors and a statement to be read to the patient.

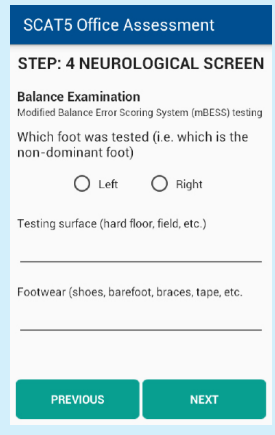


Figure A20-24:
Office Assessment mBESS 1

Balance testing – types of errors

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hip into > 30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position > 5 sec

Instructions to be read to the patient:

> "I am now going to test your balance. Please take your shoes off (if applicable), roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of three twenty second tests with different stances."

Press NEXT to navigate to SCAT5 Office Assessment mBESS 3.

NOTE: Each of the 20-second trials is scored by

counting the errors, or deviations from the proper stance, accumulated by the athlete. The examiner will begin counting errors only after the individual has assumed the proper start position. The mBESS is calculated by adding one error point for each error during the three 20-second tests. The maximum total number of errors for any single condition is 10. If an athlete commits multiple errors simultaneously, only one error is recorded but the athlete should quickly return to the testing position, and counting should resume once subject is set. Subjects that are unable to maintain the testing procedure for a minimum of five seconds at the start are assigned the highest possible score, ten, for that testing condition.

NOTE: For all SCAT5 Balance Tests the following apply:

- Once START has been selected a timer will replace "Start" and count down from 20 seconds to 0 seconds (Figure A20-25)
- Once the timer has reached 0 seconds START will reappear and the test is complete.
- During the test tap the PLUS and MINUS to increase or decrease the number of errors that occur during the 20 second testing period. Errors recorded will appear in red above the PLUS and MINUS.
- Once a test is complete tap NEXT to proceed to the next stance test.
- At any time, tap PREVIOUS to navigate to the previous screen.

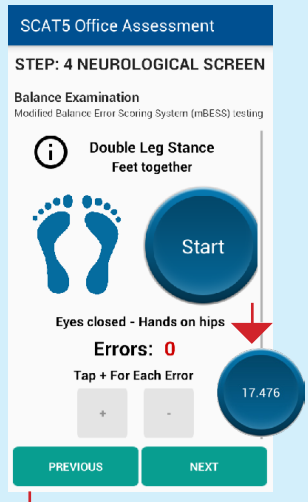


Figure A20-25: Start Button

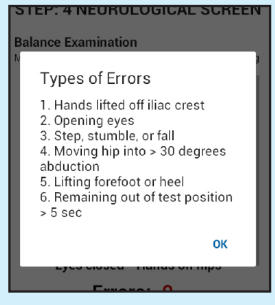


Figure A20-26: Information - Type of Errors

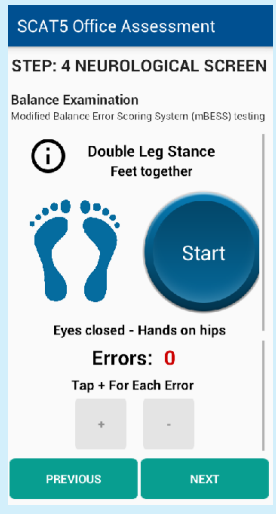


Figure A20-27: Office Assessment mBESS 4 Double Leg Stance

Double Leg Stance

SCAT5 Office Assessment mBESS 3 provides the following instructions on the screen that must be read to the subject prior to starting:

> "The first stance is standing with your feet together with your hands on your hips and with your eyes closed. You should try to maintain stability in that position for 20 seconds. I will be counting the number of times you move out of this position. I will start timing when you are set and have closed your eyes."

Confirm with the subject that they understand the instructions and tap NEXT to navigate to SCAT5 Office Assessment mBESS 4 (Figure A20-27).
Once the subject is in place, tap START on SCAT5 Office Assessment

mBESS 4 to begin testing. When completed, tap NEXT to navigate to the single leg stance assessment, SCAT5 Office Assessment mBESS 5.

Single Leg Stance

The following instructions will appear on the SCAT5 Office Assessment mBESS 5 screen and must be read to the subject prior to starting:

> "If you were to kick a ball, which foot would you use? [This will be the dominant foot] Now stand on your non-dominant foot. The dominant leg should be held in approximately 30 degrees of hip flexion and 45 degrees of knee flexion. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Confirm with the subject that they understand the instructions and tap NEXT to navigate to SCAT5 Office Assessment mBESS 6 (Figure A20-28).

Once the subject is in place, tap START. When completed, tap NEXT to navigate to the single leg stance assessment, SCAT5 Office Assessment mBESS 7.

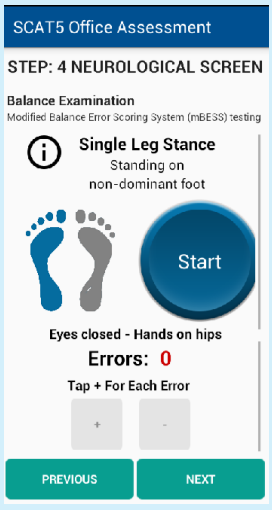


Figure A20-28:
Office Assessment mBESS 6 Single Leg Stance

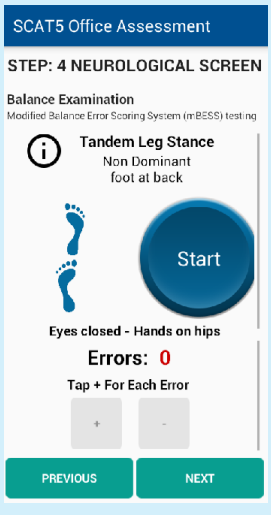


Figure A20-29:
Office Assessment mBESS 8 Tandem Leg Stance

Tandem Leg Stance

The following instructions will appear on the SCAT5 Office Assessment mBESS 7 screen and must be read to the subject prior to starting:

> "Now stand heel-to-toe with your non-dominant foot in back. Your weight should be evenly distributed across both feet. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Confirm with the subject that they understand the instructions and tap NEXT to navigate to SCAT5 Office Assessment mBESS 8.

Once the subject is in place, tap START. When completed, tap

NEXT to navigate to the delayed recall assessment, SCAT5 Office Assessment Delayed Recall (Figure A20-29).

Delayed Recall

The delayed recall should be performed after completion of the Balance Examination.

SCAT5 Office Assessment Delayed Recall (examples of 5 and 10 word lists, Figure A20-30 or A20-31) will navigate to the list that was completed in SCAT5 Office Assessment Immediate Memory 2 (5 or 10 word list).

SCAT5 Office Assessment Delayed Recall provides the following instructions that must be read to the subject prior to starting the delayed recall test:

> Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order.
>
> Score 1 pt. for each correct response

Record the time the test was started and check either the INCORRECT or CORRECT checkbox for the response.

Once the test is complete tap NEXT to proceed to the SCAT5 Office Assessment Decision 1 screen (Figure A20-32).
The SCAT5 Office Assessment Decision 1 screen (Figure A20-32)

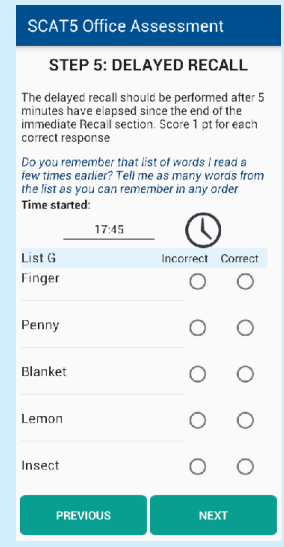


Figure A20-30:
Office Assessment Delayed Recall (5 word list)

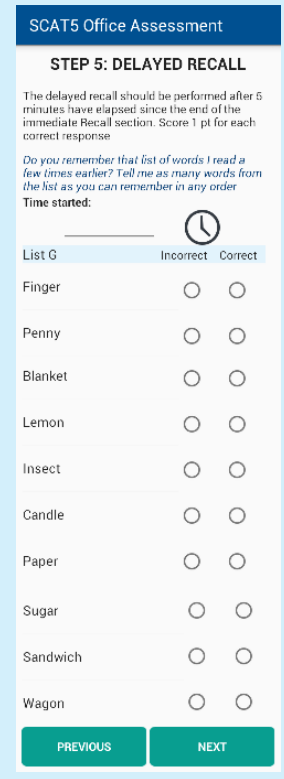


Figure A20-31:
Office Assessment Delayed Recall (10 word list)

will display results from each of the testing sections from the SCAT5.

Tap NEXT to navigate to the SCAT5 Office Assessment Decision 2 screen (Figure A20-33).

The SCAT5 Office Assessment Decision 2 screen provides a series of questions to be answered based on the operator's clinical decision.

Check the checkbox that best corresponds with the answer to the question and then tap NEXT to navigate to the SCAT5 Office Assessment Decision 3 screen (Figure A20-34).

On the SCAT5 Office Assessment Decision 3 screen use the onscreen keyboard to enter operator signature, name, title and registration number (if applicable).

NOTE: Scoring on the SCAT5 should not be used as a stand-alone method to diagnose concussion, measure recovery or make decisions about an athlete's readiness to return to competition after concussion.

Press NEXT to navigate to the SCAT5 Office Assessment Clinical Notes screen.

Using the onscreen keyboard, enter clinical notes about the assessment to be included with the results and available on the printed report.

Tap CONFIRM to navigate to the Information Hub screen.

At any time, tap PREVIOUS to navigate to the previous screen.
SCAT5 Detailed Results

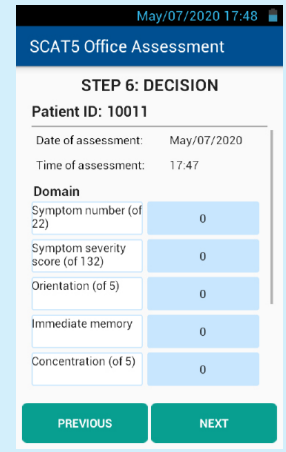


Figure A20-32: Office Assessment Decision 1

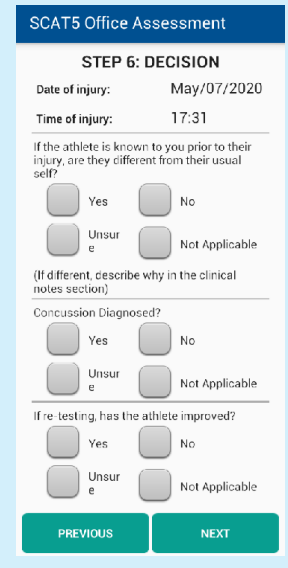


Figure A20-33: Office Assessment Decision 2

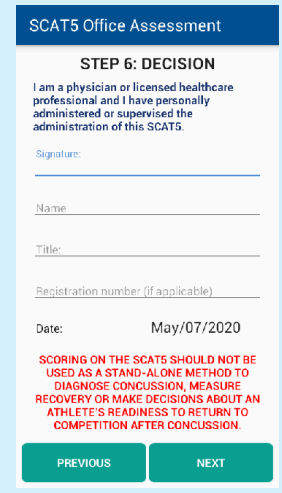


Figure A20-34: Office Assessment Decision 3

Detailed results on current and previous SCAT5 tests are stored in the database and can be accessed from the Information Hub screen.

Once a SCAT5 test session has been completed the SCAT5 scores will replace the START button next to the SCAT5 test on the Information Hub.

To access the SCAT5 Detailed Results screen do either of the following depending on what options are available:

1. Tap VIEW next to Immediate Assessment (Figure A20-35) from the Information Hub screen to view the detailed results of the Immediate Assessment testing.
2. Tap the score (Figure A20-36) from the Information Hub screen to view the detailed results of the Office Assessment testing.

NOTE: The SCAT5 Office Assessment Detailed Results will default to view the CURRENT TEST tab. The SCAT5 Immediate Assessment Detailed Results only display the current test. The SCAT5 Immediate Assessment can only be executed once whereas the SCAT5 Office Assessment can be executed several times.

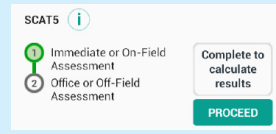


Figure A20-35:
SCAT5 After Immediate Assessment

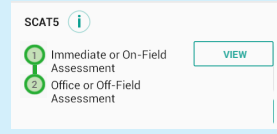


Figure A20-36:
SCAT5 After Both Immediate and Office Assessment

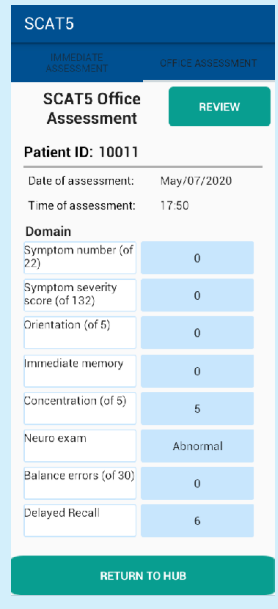


Figure A20-37:
Current Test Detailed Results for SCAT5 Office Assessment

Current Test Tab

The SCAT5 Office Assessment Current Test Detailed Results (Figure A20-37) displays a summary of the assessment results. The SCAT5 Office Assessment Current Test Detailed Results contains two options to select from:

- Review – access responses and results from the SCAT5 Office Assessment
- New Test – start a new test

Tap REVIEW to navigate to the review screens. An example of a SCAT5 Office Assessment Review screen is shown in Figure A20-38.

Tap CLOSE to return to the Information Hub.

NOTE: While reviewing patient information the screen header will contain "Review" to inform the operator that they are currently in review mode.

The SCAT5 Office Assessment Review screens will appear in the

exact order of the testing sequence.

At the end of the SCAT5 Office Assessment Review sequence (Figure A20-38) tap CONFIRM to return to the SCAT5 Office Assessment Current Test Detailed Results (Figure A20-37).

From SCAT5 Office Assessment Current Test Detailed Results (Figure A20-37) a new test can be started.

Tap NEW TEST to begin the SCAT5 test.

For instructions on completing a new SCAT5 test refer to the sections above.

Immediate or On field Assessment

SCAT5 Office Assessment Previous Summary tab (Figure A20-39) will appear displaying the test results for that selected test. To review the results tap REVIEW to navigate to the review screens. Review of the test results follow the same navigation sequence as the current test review screens.

For instructions on reviewing and starting a new test refer to the sections above.

Figure A20-38:
Example of a SCAT5 Office Assessment Review Screen

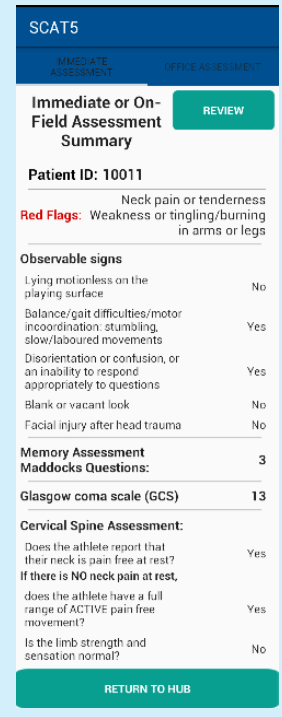


Figure A20-39:
Example of a SCAT5 immediate Summary

Appendix 5: Military Acute Concussion Evaluation 2 (MACE 2) Data Collection

The Military Acute Concussion Evaluation 2 (MACE 2) is a screening test designed for the acute evaluation of concussion developed by the Defense and Veterans Brain Injury Center (DVBIC). The test is currently the only standardized and most widely used method for evaluation of acute mild TBI (also referred to as concussion) in military operational settings.

The MACE 2 consists of 2 sections – History of Head Injury (Concussion Screening) and computerized version of the Standardized Assessment of Concussion (SAC) (Full Assessment). The sections consist of the following:

A. Description of the incident
B. Alteration of Consciousness or Memory
C. Cognitive Exam – Standardized Assessment of Concussion (SAC)

    a. Orientation
    b. Immediate Memory
    c. Neurological Screen
    d. Concentration
    e. Delayed Recall

There are two versions of the MACE available with the BrainScope:

- MACE Concussion Screening
- Full MACE 2 Exam

The Full MACE Exam test sequence will be available after the MACE Concussion Screening test sequence.

To begin a MACE assessment from the Information Hub, tap START (Figure A9-1 or A9-2) next to the appropriate assessment and the handheld will navigate to MACE Start (Figure A9-3).

The Full Mace Exam sequence, will be available after the MACE Concussion Screening test sequence.

For Concussion Screening see Figure A9-1; for Full Exam see Figure A9-2.

Figure A9-1 appears when the operator has not completed the Concussion Screening and Figure A9-2 appears when the operator has completed the Concussion Screening.

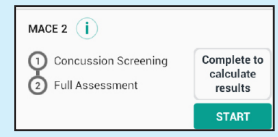


Figure A9-1:
MACE Start from the Information Hub

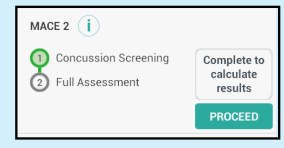


Figure A9-2:
MACE Full Assessment when Concussion Screening is completed

Concussion Screening

Tap START (Figure A9-1) and the handheld will navigate to the MACE Start (Figure A9-3a).

The Date and Time of Injury, Date and Time of Evaluation will be pre-populated from the entry in the Patient Information screens. Text entry fields are available for Service Member ID, Unit and Examiner. Tap START to navigate to the MACE RED FLAGS screen.

The MACE red flags provides the following instructions:

Evaluate for red flags in patients with Glasgow Coma Scale (GCS) 13-15, assessed from the following (figure A9-3b)

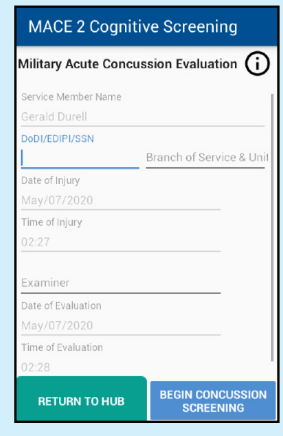


Figure A9-3a: MACE Start

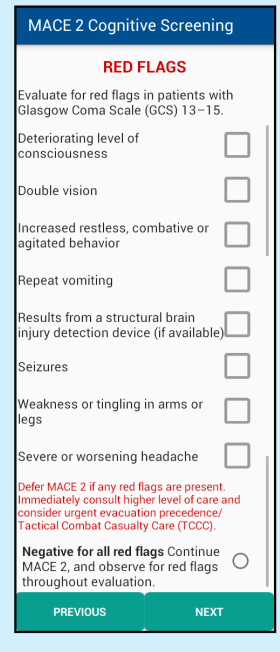
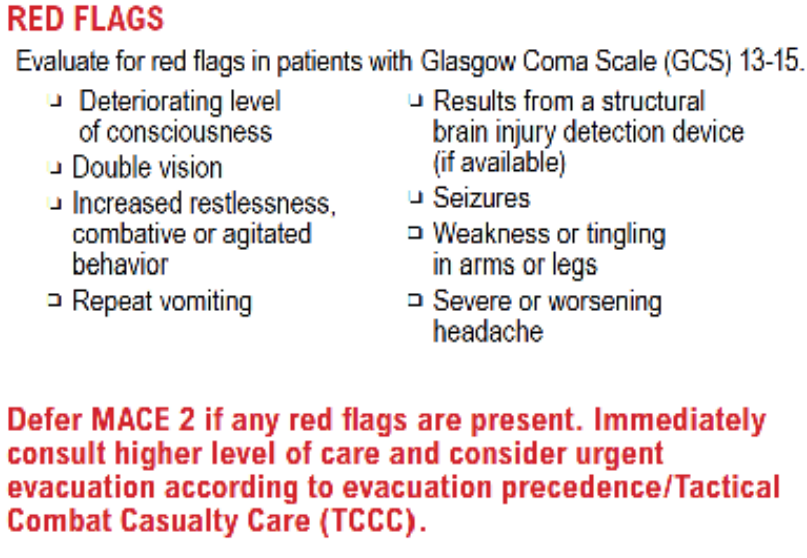


Figure A9-3b: Red Flags



The first section of the Concussion Screeing begins with description of the incident (an example of a screen in this section is provided in Figure A9-4a).

Ask the patient to describe memories of the incident and enter the text using the on-screen keyboard. Tap DONE on the on-screen keyboard when complete.

Fill out Observable signs, type of event & any jolt to the head as shown in screen A9-4b, A9-4c & A9-4d below

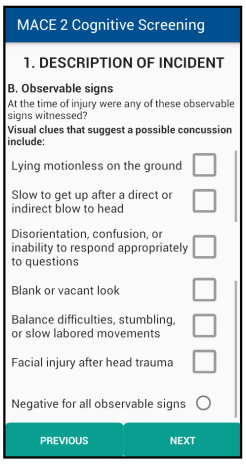


Figure A9-4b: MACE observable signs

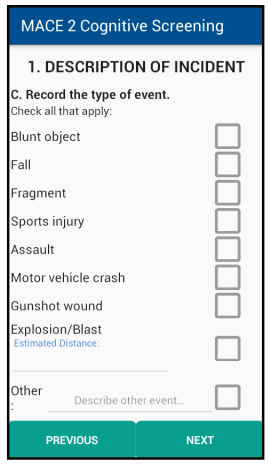


Figure A9-4c: MACE type of event

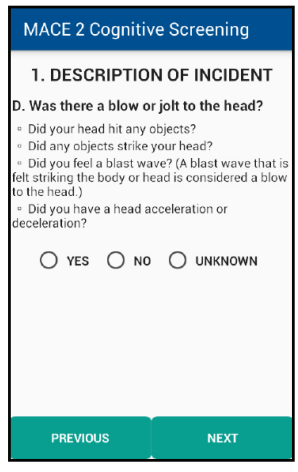


Figure A9-4d: MACE head jolt

Tap NEXT button to proceed into each sub section.

Record the type of event using a pre-populated list of possible causes. Select one or as many as applies. If you select OTHER enter a cause of injury not listed. Capture any details about head jolts. Tap NEXT to proceed to the next section.

NOTE: If a button is inadvertently selected, select the button again to unselect.

The next sections enable data collection of any amnesia, loss of consciousness, previous concussions and symptoms associated with the incident (an example of a screen in this section is provided in Figure A9-5).

Upon completion of the history of head injury section, tap NEXT to proceed with the viewing the Concussion Screening results.

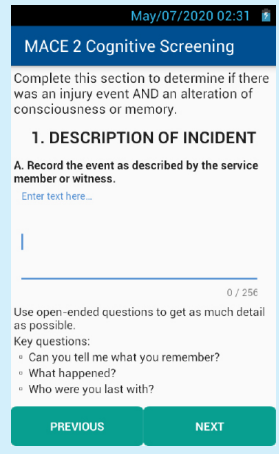


Figure A9-4a: MACE Description of Incident

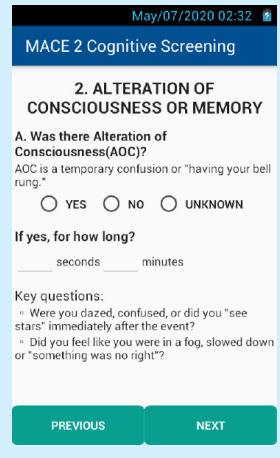


Figure A9-5: MACE Alteration of Consciousness or Memory (AOC/LOC/PTA)

There are three options for the MACE Concussion Screening Results.

1. Complete the Screening – The results are not complete
2. Continue with MACE – MACE results indicate need for further assessment
3. Stop MACE – MACE results indicate there is not a need for further assessment

If the Complete the Screening MACE Results screen is displayed (Figure A9-6) tap PREVIOUS to return to the previous pages and complete the screening. The results of the Concussion Screening have been found to be incomplete and will need to be completed prior to moving on with the full MACE exam, if available. The NEXT button will be grayed out.

Tap CONFIRM (Figure A9-7) to return to the Information Hub. The Full MACE Exam can then be started to complete the Cognitive, Neurological and Symptoms portions of the MACE. (Figure A9-2)

If the patient is not found to have an injury event and an alteration of consciousness based on the data entered by the operator, the Stop MACE Results screen will appear (Figure A9-8).

If the Stop MACE Results screen appears, tap CONFIRM to navigate back to the Information Hub.

To start Full assessment, tap on tab for Full Assessment, and tap on Begin Full Assessment as seen on figure A9-8b.

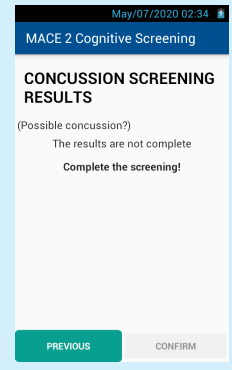


Figure A9-6:
Complete the Screening

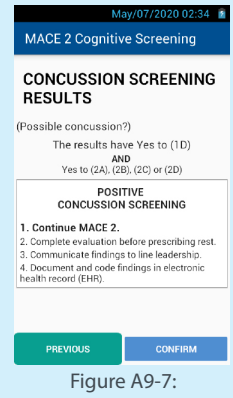


Figure A9-7:
Continue the MACE
(continue with full assessment)

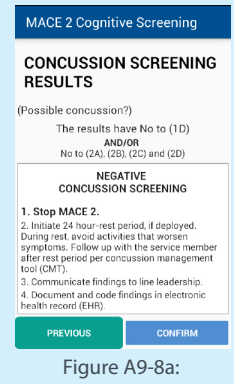


Figure A9-8a:
Stop the MACE

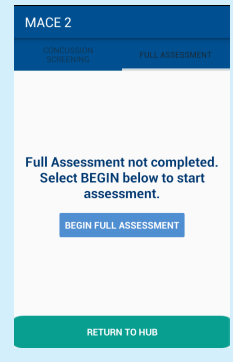


Figure A9-8b:
Full Assessment

Cognitive Assessment

The MACE 2 – Orientation provides information related to the current time of assessment. Ask the patient about the month, date, day of week, year and time and record each correct answer by selecting the corresponding button. (an example of a screen in this section is provided in Figure A9-9).

The Immediate Memory test assesses how well a list of five pre-populated words can be memorized.

From the MACE 2 – Immediate Memory, read the list of words and select the corresponding button when repeated back. After each exercise, tap NEXT to advance to the next trial. This exercise must be repeated three times to proceed (Trial 1 of 3, Trial 2 of 3, etc.) (an example of a screen in this section is provided in Figure A9-10)

Multiple lists of words exist (A-F) for subsequent testing at a later time. Tap List A/B/C/D/E from the dropdownto generate a new list of words if the patient was recently administered the A list, for example.

Complete a standard neurological screening examination and select NORMAL or ABNORMAL for speech fluency, word finding, grip strength, pronator drfit, signle leg stance, tandem gait, pupil response & eye tracking. (an example of a screen in this section is provided in Figure A9-11).

The Concentration test consists of numeric and verbal exercises (an example of a screen in this section is provided in Figure A9-12).
For the numeric exercise, read the list of numbers and ask the patient to repeat it in reverse order. If the patient correctly recalls the numbers in the correct sequence, select CORRECT; otherwise select INCORRECT. Selecting CORRECT will enable a new list with longer strings of numbers until the evaluation is complete. Selecting INCORRECT will enable a new list of numbers with the same degree of difficulty. If two consecutive evaluations are incorrect, the evaluation for this exercise is complete.

Tap SWAP to generate a new list of numbers if the patient was recently administered the A list, for example.

For this verbal exercise, ask the patient to recite the months of the year in reverse order. If this is completed accurately, select CORRECT; otherwise select INCORRECT. Tap NEXT.
Last, on the Delayed Recall screen (Figure A9-13), ask the patient to

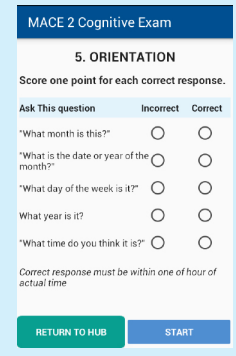


Figure A9-9:
MACE Orientation

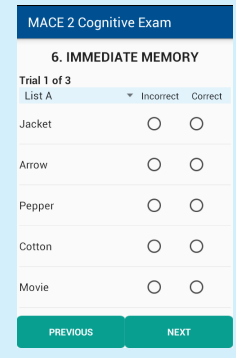


Figure A9-10:
MACE Immediate Memory

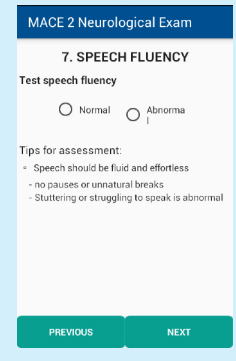


Figure A9-11:
MACE Standard
Neurological Screening

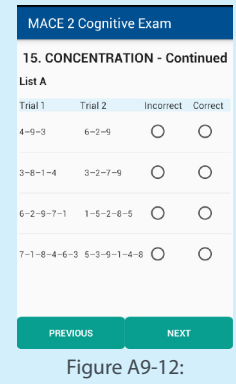


Figure A9-12:
MACE Concentration

recall the list of five words, introduced earlier during the test.

NOTE: Do not provide the list to the patient.

Select the word(s) that are repeated by selecting the corresponding button. Tap NEXT to proceed to the Symptom Screening.

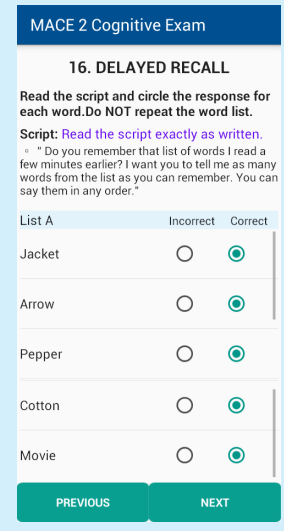


Figure A9-13:
MACE Delayed Recall

VOMS Symptom Screening

The MACE 2 – Vestibular Ocular Motor Symptom Screening (Figure A9-14a) provides information related to the patient's symptoms. Record the symptoms using a pre-populated list of possible symptoms (figure A9-14b). Select one or as many as applies. If you select OTHER enter a cause of injury not listed.

Capture baseline, Smooth pursuits, Horizontal Saccades, Vertical Saccades, Convergence, Visual Motion sensitivity. At the end you will see a VOMS score card (figure A9-14c)

Tap NEXT to proceed to the next section.

MACE 2 Summary Screen

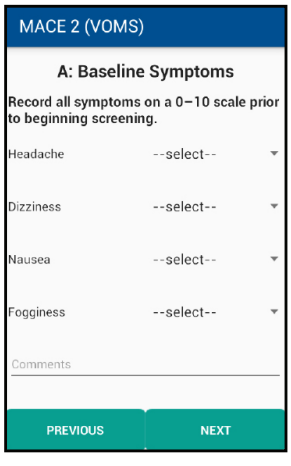


Figure A9-14b: MACE
Symptom Screening

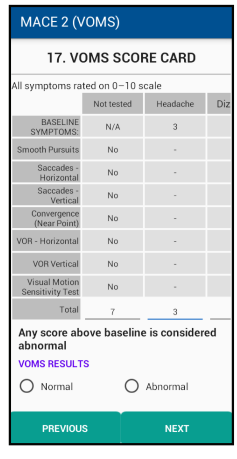


Figure A9-14c:
VOMS Score card

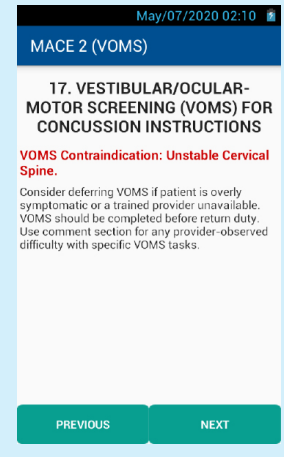


Figure A9-14a:
MACE Symptom Screening

Upon completion of all sections of the MACE 2, the results will appear (Figure A9-16).

The MACE 2 score, composed from the answers in the SAC section, ranges from 0 to 30. The maximum total score for orientation, concentration and delayed recall is 5 each and immediate memory is 15.

The Neurological Screening indicates Normal results in green and Abnormal results in red.

The Symptoms are rated "A"– no symptoms associated with injury, or "B" – symptoms associated with injury.

The MACE 2 Results located at the bottom of the screen is a summary of the Cognitive, Neurological and Symptoms sections of the test.

NOTE: Although cognitive is listed first in the summary of MACE 2 results, this should not suggest that any one of the three screening categories is more or less important than the others. Each area (Cognitive, Neurological, Symptoms) must be evaluated carefully. The results of all three evaluations must be included in any MACE 2 report for it to be considered complete. Regarding cognitive scores, in studies of non-concussed subjects, the mean total cognitive score was 28. Therefore, a score of < 30 does not imply that a concussion has occurred. Definitive normative data for a cut-off score are not available. The Concussion Management Algorithm stipulates that a cognitive score of < 25 or the presence of symptoms requires consultation with a provider.

For MACE 2 score interpretation, refer to the latest DVBIC mTBI/ Concussion Clinical Guidance, available at DVBIC website, http:// www.dvbic.org/

MACE Detailed Results

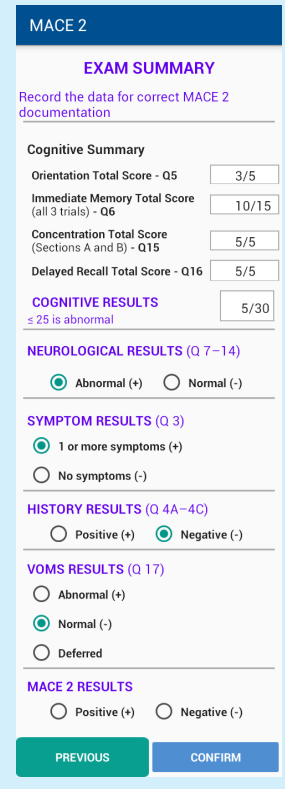


Figure A9-16:
MACE Summary

Detailed results on current and previous MACE tests are stored in the database and can be accessed from the Information Hub. In the detailed results screens the operator can review MACE 2 tests recorded.

To access the MACE Detailed Results, tap the Proceed button or View button (Figure A9-17 or Figure A9-18) from the Information Hub.

NOTE: The MACE Full Assessment Detailed Results will default to view the Consussion Screening tab. The MACE Concussion Screening Detailed Results (Figure A9-19) only display the current test.

Concussion Screening Tab

The MACE Full Assessment Current Test Detailed Results (Figure A9-19) contains two options to select from:

- Review – access responses and results for the entire MACE assessment
- Return to Hub

NOTE: While reviewing patient information the screen will only be in view mode, the operator cannot make any edits or changes.

Full Assessment Tab

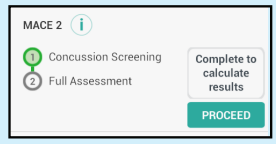


Figure A9-17:
MACE results area from the Information Hub when Concussion Screening Only has been completed

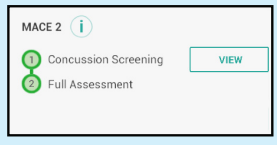


Figure A9-18:
MACE results area from the Information Hub when full assessment has been completed

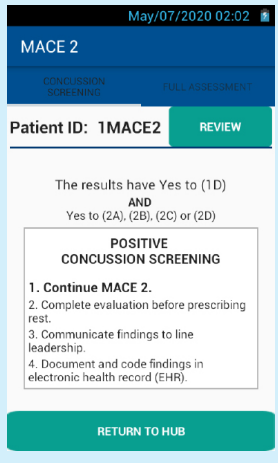


Figure A9-19:
Concussion screening

This tab show the cognitive assessment summary, congitive results, neurological results, symptom results, history and VOMS results and then MACE 2 overall results as seen in figure A9-20.
On this view, you can either

- Review all test data entry, by going into review mode
- Return to the infomation hub

Further, the text below also lists out some next steps and references.

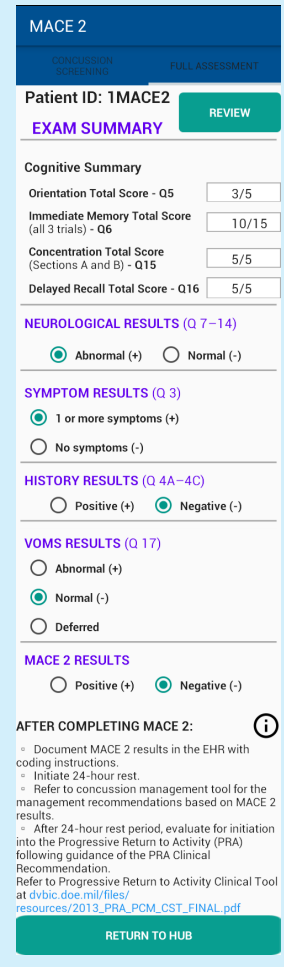


Figure A9-20:
Full Assessment view