BrainScope One User Manual

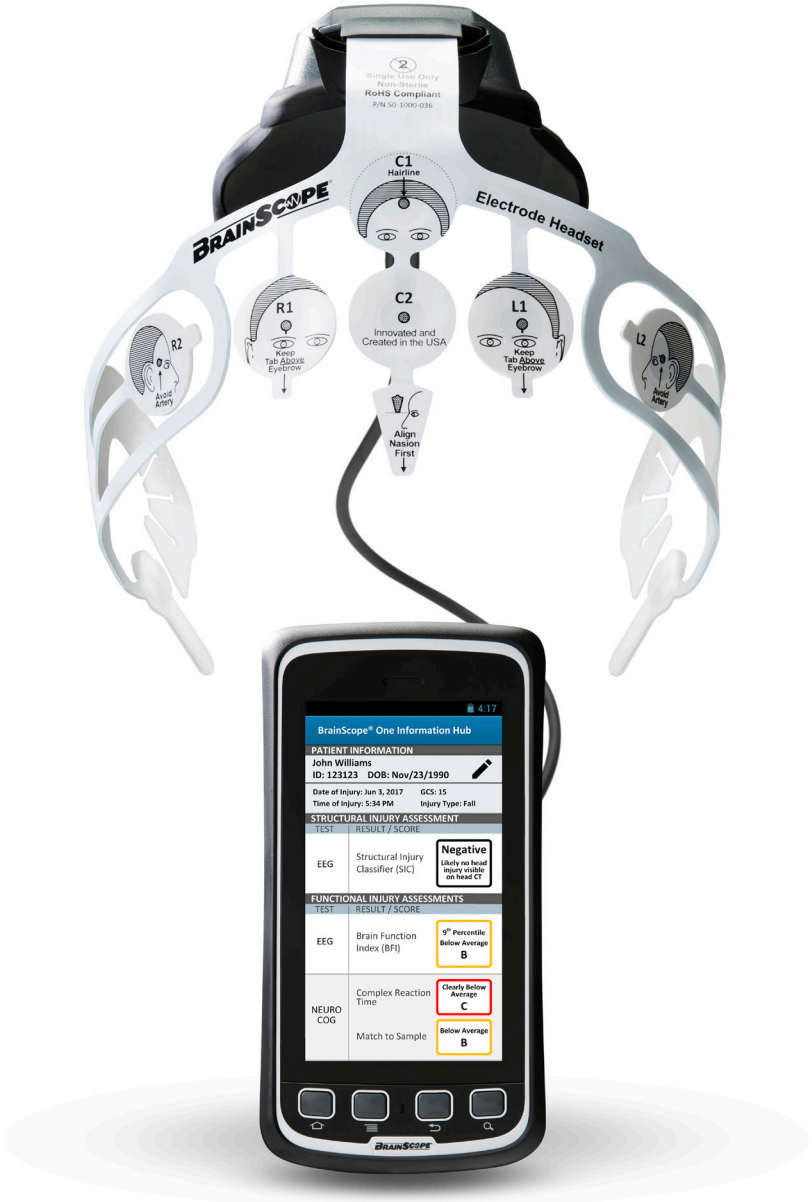
Rx ONLY

Revision: 020 Issued: April 2024

Author(s): Douglas Oberly Modified by: Sharad Baliyan

Supported Model : Ahead 300

SPC-00087



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 anyone 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 One 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® and Ahead® are registered trademarks of BrainScope Company, Inc., in the United States or other countries.

For a full list of US patents covering BrainScope One, visit www.brainscope.com/patents.

BrainScope®

Table of Contents

Appendices

CHAPTER 1: General Information

1.1 About this Manual

This user manual is designed to provide information on the proper use of BrainScope One, 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 One. 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 One

BrainScope One Head Injury Assessment Tools:

1. EEG (see Chapter 4 for detailed instructions)
   - Structural Injury Classifier (SIC)
   - Brain Function Index (BFI)
2. Cognitive Performance (see Appendix 1 for detailed instructions)
   - Complex Reaction Time (Procedural Reaction Time)
   - Match to Sample (Visuospatial Processing)
3. Vestibular / Occular Function* (See Appendix 19 for detailed instructions)
   - Vestibular/Ocular Motor Screening (VOMS)
   - Near Point Convergence
   - Accommodation
4. Vestibular / Balance* (see Appendix 3 for detailed instructions)
   - Balance Error Scoring System (BESS)
   - Modified Balance Error Scoring System (mBESS)
5. Standard Clinical Assessments* (see Appendix 4 through 18 and Appendix 20 for detailed instructions)
   - Concussion Symptom Inventory (CSI)
   - Graded Symptom Checklist (GSC)
   - Sport Concussion Assessment Tool 3 and 5 (SCAT3 & SCAT5)
   - NFL Sport Concussion Assessment Tool (NFL SCAT)
   - Standardized Assessment of Concussion (SAC)
   - Military Acute Concussion Evaluation (MACE)
   - Acute Concussion Evaluation (ACE)
     - Sports (ACE-Sports), Emergency Department (ACE-ED) and Physician / Clinician Office (ACE-PH)
   - Maddocks Memory Function (Maddocks)
   - Rivermead Post Concussion Questionnaire (Rivermead)

- Primary Care PTSD Screen (PC-PTSD)
- PTSD Checklist (PCL)
  - Civilian (PCL-C), Specific (PCL-S) and Military (PCL-M)

*BrainScope One may be configured to allow the user to select the standard clinical tools that meet their needs.

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 One Indications for Use

NOTE: BrainScope One was cleared by the U.S. Food and Drug Administration under the Trade/Device Name Ahead 300, K#161068. Subsequent clarification to Indications for Use regarding "concussion/mTBI" capabilities was cleared in May 2018 with K#181179

BrainScope One is indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who are being considered for a head CT, who sustained a closed head injury within 72 hours, present with a Glasgow Coma Scale score (GCS) of 13-15 (including concussion / mild Traumatic Brain Injury (mTBI)), and are between the ages of 18-85 years. BrainScope One should not be used as a substitute for a CT scan.

The BrainScope One 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.

BrainScope One 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.

A negative BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with no structural brain injury visible on head CT.

A positive BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with a structural brain injury visible on head CT.

An equivocal BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.

BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).

BrainScope One also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.

BrainScope One 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 One

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 One in patients with GCS scores less than 13 has not been established.

BrainScope One is a prescription use device.

Clinical decisions about patients will be made by medical professionals, and BrainScope One is an adjunct to standard clinical practice. Clinical judgment should always be used when interpreting the BrainScope One 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 One performance.

1.6 Intended Operators

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

1.7 Clinical Trial Summary (B-AHEAD III Trial)

The B-AHEAD III Trial was a multi-center, prospective clinical trial 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 trial 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 One 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 One device for the acute identification of structural brain injuries in an independent prospective TBI population, following closed head injury. In addition, the study aimed to extend findings of the B-AHEAD II Trial in a large population and replicated and extended the trial using BrainScope One 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 likely CT+ (CT-, Equivocal Zone, and CT+).

Results: The total number of completed cases subjects in this trial 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 between13-15.

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 Positive). 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 trial 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 and not associated with the device. 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.

1.8 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 One in patients with GCS scores less than 13 has not been established.
4. BrainScope One 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 One is an adjunct to standard clinical practice.
6. Clinical judgment should always be used when interpreting BrainScope One clinical results and the device should not be used as a stand-alone diagnostic device.
7. A positive BrainScope One Structural Injury Classification does not establish the presence of a structural brain injury visible on head CT, since a positive 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 One, take into consideration any medications that the patients may be taking.

WARNING!

10. As with any monitored physiological parameter, artifacts and poor signal quality may lead to inappropriate BrainScope One 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. If BFI only is configured and SIC disabled, information related to the likelihood of a structural injury will NOT be displayed. The BFI does 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 One.
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 One for uses other than specified by the Indications for Use.
18. DO NOT attach BrainScope One to the patient when connected to the USB-A Charger.
19. BrainScope One is powered by an internal lithium-ion battery. To prevent injury and/or property damage: do not expose BrainScope One 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 One 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). Heat transmission to the patient is reduced by ensuring the DAB jacket is in place during operation.
23. Never use the device without the DAB jacket attached to the base of the module.
24. Explosion Hazard: DO NOT use BrainScope One in a flammable atmosphere or where concentration of flammable anesthetics may occur.
25. To reduce the hazard of burns, DO NOT use BrainScope One with high-frequency surgical equipment.

WARNING!

26. Shock Hazard: DO NOT remove the device covers.
27. Shock Hazard: BrainScope One 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 One battery outdoors or in wet environments.
30. Routinely inspect system components for possible exposure to liquid.
31. BrainScope One 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 One 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.

1.9 User's Manual Conventions

In this User's Manual, the following conventions are used to explain operation of BrainScope One:

- Phrases in bold and all capital letters refer to **BUTTONS** on the handheld screen that should be pressed to execute a specific action.
  - Example: **SETUP** – takes you to the set up 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.

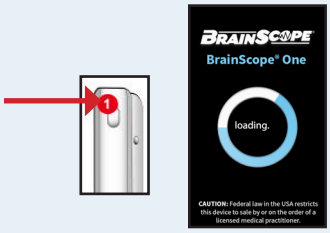
CHAPTER 2: Quick Start Guide

WARNING!
This "Quick Start Guide" is intended only as an operating checklist for users already familiar with BrainScope One. Do not proceed unless you have read the "Safety Summary" (Chapter 1 of this manual).

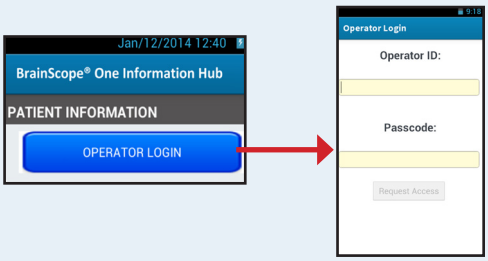
When you log in to the device you will be presented with the assessments configured by the Administrator. You are then able to perform the configured battery of assessments sequentially. You will be guided through a patient session by always starting at and returning to the ***BrainScope One Information Hub***. This process is described below:

NOTE:
- Only assessments configured in **TEST CONFIGURATION** will be accessible. See Section 3.5.2 for detailed instructions.
- If issues arise during device operation, see Chapter 7 of the manual for troubleshooting.

1. Power **ON** BrainScope One.

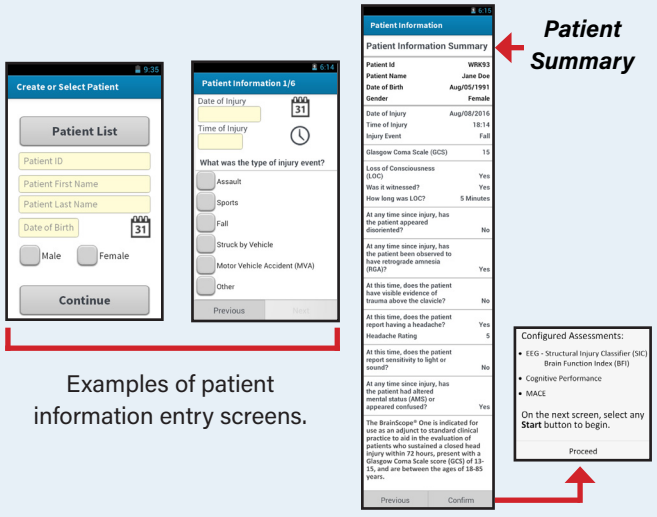


2. Perform ***Operator Authentication.***



3. Enter patient information and injury details. When all details have been entered, on the ***Patient Summary*** press **CONFIRM** that the information for that patient is accurate. The device will then provide a list of ***Configured Assessments***. Press **PROCEED** to return to the ***Information Hub*** to begin any of the configured assessments.

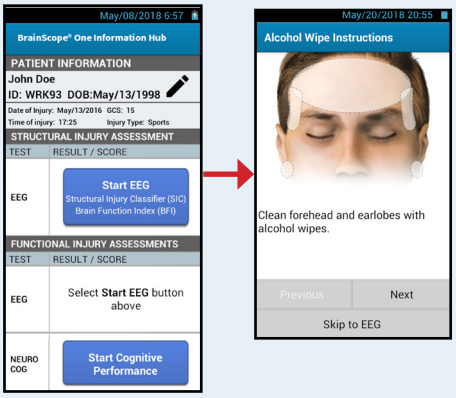
WARNING: Patient must be between 18-85 years of age, closed head injury within 72 hours, and GCS 13-15. Must read the questions and enter responses accurately.



Examples of patient information entry screens.

4. Press **START EEG** for the first assessment (in the figure on the right, the first assessment is performing the Structrucal Injury Assessment).

   The device will then provide onboard steps for preparing the patient for the headset. Press **NEXT** to follow the onboard steps or press **SKIP TO EEG** to proceed to impedance check.



5. Prep the forehead, temples and earlobes with the alcohol wipe and the skin prep pad included in the headset package.

   1) Clean the forehead, temples and earlobes with the alcohol wipe.

   2) Prep the forehead by using firm pressure and a steady wiping motion with the skin prep pad in an inverted **T** formation over the forehead, the temples and earlobes. Wipe the areas two times each with the skin prep pad.

6. Center headset and align the nasion tab properly. Apply the headset to the patient, starting from the center and working outwards toward the ears. Place ear loops behind each ear.

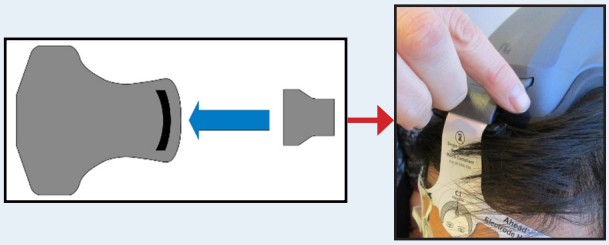
   NOTE: Remove electrode covers prior to placing electrodes.

7. Connect the headset to the DAB.

   Insert the headset straight and level into the device port unitl resistance is met.

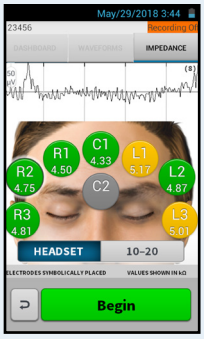
   - The headset will not click when inserted.
   - If neccessary, disconnect the headset in a straight outward path.
   - Avoid insertion or removal at any angle.

   Once the headset has been applied press **NEXT** to begin impedance testing.

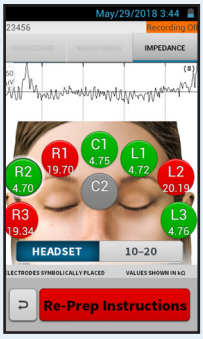


9. Check impedance values.

   - If yellow or green (< 10 kΩ), then press **BEGIN** to start recording.
   - If red (> 10 kΩ), then press **RE-PREP INSTRUCTIONS** to see steps to re-prep the area until acceptable:
     - Press electrode firmly in place
     - If remains red, lift electrode and wipe skin again with skin prep pad
     - Replace the electrode and firmly press in place



Press **BEGIN** to start recording.



Re-prep the area under the red electrodes.

10. Instruct the patient to close their eyes and stay relaxed (figure a).

    Troubleshooting instructions if artifacts detected during EEG data collection:

    - Gently place your fingers on the inner and outer corners of the eyes (figure b)
    - Stare straight ahead with eyes closed
    - Open your mouth to relax your jaw
    - Dim the lights

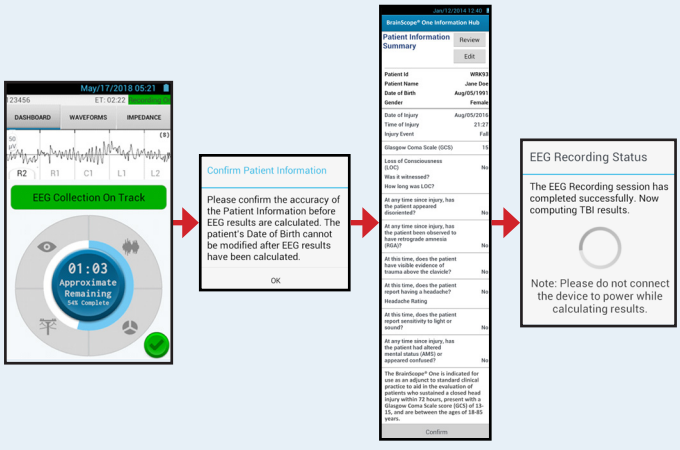
a

b

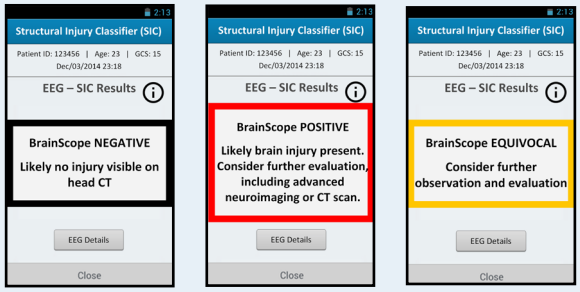
11. Perform the EEG data collection process until BrainScope One has indicated that there is enough clean data to provide results.

    Enough clean data will be collected when the blue circle is filled, or 10 minutes have passed. A ***Patient Information Confirmation*** message will display. Review the Patient Information and press **CONFIRM** to proceed with calculating the classification results.

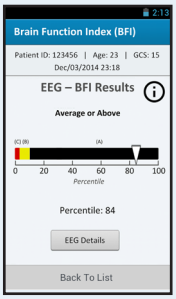
    If not enough clean data was collected, then no results will be computed, re-attempt session.



12. Review the Results presented (Both the Structural Injury Classifier (SIC) and if configured, the Brain Function Index (BFI))
    - A Negative Result indicates it likely corresponds to those with no structural brain injury visible on head CT.
    - A Positive Result indicates it likely corresponds to those with structural brain injury visible on head CT.
    - An Equivocal Result indicates it may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.

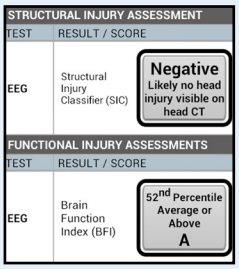


SIC Results



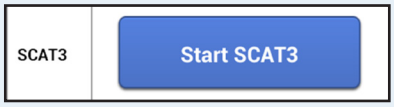
BFI Results

13. Return to the ***Information Hub***
    - The EEG Results are now displayed in place of **START**

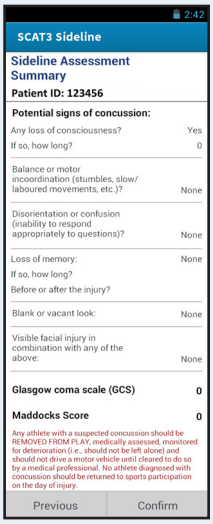
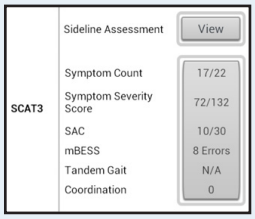


14. The cycle above is then repeated for the next selected test.

15. Press **START** for the next assessment (In the figure the example is SCAT3)



16. Conduct the assessment and record the SCAT3 responses

17. Review the Detailed Results presented	
18. Return to the ***Information Hub*** ▪ The SCAT3 results are now displayed in place of **START**	

The cycle continues for any further assessments or until the operator exits or powers **OFF** BrainScope One.

CHAPTER 3: Getting Started

WARNING!
- To avoid injury, read important safety information in Section 1.8 before using BrainScope One.

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

3.1 System Equipment and Supplies

BrainScope One consists of the following system equipment (Figure 3-1):

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 four 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. International Charging Kit
   a. International Charging Kit for recharging the internal rechargeable battery pack in the BrainScope One handheld.
   b. Connects to the DAB while charging.

Figure 3-1:
BrainScope One System Equipment

BrainScope One consists of the following accessories (Figure 3-2):

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 3-2:
Electrode Headset (package and insert)

3.2 International Charging Kit

WARNING!

- Use only the International Charging Kit shipped with BrainScope One to charge the BrainScope One EEG Acquisition Unit (Figure 3-1). Unapproved power supplies may cause damage to the device and increase the risk of electrical shock. Use of the International 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 International 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 One is internally powered by a lithium-ion rechargeable battery pack. A separate International Charging Kit is provided for battery charging (Figure 3-3). A new BrainScope One 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 charged for four hours to recharge it fully. If the battery has been stored for longer than six months, charge it completely before use.

Charging BrainScope One:

NOTE: When using the International Charging Kit, make sure that it is fully assembled prior to plugging it into a power outlet.

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).

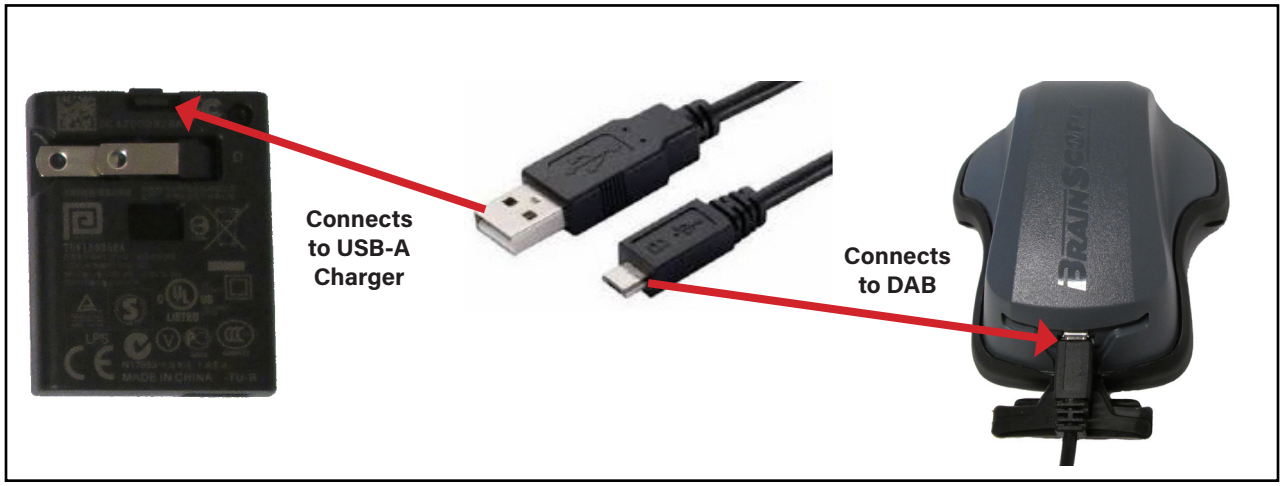


Figure 3-3:
Assembly of the International Charging Kit

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 International Charging Kit 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
Solid Orange	Battery is charging
Flashing Orange	Battery is charging, operating system notification; or, operating system notification, battery is not charging
Solid Red	Low battery charge
Flashing Red	Low battery charge, operating system notification
Solid Green	Battery fully charged
Flashing Green	Battery fully charged, operating system notification

3.3 Battery Gauge Icon

On every screen, a battery gauge icon (Figure 3-4) in the upper right corner indicates the remaining battery level in the internal rechargeable battery.

When the battery level has less than 16% remaining, a warning indication will appear requesting to check the battery status before continuing with testing. (Figure 3-5)

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 International Charging Kit.

If the battery becomes less than 12% charged and a session is not running, a warning indication will appear. Pressing **OK** on the warning screen shuts down the handheld. (Figure 3-6)

Figure 3-4:
Battery Gauge Icon

Figure 3-5:
Warning that 16% of battery level remains

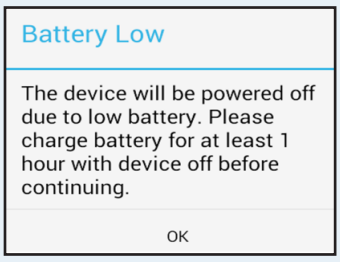


Figure 3-6:
Warning the handheld will power off

3.4 Buttons

3.4.1 Physical Buttons

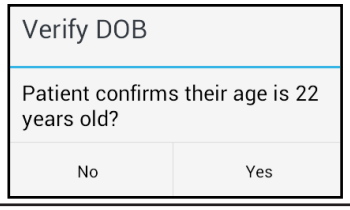
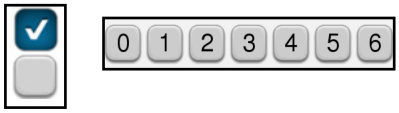
Most of the buttons on the BrainScope One handheld are virtual ones on the touchscreen. A few physical buttons control basic functions, such as powering BrainScope One ON/OFF or quick access to the ***Main Menu*** or ***Information Hub***.

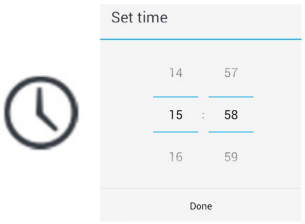
Figure 3-7:
BrainScope One Front Panel Buttons

Front Panel Buttons	
Home	▪ Returns to the ***Information Hub***. If you are performing an assessment, a dialog box will appear once pressed asking if you are sure you want to exit and inform you that data will not be saved if exited out of current screen. When pressed during EEG, the EEG menu appears.
Menu	▪ Opens the ***Main Menu*** for accessing device settings, operators, software/firmware versions, etc. ▪ The Menu button is disabled during an EEG recording.
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.
Search	▪ This button is disabled in all screens. Pressing the button will not perform any action.
Power	▪ Powers on and off the device.

3.4.2 Touchscreen Buttons

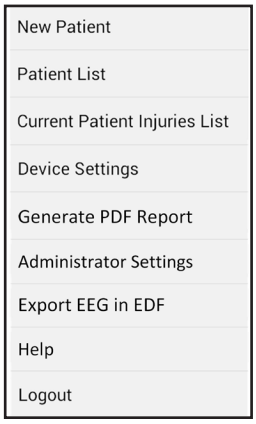
The main operation of BrainScope One is controlled via the touchscreen interface display, which comprises touch-sensitive display fields and buttons for entering, navigating and displaying information on BrainScope One. When a button is pressed, additional screens may appear to allow for data entry,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

Type of Button	Example	Action
Dialog Box Buttons	Ok, Dismiss, Save, Quit, Done, Yes, No Example of a dialog box button: 	▪ Shown at the bottom of the dialog box. Pressing the button will perform an action such as closing the dialog box.
Screen Navigation Buttons	Next, Close, Save, Confirm, Previous, Proceed Example of a screen navigation button: 	▪ Displayed at the bottom of a screen. These buttons allow for navigating to next or previous screens, saving and closing screens, etc. When a button is deactivated it will be greyed out.
Boxes	Checkboxes, scoring 	▪ Box that can be selected or deselected by pressing.
Start Button		▪ The start button is displayed on the ***Information Hub*** next to each assessment.
Text entry fields		▪ Text entry fields are identified with a yellow box and a text prompt. When pressed the onscreen keyboard will appear allowing text entry.
Onscreen Keyboard		▪ The onscreen keyboard lets you enter text when needed. Pressing **DONE** or **NEXT** on the onscreen keyboard will close the keyboard.
Pencil Icon		▪ Button that allows editing of data.

Type of Button	Example	Action
Calendar Button		▪ Pressing 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.). Press **DONE** when all information is entered.
Time Button		▪ Pressing 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.). Press **DONE** when all information is entered.

3.5 Set Up - Main Menu

The ***Main Menu*** appears when the physical **MENU** button is pressed on the handheld. (Figure 3-8)

Main Menu Screen	Menu Item	Access Level	Options
 **Figure 3-8: Main Menu**	New Patient	All Users	Add new patients to the database. When selected proceeds to the Patient Information screens (refer to sections 4.3 and 5.2 for instructions)
	Patient List	All Users	When selected proceeds to the patient database list where patient information can be reviewed and edited. (refer to section 5.1 for instructions)
	Current Patient Injuries List	All Users	Returns to the list of injuries for the current patient.
	Device Settings	All Users	Additional options under device settings includes: screen brightness, battery information, settle time, date and time and about (serial numbers).
	Generate PDF Report	All Users	Allows the user to generate a report of tests that were completed on a specific patient.
	Administrator Settings	Administrators Only	Allows for setting operator specific settings such as user name and password.
	Export EEG in EDF	All Users	Initiates EEG data to export to EDF on the SD Card.
	Help	All Users	Provides access to help topics for the device such as training videos and device troubleshooting.
	Logout	All Users	Logs out the current user of the device.

3.5.1 New Operator

At the initial set up of a new handheld, an initial Administrator must be setup with privileges to add new operators who will be granted access to use the BrainScope One. (See section 4.3.1 for detailed instructions)

Only Administrators have access to add new operators.

1. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS** and log in to the device.
3. Select **NEW OPERATOR** from the list of options.
4. Press Operator ID and the onscreen keyboard will appear.
5. Enter an Operator ID (i.e. initials or Employee ID).

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

6. Press the cursor under the Operator First Name and enter the operator's first name. Repeat and enter the operator's last name.
7. Press the cursor under the Operator Password and enter a password to be assigned to this operator.
8. When complete, press **ADD.**

NOTE: To add more operators, repeat steps 4 through 8 to enter new operator(s) authorized to use the BrainScope One handheld.

9. When complete, press the physical **BACK** button to return to the ***Administrator Settings Menu***.

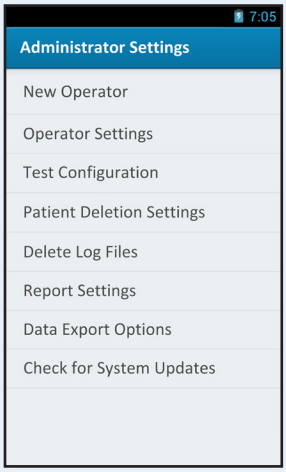


Figure 3-9:
Administrator Settings Menu

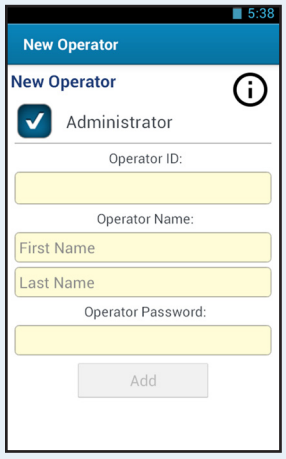


Figure 3-10:
Initial Operator Set-up

3.5.2 Test Configuration

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

NOTE: Only an Administrator can access the Test Configuration.

1. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS**
3. Enter the Administrator ID and Password and press **REQUEST ACCESS.**
4. Press **TEST CONFIGURATION.**
5. To enable or disable specific tests available on BrainScope One, select from the list by pressing the checkbox next to the test. A checkmark will appear for the tests selected.
   a. The Brain Electrical Activity section offers the following three options:
      i. Structural Injury Classifier (SIC) EEG Assessment only,
      ii. Brain Function Index (BFI) EEG Assessment only, or
      iii. Both EEG Assessments can be chosen.
   b. Remaining tests can be chosen individually.

NOTE: Any assessment checked on this screen will be present on the ***Information Hub***.

6. When complete, press the physical **BACK** button to return to the ***Administrator Settings Menu***.

WARNING!
- If BFI only is selected and SIC disabled, information related to the likelihood of a structural injury will NOT be displayed. The BFI does not indicate the presence or absence of structural brain injury.

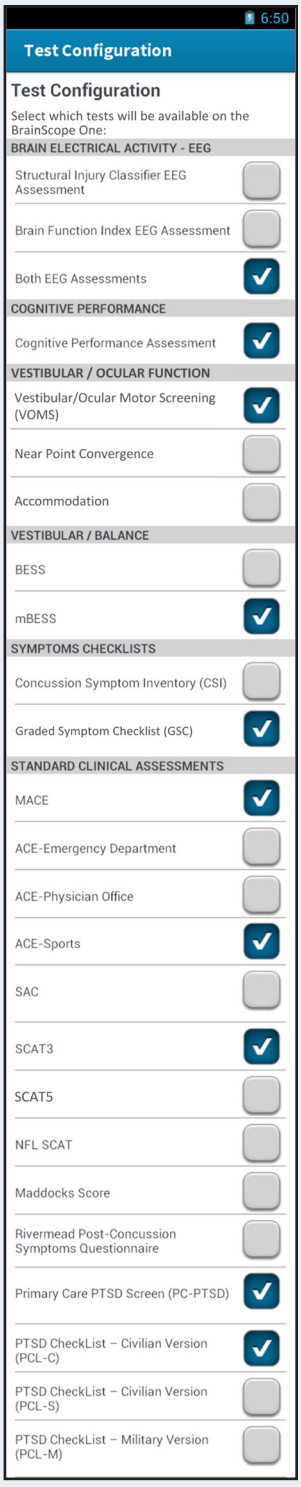


Figure 3-11:
Test Configuration Set-up

3.5.3 Device Settings – Device

Brightness:

1. Press the physical **MENU** button on the handheld.
2. Press **DEVICE SETTINGS**.
3. Press **BRIGHTNESS** and a pop-up box will appear.
4. Choose either:
   a. Auto Brightness to automatically adjust the screen brightness based on the current environment, or
   b. Use your finger and slide the blue dot to make the screen brightness darker or lighter.
5. Press **OK** when complete or **CANCEL** to reject changes made.

Battery:

Under Device in Device Settings you can view the remaining percentage (%) of battery level. The percentage will be displayed next to Battery.

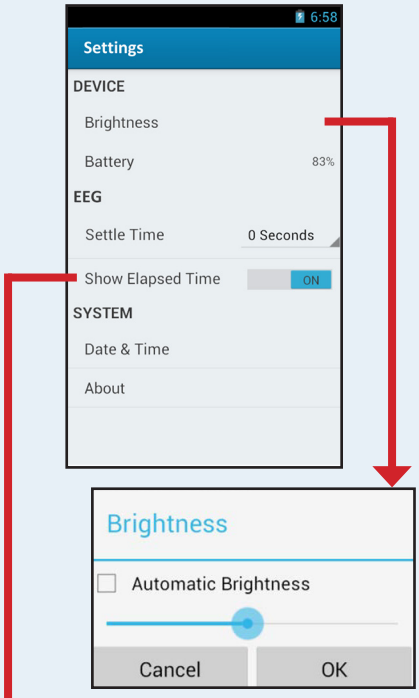


Figure 3-12:
Brightness Settings

3.5.4 Device Settings - EEG

Settle Time:

Settle time will delay the recording of the EEG data for a specified time (0 seconds, 30 seconds, or 1 minute). This time allows for the patient to relax and prepare for clean EEG data to be recorded. The handheld defaults to 0 seconds.

The settle time selections in Device Settings will result in the following:

- Selecting 0 seconds will result in the timer on EEG Acquisition starting at 0:00 seconds
- Selecting 30 seconds will result in the timer on EEG Acquisition starting at -0:30 seconds
- Selecting 1 minute will result in the timer on EEG Acquisition starting at -1:00 minute

Show Elapsed Time:

Elapsed time will allow for displaying elapsed time during an EEG recording. When the **OFF** switch is shown, the application will not display the elapsed time and will instead display the estimated time to completion inside the blue circle on the ***EEG Acquisition Dashboard***. When the **ON** switch is selected the application shall display the elapsed time in the blue circle and the estimated time to completion in the header of the ***EEG Acquistion Dashboard.***

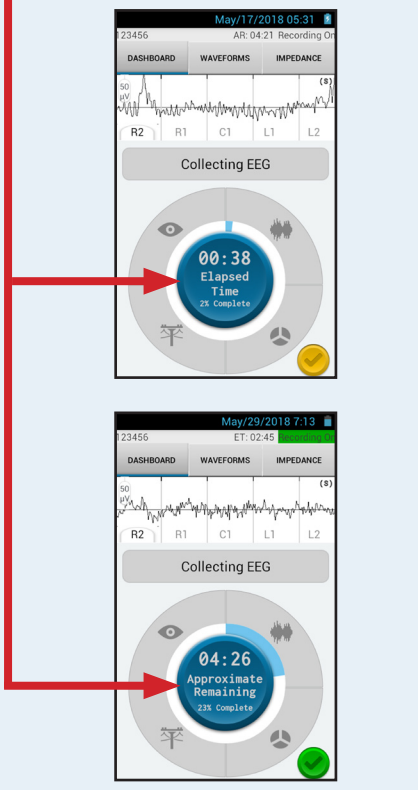


Figure 3-13:
Examples of Elapsed and Approximate Remaining Time on the *EEG Acquisition Dashboard*

3.5.5 Device Settings - System

Date and Time:

1. Press the physical **MENU** button on the handheld.
2. Press **DEVICE SETTINGS**.
3. Press **DATE & TIME**

Set Time Format

Press **24 HOUR** to toggle between 24 hour and 12 hour.

Set Time Zone

1. Press **SET TIME ZONE** and a dialog box will appear.
2. Press on the current time zone and a list of time zones will appear.
3. Use your finger to scroll and set the desired time zone.
4. Press **APPLY AND SHUT DOWN** when complete. The BrainScope One handheld will power OFF to apply the change to the current time zone.

Set Date & Time Using GPS

1. Press **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. Press **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.

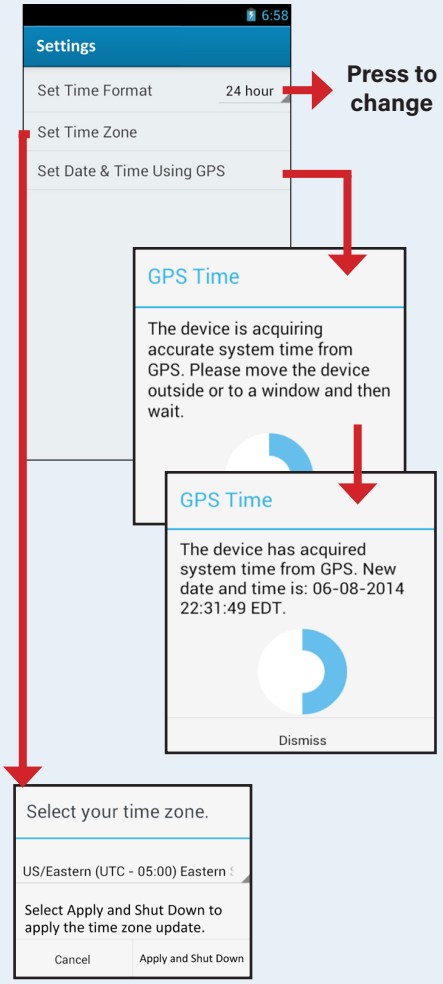


Figure 3-14:
Setting Date and Time

About

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

1. Press the physical **MENU** button on the handheld.
2. Press **DEVICE SETTINGS** from the list.
3. Press **ABOUT** and a dialog box will appear displaying the information.
4. Press **SHOW LICENSES** to display all supporting software libraries with required licensing information.
5. Press **DISMISS** and the About box will close.

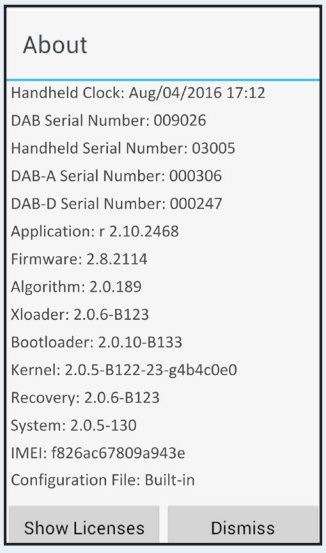


Figure 3-15:
About BrainScope One

3.5.6 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. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS** and log in to the device. Press ***Operator Settings*** and the ***Operator Settings Menu*** will display (Figure 3-16).
3. When the ***Operator Timeout*** is set to ***OFF***, the operator timeout is disabled. When the ***Operator Timeout*** is set to ***ON***, the operator timeout is enabled.
4. The time of inactivity can be set to either 10, 15, 20, or 30 minutes.

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

5. Press **EDIT OPERATORS** and the ***Operators List*** will display listing the Operator ID and Operator Name associated with the handheld.
6. Select the Operator ID from the list to go to ***Edit Operator.*** Follow the guidelines below when creating and editing operator passwords:
   a. Operator Password must:
      - Be between 7 and 20 characters
      - Contain letters and at least one number/special character (except @)
      - Not be one of the last 7 passwords
7. Press the New Password field and enter a new password.
8. Press the Re-enter New Password field and re-enter the new password assigned.
9. Press **SAVE** to save the record.
10. Press **CANCEL** to exit the screen and return to the ***Operators List***.
11. Check the Administrator box if the operator is being given Administrator rights.
    a. Un-check the Administrator box and the operator will be removed from the administrator list.

NOTE: Only Administrators have rights to check and un-check this box.

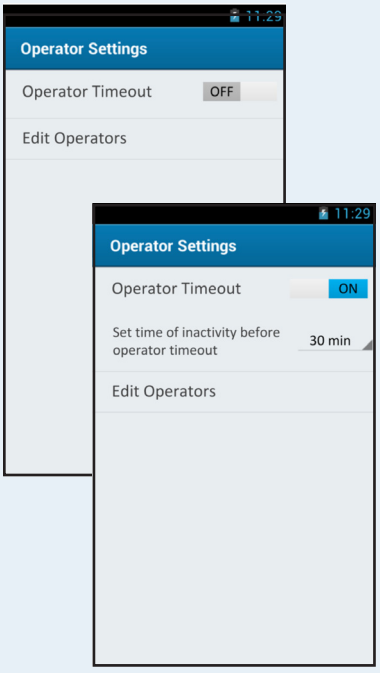


Figure 3-16:
Operator Settings Menu

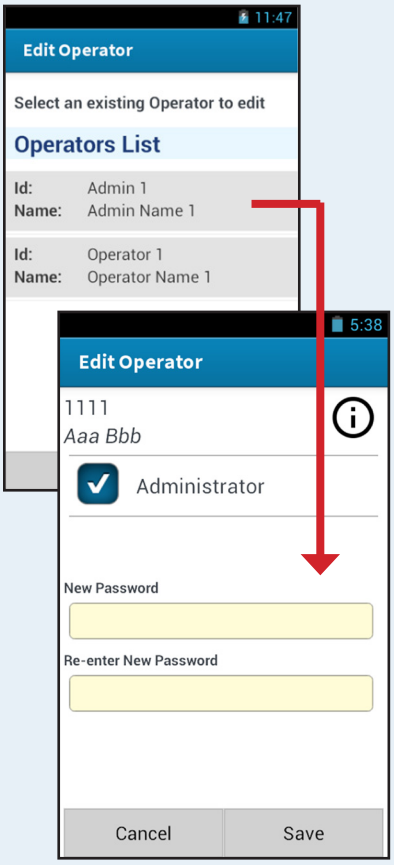


Figure 3-17:
Operator Settings

3.5.7 Patient Deletion Settings

The patient deletion settings allow an administrator to select automatic deletion settings to manage data storage on the handheld, as well as delete all patients on the handheld. Only Administrators have access to Patient Deletion Settings.

1. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS** and log in to the device. Press ***Patient Deletion Settings*** and the ***Patient Deletion Settings Menu*** will display (Figure 3-18).
3. When the ***Automatic Patient Deletion*** is set to ***OFF***, the automatic patient deletion feature is disabled. When the ***Automatic Patient Deletion*** is set to ***ON***, patient data is automatically deleted.
4. When ***Automatic Patient Deletion*** is set to ***ON,*** the administrator must set record age (in days) before automatic deletion will occur. Choose the following options from the drop down list - 10, 15, or 30 days. The handheld will prompt a confirmation when ***Automatic Patient Deletion*** is selected.

   NOTE: For example, if the set record age was set at "10 days", patient records would remain on the device for 10 days. On the 11th day, at device start-up, that patient record would be deleted automatically.

5. The ***Patient Deletion Settings*** allow for the following manual deletion actions:
   - Delete Patient - review and select individual patient records to delete (Figure 3-19).
   - Delete All Patients - all patient data will be permanently deleted from the handheld. Press **CONTINUE** to confirm deletion. Press **CANCEL** to return to ***Patient Deletion Settings.***
6. The amount of internal database storage available in megabytes (MB) is displayed on the ***Patient Deletion Settings Menu***.

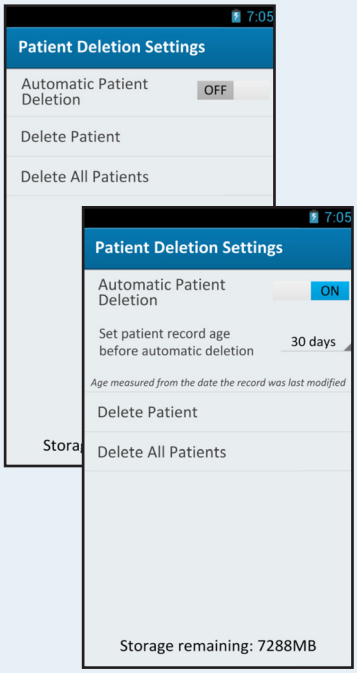


Figure 3-18:
Patient Deletion Settings Menu

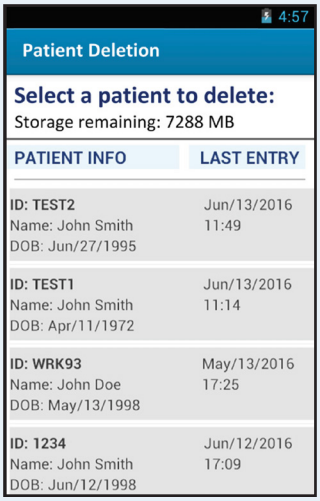


Figure 3-19:
Patient Deletion

3.5.8 Delete Log File

BrainScope One allows an administrator to delete log files from internal storage on the device. All log files, except for the unencrypted Device Log, will be deleted when selecting Delete Log Files from Administrator Settings.

1. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS** and log in to the device. Press ***Delete Log Files*** and the a message screen will display (Figure 3-20).
3. Press **CONTINUE** to proceed with deleting the log files. A message will indicate when the deletion of the files was a success.

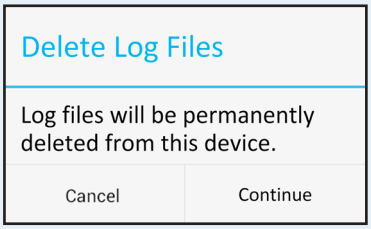


Figure 3-20:
Delete Log Files

3.5.9 Report Settings

The Report Settings option allows the operator to turn on/off automatic report generation and configure specific patient information fields on the report. Only Administrators have access to Report Settings.

When the Automatic Report Generation switch is set to ON, patient reports will automatically generate when leaving a session. To turn off the automatic generation, toggle the switch to the OFF position. Operators can still generate the Patient Report manually from the **MENU** button.

The Administrator can toggle on/off patient information fields on the patient report. To populate the report header with *Patient Name, Patient Date of Birth,* and/or *Patient Gender*, slide the toggle switch from OFF to ON.

NOTE: The Automatic Report Generation will default to the ON position.

WARNING!
By populating these fields, Protected Health Information (PHI) data will be printed on the report. Take necessary steps to protect the privacy and security of the content as mandated by HIPAA.

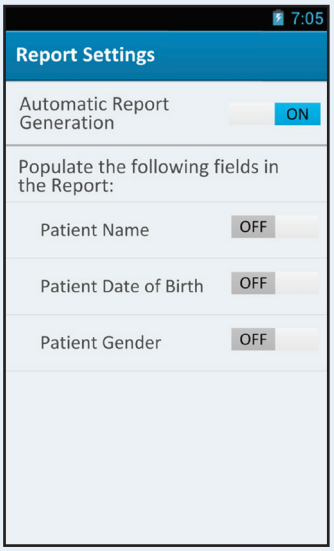


Figure 3-21:
Report Settings

3.5.10 Help Menu

The ***Help Menu*** provides access to useful information about the operation of the device and troubleshooting tips.

1. Press the physical **MENU** button on the handheld.
2. Press **HELP** to enter the ***Help Menu***.

Once in the ***Help Menu***, there are options to view a refresher training video, instructions for PDF Report Printing and troubleshooting topics.

- **View Refresher Training Video** - onscreen video of the BrainScope One training.
- **PDF Report Printing Instructions** - instructions for how to print a PDF Report.
- **Impedance Troubleshooting** - tips to help with unacceptable impedance values and if impedance values indicate OFF.
- **Handheld Troubleshooting** - tips to help with the handheld not responding to user commands, incorrect Date and Time, and battery depletion.
- **EEG Data Troubleshooting** - tips to help with EEG data connection failure and insufficient data collected.
- **SD Card Troubleshooting** - tips to help when the SD card is full.

3.5.11 Logout

The Logout option allows the operator to logout of the handheld.

1. Press the physical **MENU** button on the handheld.
2. Press **LOGOUT** and the current operator will be logged out.
3. The application will navigate to the ***Disabled Information Hub*** (see Section 4.3.1 for more information on the ***Information Hub***).

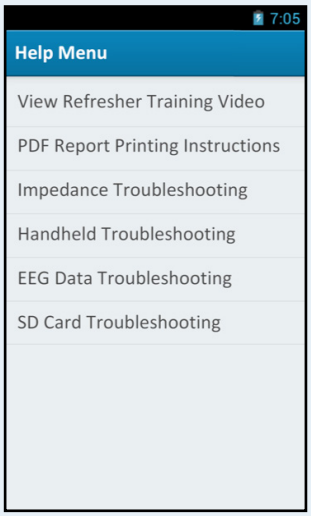


Figure 3-22:
Help Menu

Figure 3-23:
Refresher Training Video

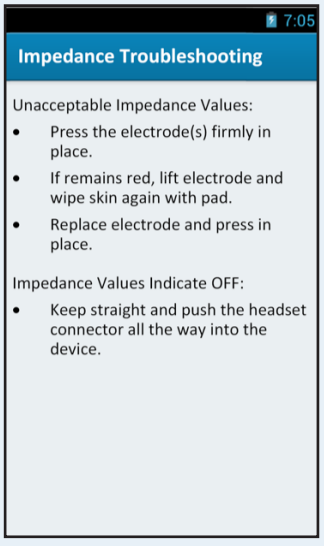


Figure 3-24:
Example of troubleshooting tips

CHAPTER 4: Principles of Operation

4.1 Introduction

This section describes the principles of device operation. It is assumed that the BrainScope One handheld has been set up with operators and test configurations already. If initial set up has not been completed, please refer to Chapter 3 for instructions on how to do so before proceeding with this chapter.

Read this chapter before operating BrainScope One in a clinical setting.

4.2 Power ON / OFF

Turn on the handheld by pressing the power switch (1) located on the right side of the handheld (Figure 4-1).

Before collecting data, make sure that BrainScope One has sufficient charge. The Battery Gauge icon should indicate at least 15%. If not, recharge the battery (see Chapter 3).

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

Figure 4-1: Power ON/OFF

4.3 Session Initiation – Information Hub and Patient Information

4.3.1 Initial Set Up

At the initial set up of a new handheld, an initial Administrator must be setup with privileges to add new operators who will be granted access to use BrainScope One.

1. Press the **OPERATOR LOGIN** from the ***Disabled Information Hub***.
2. Enter the default password that has been provided by BrainScope.
3. Press **REQUEST ACCESS**.
   a. The ***New Operator*** screen will then be displayed with the Administrator field checked.
4. Press Operator ID and the onscreen keyboard will appear.

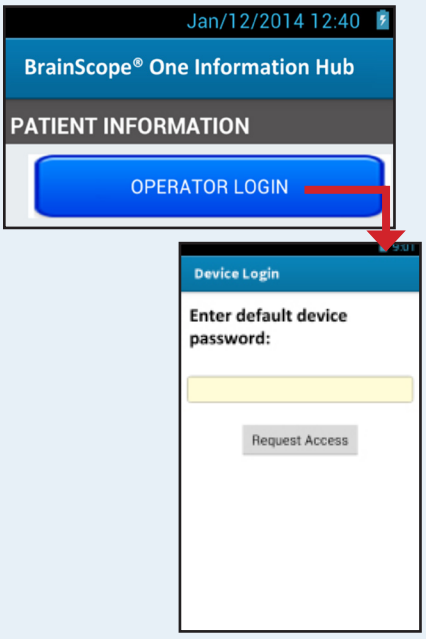


Figure 4-2:
Initial Device Operator Set Up

5. Enter an Operator ID (i.e. initials or Employee ID).
6. Press the cursor under the Operator First Name and enter the operator's first name. Repeat and enter the operator's last name.
7. Press the cursor under the Operator Password and enter a password to be assigned to this operator.
8. When complete, press **ADD.**
9. Once the Administrator has been added press **NEXT** and the Administrator/Operator will navigate to a ***Warning***. Press **PROCEED** to advance to the ***New Patient Entry*** to either create or select a patient (See section 4.3.3 for detailed information).

NOTE: 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 3.5.7 Operator Settings for details.

4.3.2 BrainScope One Information Hub

The ***Information Hub*** is the BrainScope One home screen that provides the following functions:

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

Upon initial use of BrainScope One, whether powered on for first use or an operator has "logged off", the ***Information Hub*** will appear as disabled until Operator Authentication has been completed.

To perform Operator Authentication:

1. Press **OPERATOR LOGIN**.
2. Enter the Operator ID field via the onscreen keyboard.
3. Press 'Next' on the keyboard, or press the Passcode field and enter the corresponding password.
4. When complete, press 'Done' on the onscreen keyboard.
5. Press **REQUEST ACCESS**.

NOTE: If the Operator ID and the Passcode do not match, contact your authorized user for proper credentials.

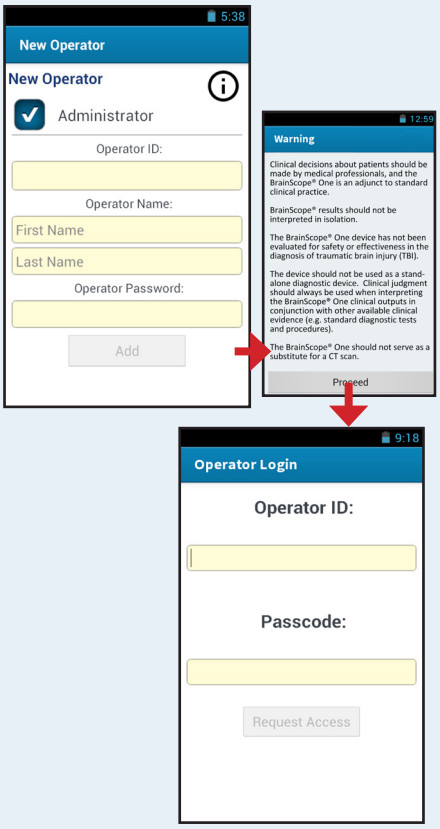


Figure 4-3:
Initial Administrator Operator Entry

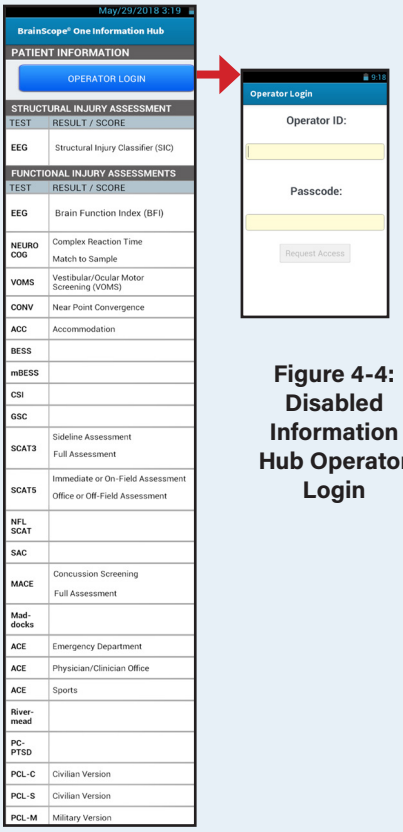


Figure 4-4:
Disabled Information Hub Operator Login

The following describes each area of the ***Information Hub***:

Patient Information Section:
The Patient Information section displays the information entered on the Patient Information screens including the Date/Time of Injury and the GCS score entered. Pressing the pencil icon will allow you to review and edit detailed patient information.

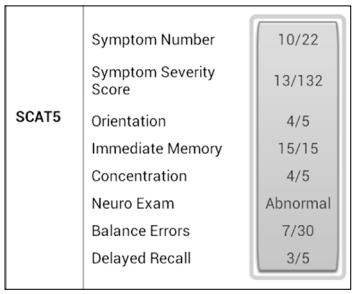
Assessments Sections:
Each assessment configured on BrainScope One will be listed on the ***Information Hub***. If an assessment is not configured it will not be listed.

The BrainScope One ***Information Hub*** is segmented into 2 main Assessment Sections:

1. Structural Injury Assessment
2. Functional Injury Assessment

Assessments that have been configured for use, by the Administrator in the Test Configuration settings, will display **START** to the right in the Result/Score area until a test has been completed.

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



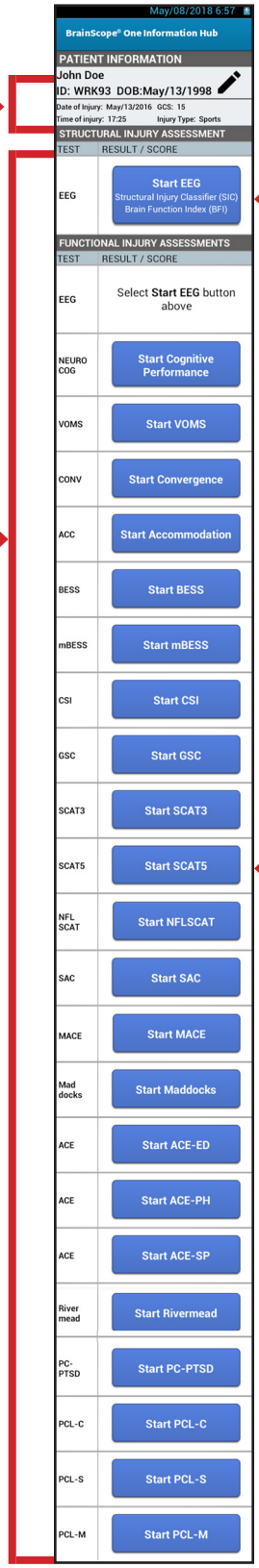


Figure 4-5: Active Information Hub

When the operator leaves the ***Information Hub*** by proceeding to the ***Main Menu*** (see Section 3.5 for more information) and selecting any option except Device Settings, Generate Report, or Administrator Settings, the application will advance to ***Leave Session*** to confirm.

When **NO** is selected, the application will return to the ***Information Hub***.

When the **YES** is selected, the application will display one of the following screens:

- ***Report Notes*** (Figure 4-6), if not all assessments available on the ***Information Hub*** were completed.
- ***Report Generation Progress Message*** if all assessments available on the ***Home*** screen were completed. The application will navigate to the ***Home*** screen.
- ***New Patient Entry*** (Figure 4-7), if all assessments on the ***Information Hub*** were completed and the operator selected **NEW PATIENT** on the ***Main Menu.***
- ***Existing Patient*** screen if the operator selects to Leave Session.
- ***Patient List*** (Figure 4-8), if all assessments on the ***Information Hub*** were completed and the operator selected **PATIENT LIST** on the ***Main Menu***.
- ***Disabled Information Hub*** (Figure 4-9), if all assessments on the ***Information Hub*** were completed and the operator selected **LOGOUT** on the ***Main Menu***.

NOTE: ***Report Notes*** (Figure 4-6) allows the operator to enter any relevant information about each assessment that the clinician can document in the permanent record. The comments made in the ***Report Notes*** will be viewable on the exported PDF report for this patient. (See Appendix 2-Reports)

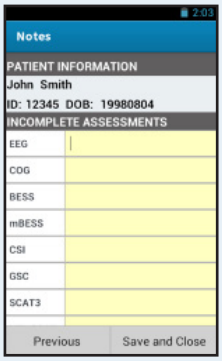


Figure 4-6: Report Notes

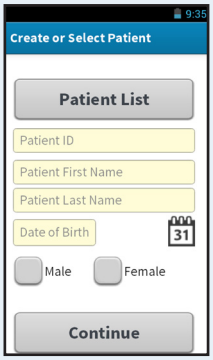


Figure 4-7: New Patient Entry

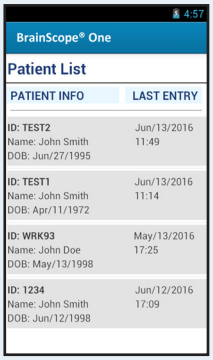


Figure 4-8: Patient List

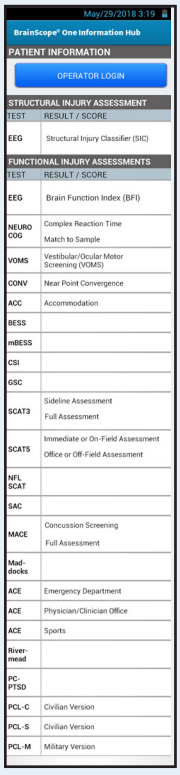


Figure 4-9: Disabled Information Hub Operator Logged On

4.3.3 New Patient Entry

Once the operator has been authenticated the handheld will advance to ***New Patient Entry*** screens.

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

- Patient ID
- Date of Birth (DOB)
- Gender

CAUTION: The patient ID appears in unencrypted files generated by BrainScope One, such as the PDF Report and Device Log.

1. Enter all of the information by selecting the field and typing the information using the onscreen keyboard.
   a. Press 'Done' on the onscreen keyboard when completed with that field.
   b. Press the **CALENDAR** to enter the patient's Date of Birth (DOB).
   c. Press the checkbox to select the gender.
2. When complete, press **CONTINUE**.

NOTE:

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

3. Verify the DOB in the dialog box:
   a. If the age calculated from the DOB is correct, press **YES** to continue.
   b. If the age is not correct, press **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.

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

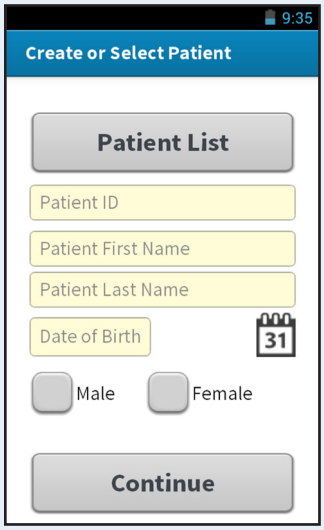


Figure 4-10:
New Patient Entry

Figure 4-11:
Verify DOB Message

4.3.4 Patient Information and Injury Entry

The ***Patient Information*** and ***Injury Entry*** screens gather patient signs and symptoms information, as well as details about the injury event.

There are 6 ***Patient Information*** and ***Injury Entry*** screens (one example is shown in Figure 4-12) to record the following information:

- Date and Time of Injury
- Type of Injury Event
- GCS (time of assessment)
- Loss of Consciousness (witnessed and duration)
- Orientation
- Amnesia
- Trauma Above the Clavicle
- Headache(s)
- Light Sensitivity
- Altered Mental Status

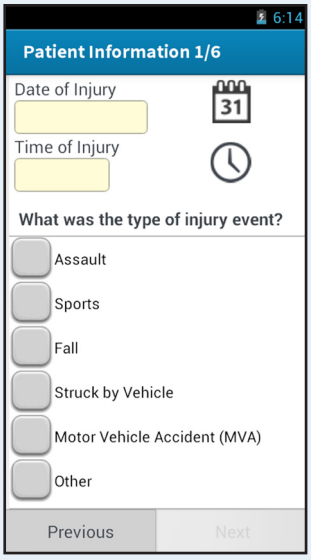


Figure 4-12: Example of a Patient Information screen

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 press either **NEXT** to navigate to the next screen or ***PREVIOUS*** to return to the previous screen.

NOTE:

- On ***Patient Information 2/6*** press **SHOW GCS TABLE** for a reference of the GCS Table. Display of the GCS Table is optional and not required to enter the GCS or continue with the test. If the GCS is less than 13, press the **SELECT** field and a drop down box will appear. Choose the GCS value.
- On ***Patient Information 3/6*** decimal minutes can be entered, such as 2.5 to indicate 2 minutes and 30 seconds.

When all information is entered, the information entered will display in the ***Patient Information Summary*** (Figure 4-13). The ***Patient Information Summary*** provides a comprehensive assessment list with results for the clinician to use in their clinical assessment of the patient.

When all information has been reviewed, press **CONFIRM**. The device will then provide a list of ***Configured Assessments***. Press **PROCEED** to navigate to the ***Information Hub***.

If any of the responses need to be corrected, press ***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 and editing patient information see Section 5.2.

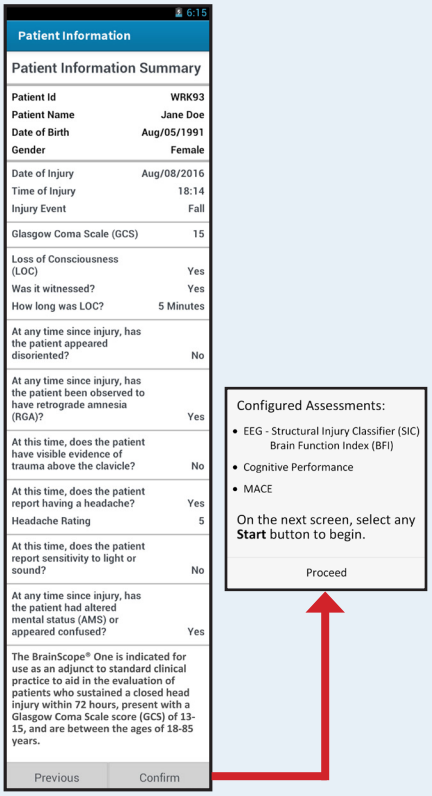


Figure 4-13: Patient Information Summary

4.4 Electrode Headset Preparation

The headset (Figure 4-14) 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 below shows the corresponding headset labeling and position on the patients head.

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

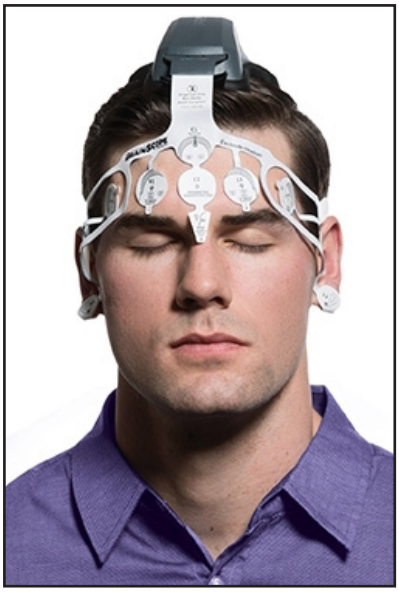


Figure 4-14:
Electrode Headset

The headset is packaged with skin preparation materials to aid in the preparation of the patient: (Figures 4-15 and 4-16):

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

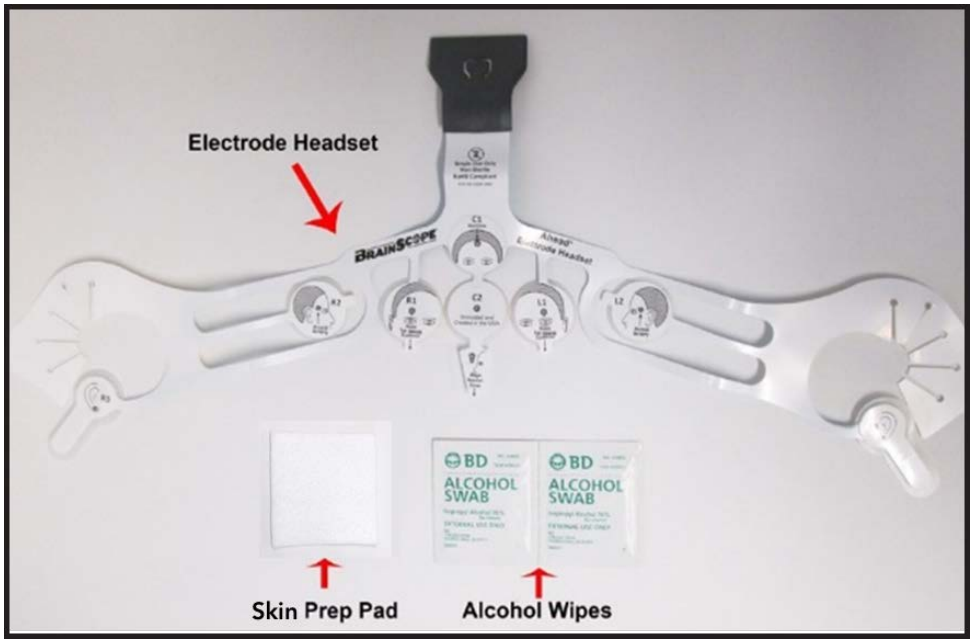


Figure 4-15: Electrode Headset and Skin Preparation Materials

NOTE: The packaging 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 4-16 shows the headset and skin preparation materials still packaged in the plastic insert. Remove the three plastic covers and gently detach the headset from the plastic insert.

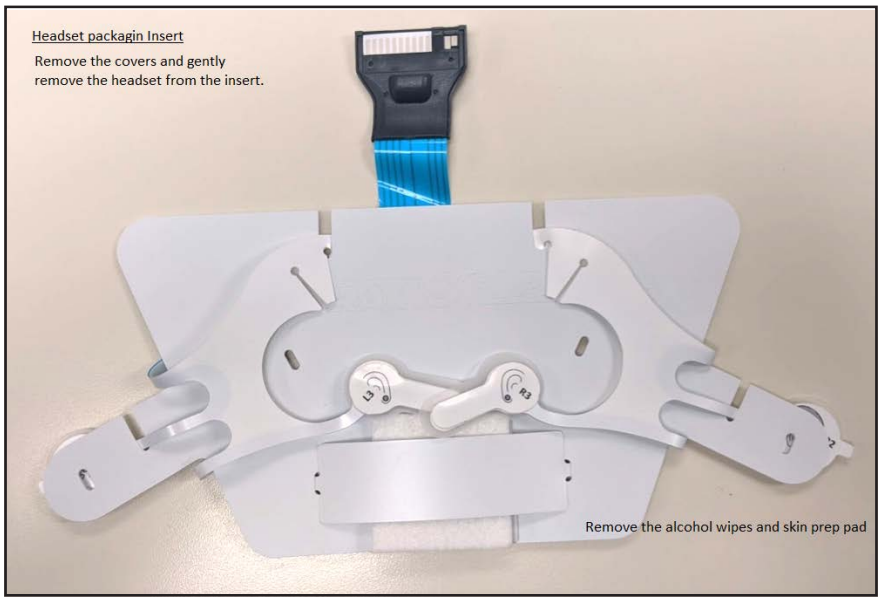


Figure 4-16:
Electrode Headset packaging removal

4.4.1 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.
- Do not use the Electrode Headset if the packaging pouch is damaged.
- 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.

WARNING!

- 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.

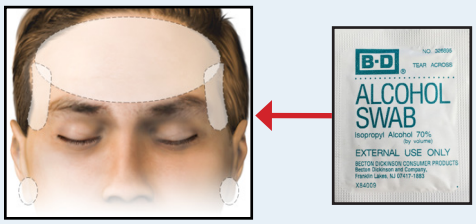
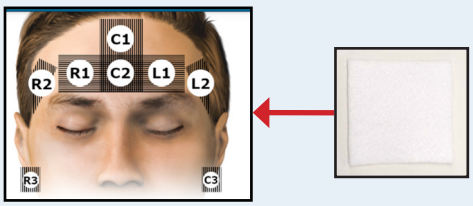
CAUTION!

- Proper Electrode Headset placement is critical to the operation of BrainScope One. 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 One 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 One handheld must be used in conjunction with the headset that incorporates integrated electrodes. Application instructions can be found on the headset packaging pouch.

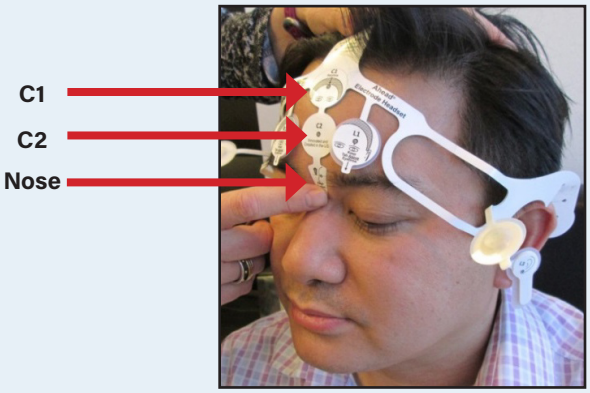
Prior to conducting a new EEG test, the patient's skin should be prepared for placement of the headset. Before beginning skin preparation, ensure patient's hair has been pulled back to expose the forehead. When **START EEG** has been pressed the device will provide onscreen steps for preparing the patient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

1. Start preparing the skin by using an 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. Using the headset skin prep pad, apply firm pressure to the skin while using a wiping motion over the cleaned areas: forehead, temporal areas and earlobes. This will ensure that skin is properly exfoliated. For the forehead area, trace an inverted **T** as shown in the picture below. Wipe the areas two times each with the skin prep pad.	

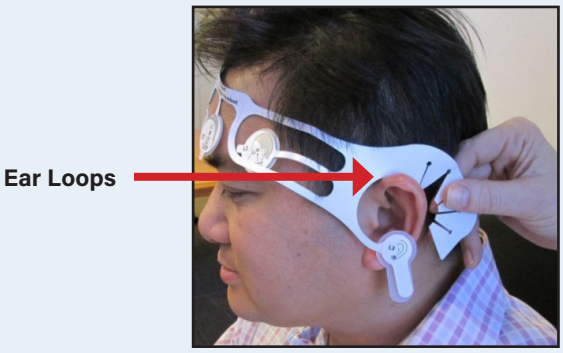
3. Before placing headset, align the lower edge of the nose tab with the bridge of the patient's nose and check to see whether the C1 electrode will fall in the hairline. If C1 falls under the hairline, remove adhesive backing from center electrodes C1 and C2, and apply the electrodes making sure the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

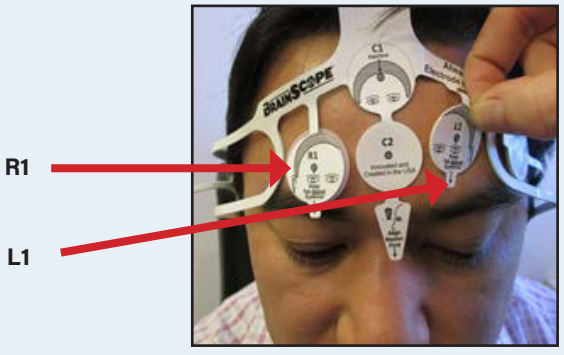
   Once the headset appears to be centered, it may be applied to the skin. Ensure that both electrodes are firmly affixed to the skin by pressing down on the electrode.



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

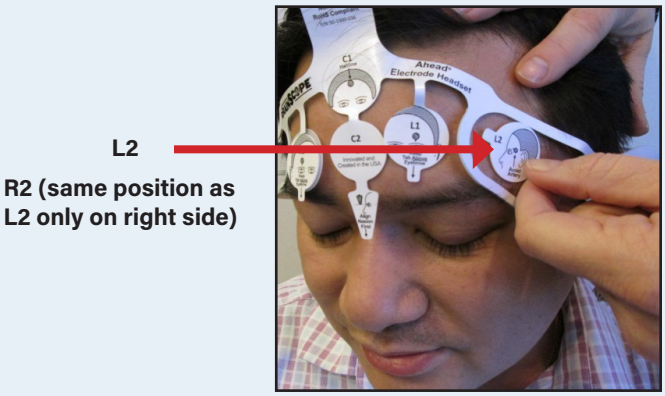


5. Locate L1 and R1 above the eyebrows. If the tab on either electrode is touching the eyebrows, raise the electrode upwards so the end of the tab touches the eyebrow but is out of the eyebrow hairs. Ensure that the electrode falls just above the eyebrow bone and firmly affix it to the skin by pressing 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.

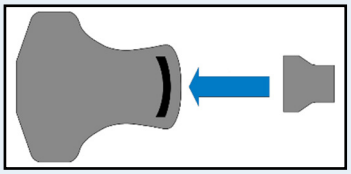
8. Once the headset is firmly in place, apply pressure to all of the electrodes to ensure adhesion to the patient's skin.

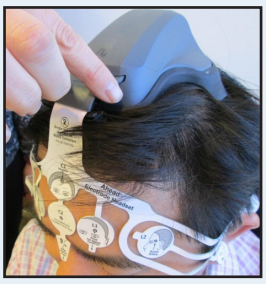
9. Alternatively, all Left side electrodes (L1, L2 and L3) and then all Right side electrodes (R1, R2 and R3) (or vice-versa) can be placed if convenient for the operator. Ensure to keep electrode symmetry in placement as noted above.

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 possible. However, the time between first insertion and last insertion must be within 60 minutes.





4.5 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. The operator should 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 One 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. Press **START EEG** in the Structural Injury Assessment section on the ***Information Hub***.
2. The ***EEG Acquisition Dashboard*** will display the ***Impedance*** tab and begin measuring impedance.
3. The device will navigate through the ***Headset Placement Instructions***. Press **NEXT** to navigate through the instructions or press **SKIP TO EEG** to navigate to the impedance check.

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 4-17)

- Green - The impedance value is within the normal range (0.5 kΩ – 5 kΩ).
- Yellow - The impedance value is acceptable (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. Press **RE-PREP INSTRUCTIONS** for assistance (Figure 4-18). (Refer to Chapter 7 for additional support troubleshooting impedance)
- Gray - The C2 electrode is the electrical ground and will not display an impedance value.

To view the electrode labels using the 10-20 System, press the **10-20** button.

3. When all electrodes (except C2) are displaying acceptable impedances (Green or Yellow), press **BEGIN** to begin the recording.

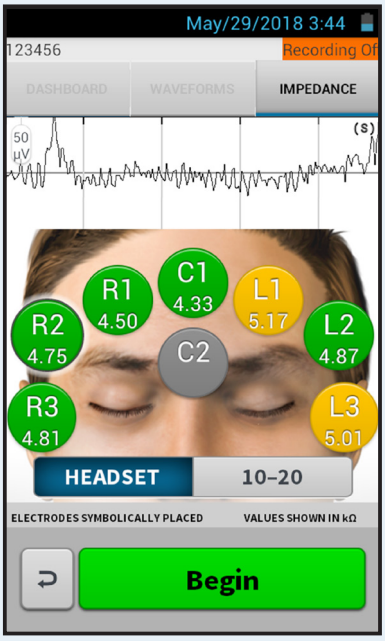


Figure 4-17:
Impedance Screen - Begin (Headset)

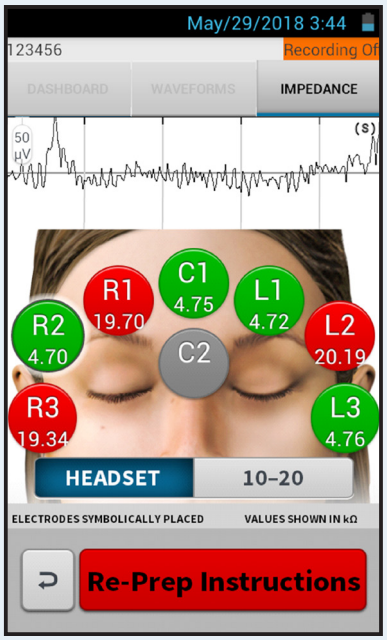


Figure 4-18:
Impedance Screen Re-Prep - (Headset)

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. Press **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. Press **OK** to dismiss the warning message and obtain a new headset to complete the test.

4.5.1 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 4-19)

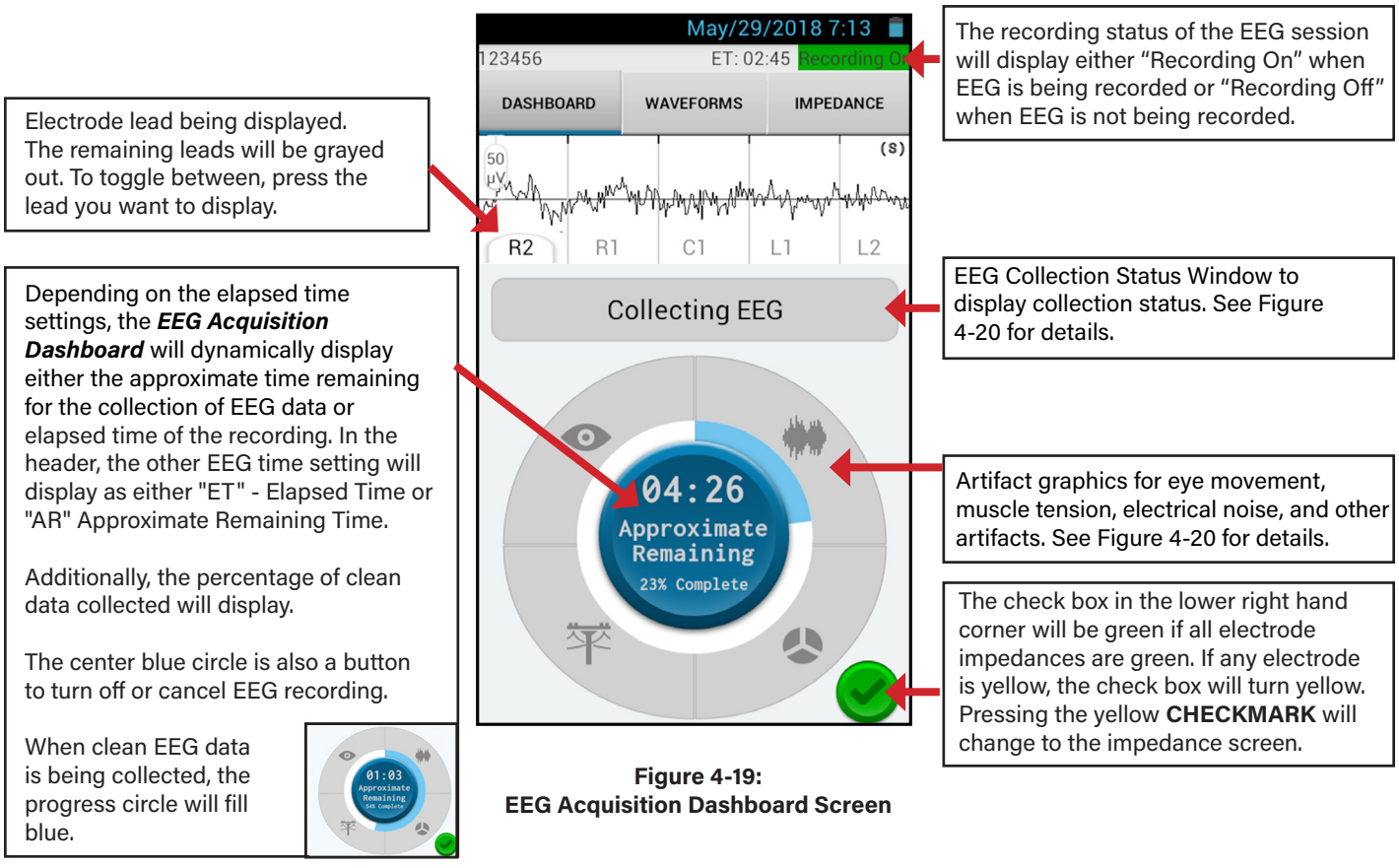


Figure 4-19:
EEG Acquisition Dashboard Screen

The BrainScope One handheld includes software for automatic identification and rejection of non-brain-generated artifacts (Figure 4-20). 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.

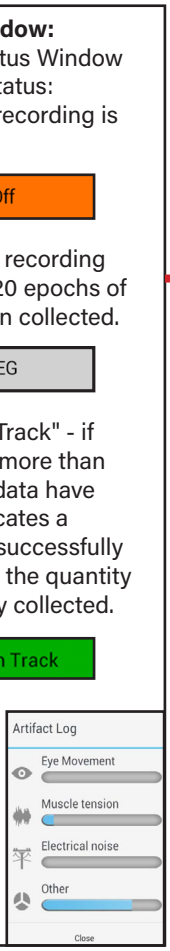
EEG Collection Status Window:

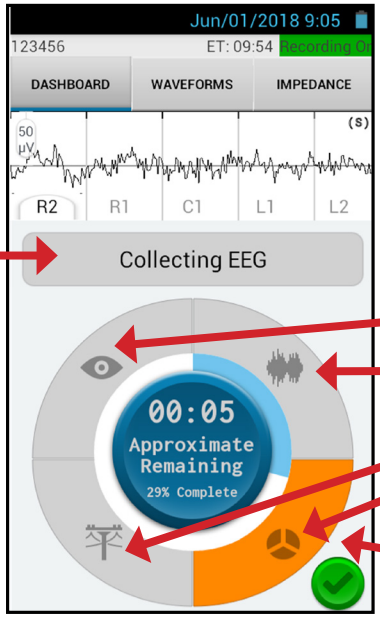
- The EEG Collection Status Window will display collection status:
  - "Recording Off" - if recording is off.

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

    Collecting EEG
  - "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.

    EEG Collection On Track
- To see a cumulative listing of all the artifacts during the session, press the EEG Collection Status Window and a dialog box will appear listing the 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 4-20:
EEG Acquisition Dashboard Screen - Artifacts

Turning off/on or cancel an EEG recording

To turn off the recording, press the dark blue button in the center of the circle. A dialog box will appear (Figure 4-21) allowing the user to turn off the recording, cancel the EEG, or dismiss the dialog box and return to the ***EEG Acquisition Dashboard***.

Press **RECORDING OFF** to pause the recording, the button will then be labeled **RECORDING ON**. 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 press the dark blue button and the dialog box will appear again. Press the **RECORDING ON** button. The ***EEG Recording Menu*** will close and the EEG will be recorded.

To cancel the test, press the dark blue button and the dialog box will appear again, press **CANCEL EEG**. A dialog box (Figure 4-22) will appear asking to confirm. Press **YES** to cancel the test, Press **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***.

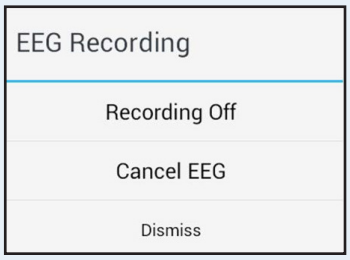


Figure 4-21:
EEG Recording Dialog Box

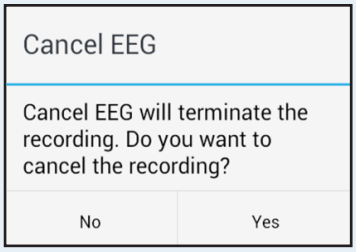


Figure 4-22:
EEG Recording Cancel EEG

Waveforms

To view real-time wave forms during data collection, press the **WAVEFORMS** tab (Figure 4-23).

The Waveform screen displays up to 7 real-time EEG waveforms as they are collected during the session (Figure 4-23). The labels are displayed according to the user setting (Headset or 10-20).

- 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

where "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.

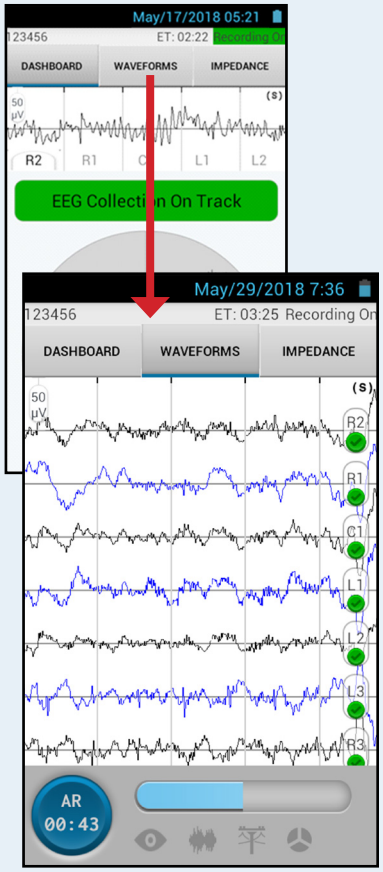


Figure 4-23:
Waveforms Screen

Recording Complete

Once sufficient artifact-free EEG data has been collected from the patient, the handheld will stop the EEG recording and compute the Structural Injury Classifier results. A ***Patient Information Confirmation*** message will display (Figure 4-24) advising the user to confirm patient information before the EEG results are calculated.

Disconnect the headset from the DAB. A pop up message will appear on the screen indicating that the headset is disconnected.

NOTE: The ***Data Quality Failure*** dialog box will appear if enough clean epochs are collected, but the data quality is inadequate to calculate results. (Figure 4-25).

NOTE: Typically sufficient clean data is acquired within 5 minutes of EEG recording. If sufficient clean data is not acquired, a ***Artifacts Detected*** dialog box will appear (Figure 4-26) 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. Press **DISMISS** to return to the ***EEG Acquisition Dashboard*** (if greater than or equal to 20 epochs have been collected).

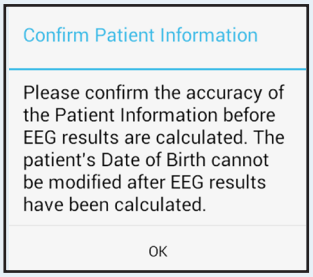


Figure 4-24:
Patient Information Confirmation

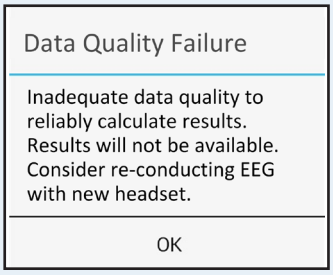


Figure 4-25:
Data Quality Failure

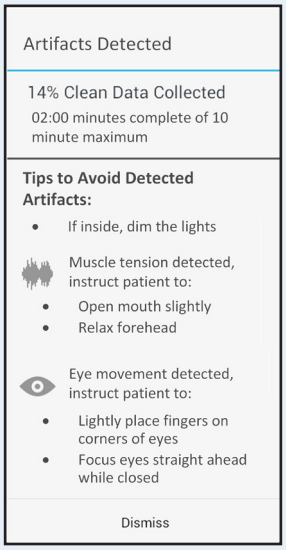


Figure 4-26:
Artifacts Detected Message

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 4-27). Press **CLOSE** to return to the ***Information Hub*** or press **START NEW EEG** to begin a new recording using the same headset. When the **START NEW EEG** button is pressed ***Tips to Avoid Detected Artifacts*** will appear (Figure 4-28).

WARNING!

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

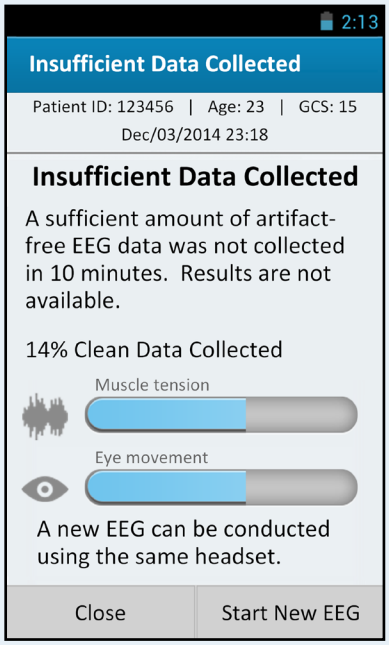


Figure 4-27:
No results EEG Recording Status

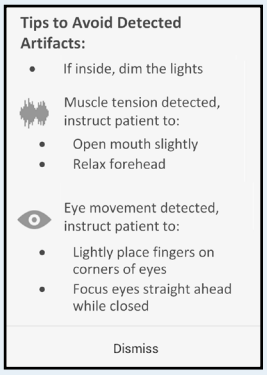


Figure 4-28:
Artifact Free Data Tips Message

4.5.2 EEG Results

Structural Injury Classifier Assessment

The ***Structural Injury Classifier Summary*** displays the result of the structural injury classification algorithms, indicating the presence or absence of structural brain injury.

The results screen includes an EEG Details button to view EEG details and review EEG Data. See Section 5.3 for detailed instructions.

BrainScope One places a patient into one of three categories based on the patient's brain electrical activity. The classifications and their corresponding instructions are to be used in conjunction with other clinical assessments. The Structural Injury Information Messages appear when **INFORMATION** is selected on each of the Structural Injury Classifier Summary screens.

- A negative BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours and GCS 13-15, likely corresponds to those with no structural brain injury visible on head CT.
- A positive BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours and GCS 13-15, likely corresponds to those with a structural brain injury visible on head CT.
- An equivocal BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours and GCS 13-15, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.

Press **CLOSE** when finished reviewing the results.

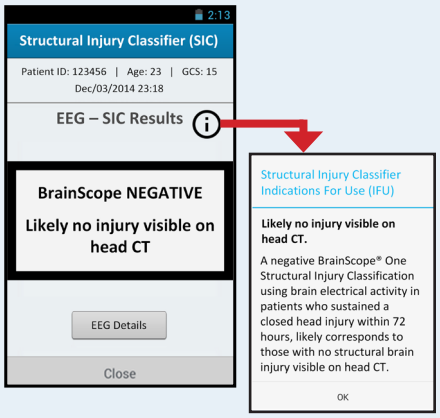


Figure 4-29:
Negative Results

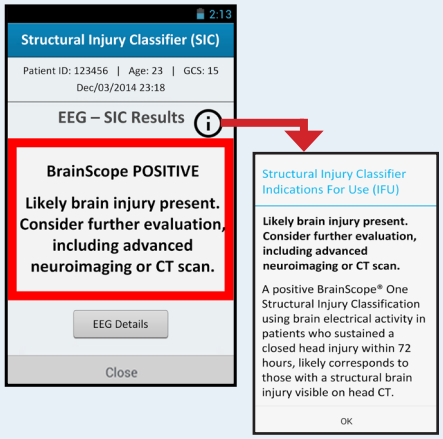


Figure 4-30:
Positive Results

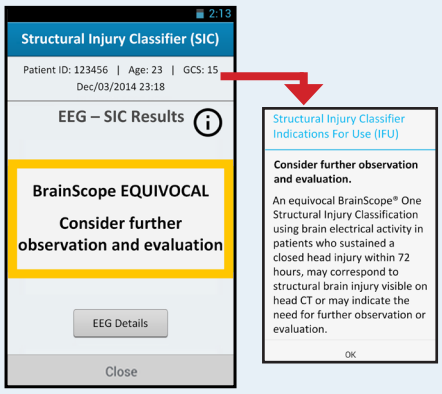


Figure 4-31:
Equivocal Results

If BrainScope One is configured to display the Brain Function Index (BFI), the handheld will navigate to the ***Brain Function Index*** screen. If BrainScope One is configured for Structural Injury Classifier Assessment only, the handheld will return to the ***Information Hub***.

After a Structural Injury Classifier session has been completed, the Structural Injury Classifier section of the ***Information Hub*** (Figure 4-32) will display the results of the test.

Brain Function Index

The ***Brain Function Index Summary*** summarizes the results of the EEG - Brain Function Index assessment (Figure 4-33).

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:

- EEG Details – provides detailed information about the recording

See EEG View Details and EEG Data Review in Chapter 5 for detailed instructions.

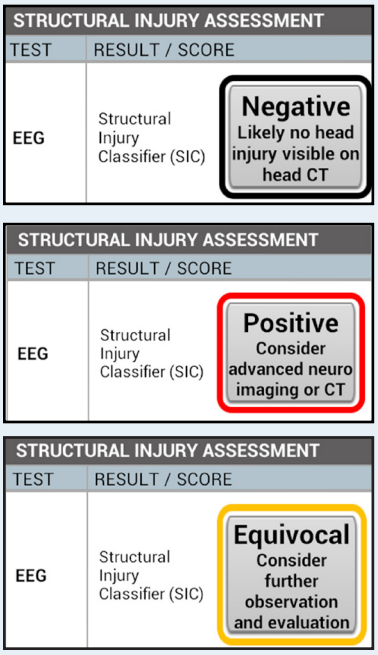


Figure 4-32:
Structural Injury Classifier section of the Information Hub

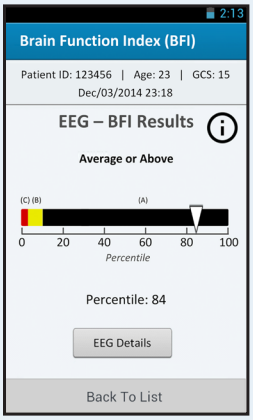
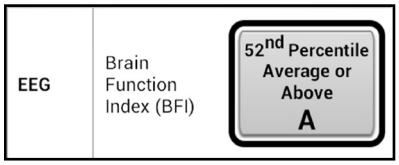
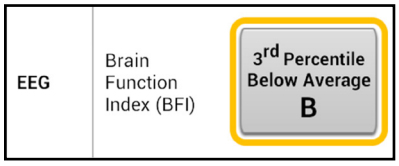


Figure 4-33:
Brain Function Index Results

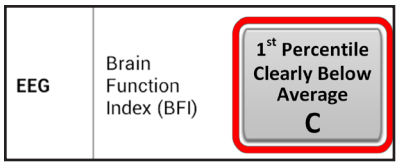
After a Brain Function Index session has been completed, the Brain Function Index section of the ***Information Hub*** screen (See Section 4.3.1 ***Information Hub***) will display the results of the test.



Average or above – patient's BFI result was equal to or above the 10th percentile to the 100th percentile.



Below average – patient's BFI results was equal to or above the 2.5th percentile to the 10th percentile.



Clearly below average – patient's BFI was equal to or above the 0th percentile to the 2.5th percentile.

The BrainScope One'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 func-tional 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% (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.

4.6 Patient Session Closure and Summary Report

To exit the current patient session, select the physical **MENU** button on the handheld to access the ***Main Menu*** (Figure 3-8). See page 4-4 for more information. When exiting a patient session, if all assessments on the Information Hub screen were completed and the Automatic Report Generation option is enabled (See section 3.5.10), the PDF Report message will appear indicating that a PDF summary report is being generated for the session. If the Automatic Report Generation option is disabled, the operator must generate the report manually. A sample PDF summary report that includes all assessments available on BrainScope One can be found in Appendix 2.

The PDF report is stored on the SD card. For technical specifications, please see section 5.4.

To print the report:

1. Connect the device to a computer running Windows 7 or Windows 10 using the micro USB cable (P/N 40-1000-013).
2. Be sure the handheld device is turned ON.
3. BrainScope One will appear on the PC as a MTP (media transfer protocol) device.
4. On your computer navigate to the SD Card, then click **BRAINSCOPE** folder, then **REPORTS**.
5. Choose the appropriate patient folder identified by Patient ID and locate the PDF within the sub-folder.

NOTE: There will only be one PDF report for each patient injury. When new assessments associated with that injury are performed, the PDF is recreated with the newest assessment. Data that was collected previously will also be reflected in the new PDF.

CHAPTER 5: The Patient Database

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

- Patient list
  - Patient demographics and injury information (review and edit)
- Previous tests
  - Detailed results (data review) for EEG

Instructions on how to access previous tests and review details for Vestibular/Balance, Vestibular/Ocular, and Standard Clinical Assessment tests can be found in their respective appendices.

5.1 The Patient List

The ***Patient List*** (Figure 5-1) provides access to all stored information on patients that have been entered into the BrainScope One handheld.

To access the ***Patient List***:

1. Press the physical **MENU** button on the handheld.
2. Press **PATIENT LIST** and login.
   - The ***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.
3. Press on the row of patient name/ID number that you want to view.
4. The ***Patient Injury List*** will display in list form all "Previous Injuries" recorded for that patient.
5. The ***Patient Injury List*** allows for the following actions:
   - New Injury - entry of new injury details (See Section 4.3.4 Patient Information and Injury Entry for instructions)
   - Review - review detailed results on tests performed for that injury (See Section 5.2, 5.3 and 5.4 for instructions)
   - Resume - resume testing for that injury (See Section 4.3.1 BrainScope One Information Hub for instructions
   - Delete Patient - press **DELETE PATIENT** to delete the patient's data from the handheld

NOTE: The ***Patient Injury List*** can also be accessed by selecting **CURRENT PATIENT INJURIES LIST** from the **MENU** during a patient session.

Figure 5-1:
Patient List screens

5.2 Patient Information - Review and Edit

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

Patient Information Detailed Results can be accessed by pressing the pencil icon next to the patient summary while in the ***Information Hub*** (Figure 5-2).

Patient Information Detailed Results (Figure 5-3) will display the summary of patient signs and symptoms information, as well as details about the injury event that were gathered during ***Patient Information and Injury Entry*** (See Section 4.3.4 Patient Information and Injury Entry for more information).

The ***Patient Information Summary*** (Figure 5-3) contains two options to select from:

- Review – access results of all entries
- Edit – edit data recorded

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

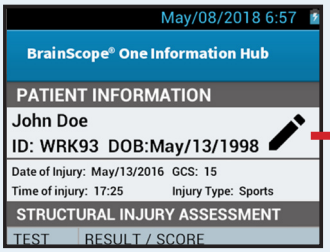


Figure 5-2:
Access to review and edit stored Patient Information

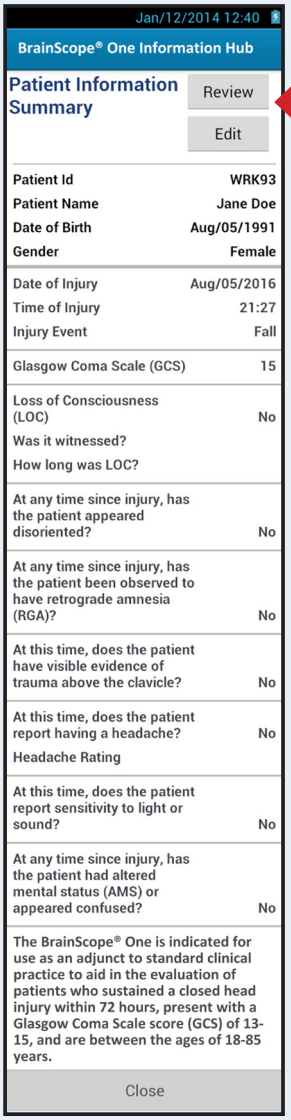


Figure 5-3:
Patient Information Detailed Results

Patient Information – Review

Press **REVIEW** from the ***Patient Information Summary*** to navigate to the ***Patient Information Review*** screens.

An example of a ***Patient Information Review*** screen is shown in Figure 5-4.

To navigate through the ***Patient Information*** screens press **NEXT**.

The ***Patient Information Review*** screens will appear in exact order of ***Patient Information*** and ***Injury Entry*** screens.

At any time press **PREVIOUS** to navigate to the previous page.

From the ***Patient Information Summary Review*** screen press **CONFIRM** to exit review mode and return to the ***Patient Information Detailed Results*** (Figure 5-3)**.**

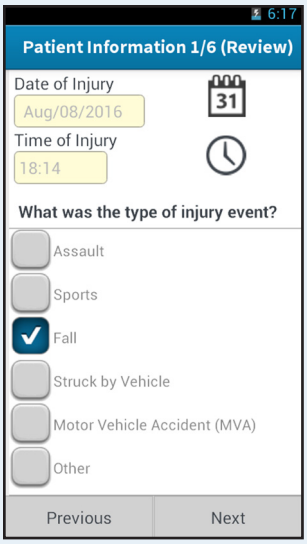


Figure 5-4:
Patient Information Review

Patient Information – Edit

The ***Patient Information Edit*** screens will allow for editing the responses to any of the questions from the ***Patient Information*** and ***Injury Entry*** screens.

Press **EDIT** from the ***Patient Information Summary*** to navigate to the ***Patient Information Edit*** screens.

An example of a ***Patient Information Edit*** screen is shown in Figure 5-5.

The ***Patient Information Edit*** screens will appear in exact order of the ***Patient Information*** and ***Injury Entry*** screens.

All fields on all screens will allow for editing. To navigate through the ***Patient Information Edit*** screens press **NEXT**.

At any time press **PREVIOUS** to navigate to the previous page.

From the ***Patient Information Summary Edit*** screen press **CONFIRM** to exit edit mode and return to the ***Patient Information Detailed Results*** (Figure 5-3).

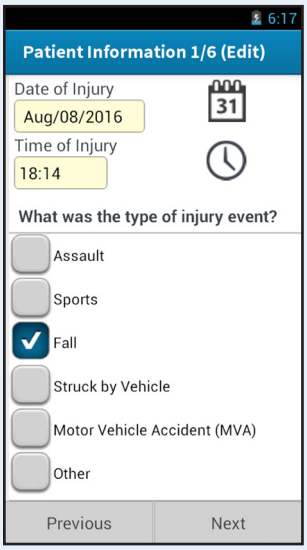


Figure 5-5:
Patient Information Edit

5.3 EEG Results

Detailed results on current and previous EEG tests are stored in the patient database and can be accessed from the ***Information Hub***.

In the detailed results screens the operator can review all tests recorded and start a new EEG test.

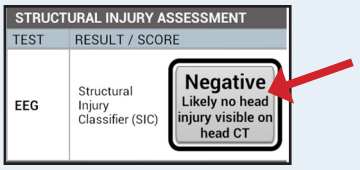


Figure 5-6:
Brain Electrical Activity results area from the *Information Hub*

5.3.1 Structural Injury Classifier Detailed Results

To access the ***Structural Injury Classifier Detailed Results***, press the "Structural Injury Classifier" result (Figure 5-6) from the ***Information Hub***.

NOTE: The ***Structural Injury Classifier Detailed Results*** will default to view the **CURRENT TEST** tab.

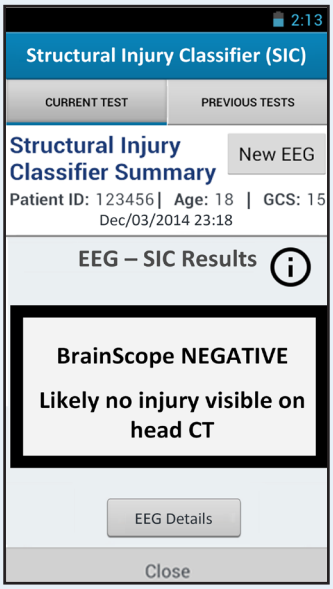


Figure 5-7:
Summary of Structural Injury Classifier (Current Test)

Current Test Tab

Structural Injury Classifier Current Test - Summary (Figure 5-7) contains two options to select from:

- EEG Details – provides detailed information about the recording and playback of the EEG Data session.
- New EEG – start a new EEG test

Press **CLOSE** to return to the ***Information Hub***.

Previous Test Tab

To view previous tests, select the **PREVIOUS TESTS** tab from the ***Structural Injury Classifier Current Test - Summary*** screen.

Structural Injury Classifier Previous Tests Detailed Results (Figure 5-8) lists all tests recorded by test date, time and summary of results.

To view detailed results from a previous test, press the desired test from the "Structural Injury Classifier Tests List".

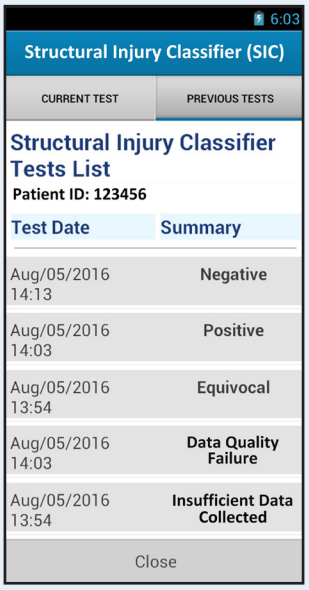


Figure 5-8:
Test list of previous test results

Once a test has been selected from the test lists the ***Structural Injury Classifier Previous Test - Summary*** (Figure 5-9) will appear displaying the test results.

Structural Injury Classifier Previous Test - Summary (Figure 5-9) contains the following option to select from:

- EEG Details – provides detailed information about the recordingand playback of the EEG Data session.

Press **BACK TO LIST** to return to ***Structural Injury Classifier Previous Tests Detailed Results***.

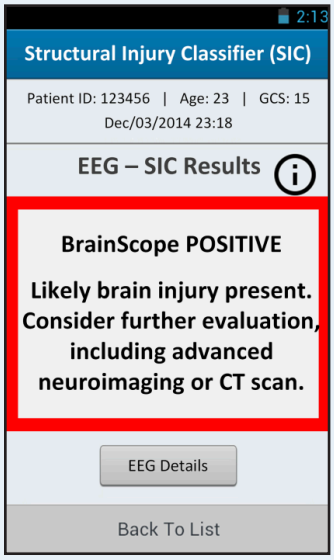


Figure 5-9:
Summary of EEG - Structural Injury Classifier (Previous Test)

5.3.2 Brain Function Index Detailed Results

To access ***Brain Function Index Detailed Test Results***, press the "Brain Function Index" result (Figure 5-10) from the ***Information Hub***.

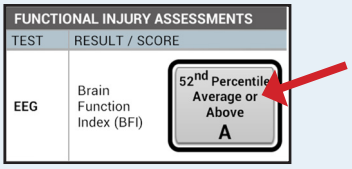


Figure 5-10:
Brain Electrical Activity results area from the *Information Hub*

NOTE: The ***Brain Function Index Detailed Test Results*** will default to view the **CURRENT TEST** tab.

Current Test Tab

The ***Brain Function Index Current Test - Summary*** (Figure 5-11) contains three options to select from:

- EEG Details – provides detailed information about the recording and playback of the EEG Data session.
- New EEG – start a new EEG test

Press **CLOSE** to return to the ***Information Hub***.

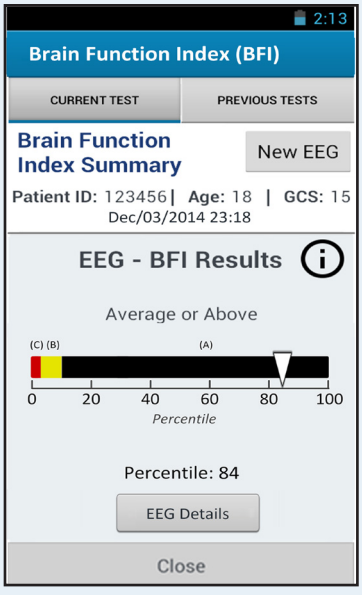


Figure 5-11:
Summary of Brain Function Index (Current Test)

Previous Test Tab

To view previous tests, select the **PREVIOUS TESTS** tab from the ***Brain Function Index Detailed Results*** screen.

Brain Function Index Previous Tests Detailed Results (Figure 5-12) lists all tests recorded by test date, time and summary of results.

To view detailed results from a previous test, press the desired test from the "Brain Function Index Tests List"

Once the test has been selected the ***Brain Function Index Previous Test - Summary*** screen (Figure 5-13) will appear displaying the test results.

Brain Function Index Previous Test - Summary (Figure 5-13) contains the following optionto select from:

- EEG Details – provides detailed information about the recording and playback of the EEG Data session.

Press **BACK TO LIST** to return to the ***Brain Function Index Previous Tests Detailed Results***.

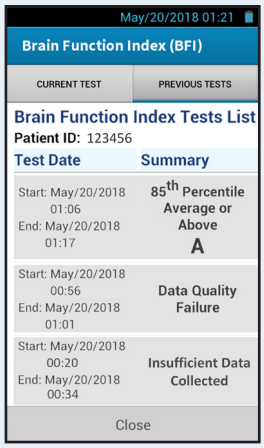


Figure 5-12:
Test list of previous test results

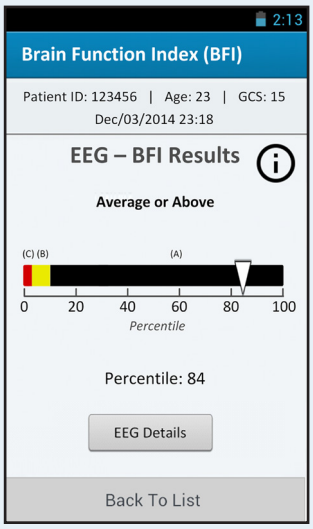


Figure 5-13:
Summary of Brain Function Index (Previous Test)

5.3.3 EEG Details

BrainScope One 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 **EEG DETAILS** 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 pressing the name of the feature. A sample of each of the tables and graphs are provided below (Figure 5-14 and 5-15).

Figure 5-14:
Examples of Spectral Plot Data and EEG Tables of Measures for Mono-polar

To view more data on each screen press the + and - buttons in the top right corner.
(Available on the Spectral Plot Data Screen only)

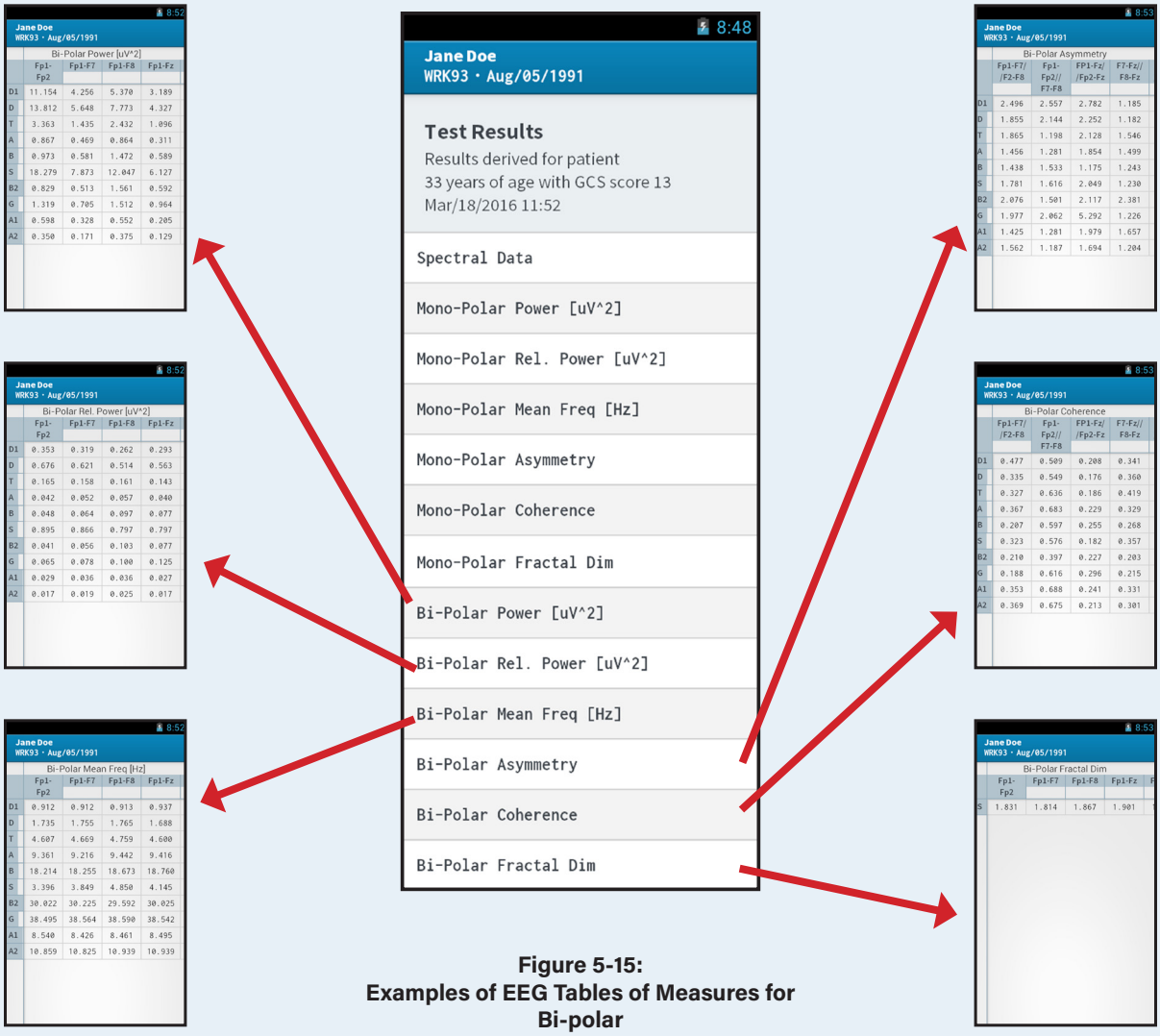


Figure 5-15:
Examples of EEG Tables of Measures for Bi-polar

5.3.4 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 press **EEG DETAILS** and then **DATA REVIEW** in the message box to navigate to ***Data Review***.

Data Review provides the following options:

- Back button – returns to the previous screen
- Round Timer Counter button – displays the Playback Control Menu (Figure 5-17)

Data Review will automatically begin playback of the recorded EEG. Seven (7) raw EEG waveforms will be displayed relative to linked ears (Figure 5-17):

1. "R2", "R1", "C1", "L1", "L2", "L3" and "R3" from the top down if the HEADSET button is selected on the ***Impedance*** screen (Figure 4-17), or
2. "F8", "Fp2", "AFz", "Fp1", "F7", "A1", and "A2" from the top down if the 10-20 button is selected on the ***Impedance*** screen (Figure 4-16).

The **ROUND TIMER COUNTER** button 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, press the **ROUND TIMER COUNTER** button and the ***Playback Control Menu*** screen will appear (Figure 5-17).

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***.

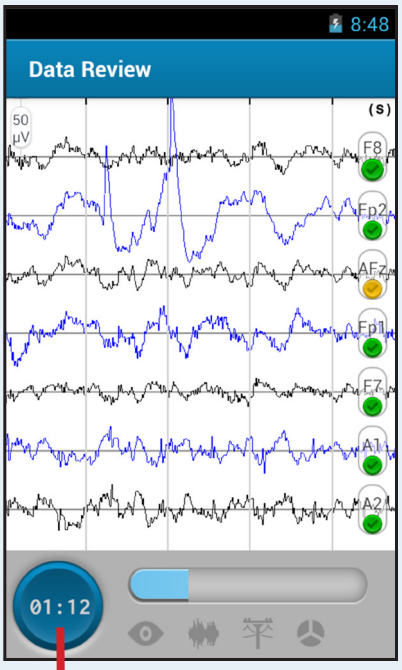


Figure 5-16:
EEG Data Review

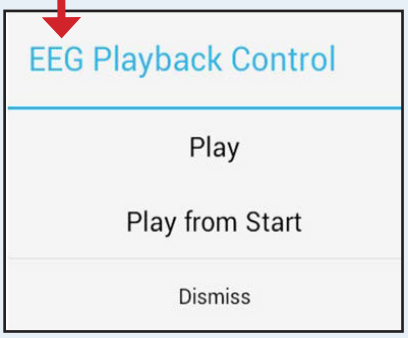


Figure 5-17:
EEG Playback Control

5.3.5 New EEG

To start a new EEG from any of the EEG detailed results screens press **NEW EEG**. The handheld will navigate to ***Headset Placement Instructions*** where testing can begin. (Refer to Section 4.5 for detailed instructions).

5.4 Patient 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 One device will appear on the PC as a MTP (media transfer protocol) device presenting the contents of the SD card. The patient's PDF formatted summary report or data exported can be located on the SD card, using the patient's ID, and then transferred to the desired location on the PC. BrainScope One software updates shall not be performed by the user of the device, see Section 6.4.

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 One 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 One 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 to Use or Maintenance of BrainScope One.

5.5 Exporting Data

The data export options include exporting individual patient data, exporting all patient data, and exporting log files for technical support purposes. The data exported will be available on the handheld via USB connection. See section 5.4 Patient Data Transfer and Networking for information on transferring data from the handheld to a PC. Only Administrators have access to ***Data Export Options***.

1. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS** and log in to the device. Press ***Data Export Options*** and a menu of options will display (Figure 5-18).
3. The ***Data Export Options*** allow for the following manual data export actions:
    - Export Patient Data - select individual patient records to export (Figure 5-19). Press **CONTINUE** to confirm data export. Press **CANCEL** to return to ***Data Export Options***.
    - Export All Patient Data - all patient data stored on the handheld will be exported. Press **CONTINUE** to confirm data export for all patients. Press **CANCEL** to return to ***Data Export Options***.
    - Export Log Files - log files stored on the handheld can be exported. Press **EXPORT LOG FILES** and select the log files to export based on date range. Press **EXPORT LOG FILES** to initiate log file export. Press **CONTINUE** to confirm log file export. Press **CANCEL** to return to ***Data Export Options***.
    - Export Database - the entire database stored on the handheld will be exported. Press **CONTINUE** to confirm database export. Press **CANCEL** to return to ***Data Export Options***.

NOTE: Exported files may include patient data files, device log files, etc. Some of these files may contain PHI that may not be encrypted when exported from the device. Follow your internal procedures to ensure privacy and security of patient information. Contact BrainScope customer support for further details.

NOTE: All patient data is exported in multiple formats including binary files and XML format. The database export will create a database file only (ex. BrainScopeDB.db). All data is stored on the SD Card after the export process is complete.

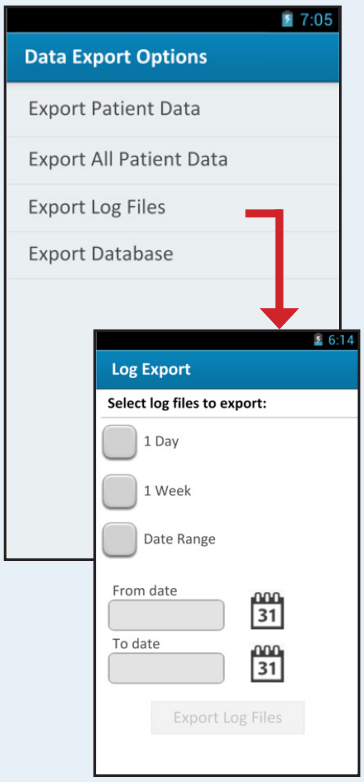


Figure 5-18:
Data Export Options Menu

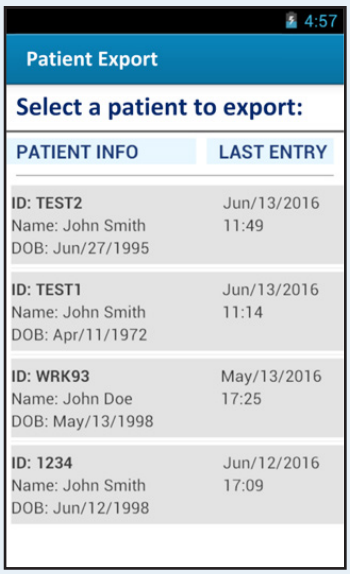


Figure 5-19:
Patient Export

CHAPTER 6: Maintenance

6.1 Cleaning BrainScope One

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.

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 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.

To clean the International Charging Kit:

- The International 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.

6.2 General Maintenance

There are no user-serviceable parts contained within the BrainScope One EEG Acquisition Unit, patient interface, or the International 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 International Charging Kit will void the warranty and may adversely impact handheld performance and safety.

6.3 Preventative Maintenance

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

6.4 Software Update

All software updates shall be performed by BrainScope personnel. If you encounter software related issues please contact BrainScope Technical Support (See Section 6.5).

6.5 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

6.6 Product Life

The BrainScope One EEG Acquisition Unit life is expected to be 5 years with battery replacement expected every 2 years, depending on use. The headset shelf life is 24 months*. 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: Ensure all patient data including any PHI is deleted prior to returning devices to BrainScope Company, Inc.

* 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.

6.7 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. Instructions on how to transfer or export and then delete all such files can be found in Sections 3.5.8 Patient Deletion Settings, 3.5.9 Delete Log File Settings, 5.4 Patient Data Transfer and Networking and 5.5 Exporting Data.

CHAPTER 7: Troubleshooting

7.1 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 the unacceptable impedance value remains, lift electrode, wipe the skin again with the headset skin prep pad (See Section 4.4). 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.

7.2 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 One battery is fully drained, the BrainScope One'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 One, but the software may not immediately apply the automatic change to or from Daylight Savings Time. Restart BrainScope One 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 3.5.7 Device 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. ▪ If the Date/Time is still incorrect, contact BrainScope (See Chapter 10).
Battery Depletion	▪ If BrainScope One shuts down because the battery is fully depleted (see section 3.2), recharge the handheld for a minimum of 4 hours. ▪ If the handheld does not turn on when the green power button is pressed after battery depletion, press and hold the green 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 green 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.

7.3 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.Press **OK** to dismiss. ▪ If the connection is not re-established in 30 seconds, the handheld will power off in 60 seconds. ▪ Press **CANCEL** to dismiss the message. Press **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.	▪ Press **OK** to return to the home screen. ▪ If you wish to start a new EEG session, press **INSUFFICIENT DATA COLLECTED** next to the EEG result and then press **NEW EEG** in the upper right corner. ▪ The same headset can be used for up to 3 EEG sessions. ▪ Follow artifact troubleshooting instructions to reduce artifacts (see Chapter 2, Page 2-3, Step 10)

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

7.4 Micro SD Card

Message	Meaning	Corrective Action(s)
SD Card Full	The SD card has less than 1GB of free space available	▪ Move data off of the SD card, shut down the handheld and re-start the handheld before continuing.

7.5 Other Operational Problems

There are no user-serviceable parts contained within the BrainScope One handheld, DAB, or the International 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 (R-00295) located on the Micro SD Card.

Contact BrainScope Technical Support for any technical issue. See Section 6.5 for more information.

7.6 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. Press the physical **MENU** button on the handheld.
2. Press **ADMINISTRATOR SETTINGS**.
3. Scroll down on the screen and press **RESET DEVICE** (Figure 7-1).
4. A warning box will appear (Figure 7-2). Press **CANCEL** to exit the message and return to the ***Administrator Login*** screen.
5. Press **RESET DEVICE** to initiate the reset.
6. When all patient and operator data have been removed, the handheld will navigate to the ***Information Hub*** (See Section 4.3).

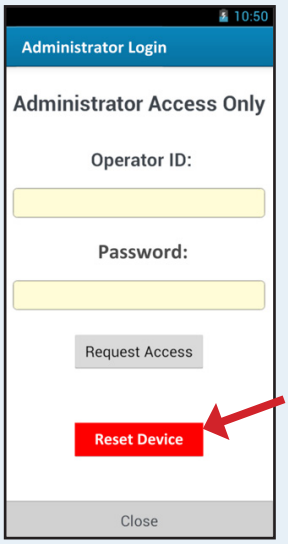


Figure 7-1:
Adminstrator Login

Figure 7-2:
Reset Warning Message

CHAPTER 8: Regulatory Standards

BrainScope One is designed and developed in accordance with the following –

Electrical Safety Standards

BASE

- IEC 60601-1/A1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI ES60601-1/A1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- EN 60601-1/A1:2012 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- CAN/CSA-C22.2 No. 60601-1:2014 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

COLLATERAL

- IEC 60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Emission & Clause 6.2 Immunity Non-Life Supporting Equipment)
- EN 60601-1-2: 2007: AC: 2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Emission & Clause 6.2 Immunity Non-Life Supporting Equipment)
- EN 55011:2009 + A1:2010 (Group 1 Class B Limit)
- ETSI EN 301 489-3 V1.6.1: 2013 (Clause 7.2 Immunity)
- ICES-001, Issue 4: 2006
- FCC Part 15 Subpart B (Class B Limit)
- IEC 60601-1-6/A1:2013 General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability

PARTICULAR

- IEC 60601-2-26:2012 Particular requirements for the basic safety and essential performance of electroencephalographs

BrainScope One is intended for continuous operation, is internally powered and has a protective classification of Type BF. Refer to section 10.6 for additional details.

BrainScope One RF emissions are compliant with Group I, Class B.

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

CHAPTER 9: 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 10: Specifications

10.1 Labeling Symbols

This section contains various international symbols which may appear on BrainScope One 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
	Reference Number
	Serial Number
	Part Number

Symbol	Description
	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
IPN_1N_2	Ingress Protection N1N2 = Rating

10.2 BrainScope One Part Numbers

Item	Part Number
BrainScope One Kit	99-1403-002
EEG Acquisition Unit (Handheld and DAB)	99-1403-004
Micro SD Card	40-1000-070
International Charging Kit	99-1403-028
International Charging Clips with USB-A Charger	50-1000-035
USB-A Charger	40-1000-012
USB-A to Micro-B USB 1ft Cable	40-1000-013
Quick Start Guide	50-1000-172
Safety Summary	50-1000-181
Case Insert	50-1000-040
Electrode Headset	99-1403-202

NOTE: The Micro SD Card stores all data records on the BrainScope One handheld (after data export) along with other important information about the recording including all patient information. High reliability Micro SD cards are supplied by BrainScope for use with the BrainScope One handheld.

WARNING!

- The BrainScope One handheld will only work properly when used with the Electrode Headset.
- Explosion Hazard: DO NOT use BrainScope One in a flammable atmosphere or where concentrations of flammable anesthetics may occur.
- Operate the BrainScope One EEG Acquisition Unit only with the Micro SD cards supplied by BrainScope. Use of any other Micro SD cards could increase the risk of device malfunction and / or cause Micro SD card corruption.

The following BrainScope One EEG Acquisition Unit and Accessories are packaged together as a kit (99-1403-002):

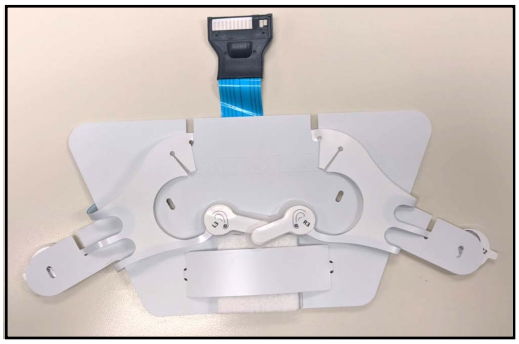
A - EEG Acquisition Unit
- A1 - Data Acquisition Board (DAB) Module
- A2 - Handheld

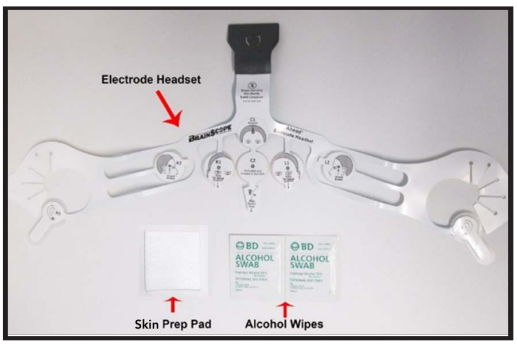
B - International charging Kit
- B1 - USB-A to Micro-B USB 1ft Cable
- B2 - USB-A Charger
- B3 - International Charging Clips with USB-A Charger

C - Quick Start Guide and Safety Summary

D - Case Insert

The Electrode Headset (99-1403-202) is not included as part of the packaged system. Headsets are obtained separately from BrainScope. The user should obtain only Electrode Headsets for use with the BrainScope One EEG Acquisition Unit.





10.3 Technical Specifications

Brain^{S}cope One EEG Acquisition Unit Components Physical Dimensions	
Size (nominal)	Handheld: 82 mm (3.2") x 155mm (6.1") x 25 mm (0.9") 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: 0.4 kg (0.88 lb) DAB: 0.206 kg (0.45 lb)
BrainScope One EEG Acquisition Unit Components Operational Environment	
Ingress Protection	IP54 with DAB Jacket plug inserted
Temperature	0°C to 38°C (32°F to 100°F)
BrainScope One EEG Acquisition Unit Components Transportation and Storage Environment	
Temperature	-40°C to 71°C (-40°F to 160°F)
Altitude	14,000 ft. (4,267 m)
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	
Range	0.1 kΩ to 200 kΩ combined electrodes
Accuracy	Maximum of ±15% or ±500Ω

[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 (480px x 800px)
Size	4.3" diagonal
Battery	
Chemistry	Lithium-ion
Nominal Voltage	3.7 V
Nominal Capacity	3300 mAh
Run-Time	160 minutes assuming equal EEG and non-EEG assessment use. Run-time will vary based on usage.
Longevity	At least 80% 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 4 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

10.4 Protective Classification

BrainScope One 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 One 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 One is connected to an external power source.

10.5 Environment

BrainScope One Components Shipping and Storage

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

The BrainScope One 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 One away from water and other fluids, do not use in wet conditions, and routinely inspect system components for possible exposure to liquid.

10.6 Power Requirements and System Grounding

Use only the BrainScope One USB-A Charger (40-1000-012) and USB-A to Micro-B USB 1ft Cable (40-1000-013) packaged with the BrainScope One Kit.

WARNING!
The BrainScope One 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 One 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.

Electromagnetic Compatibility (EMC)

NOTE:

- Medical electrical equipment such as BrainScope One needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the Instruction Manual.
- All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, transmitted either through air or connecting cables. The term “electromagnetic compatibility” (EMC) indicates the capability of the equipment to curb electromagnetic influence from other equipment, while at the same time not affecting other equipment with similar electromagnetic radiation. Radiated or conducted electromagnetic signals can cause distortion, degradation, or artifacts which may impair BrainScope One’s essential performance (see page

10-7 for table of essential performance). There is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:

  - Re-orient or re-locate BrainScope One
  - Increase the separation between BrainScope One and affected device
  - Consult Technical Support (see Section 6.5 for further suggestions)

- The manufacturer is not responsible for any interference or responses caused by the use of cables and accessories other than those provided (see page 10-11 for list of cables and cable accessories). To comply with the regulations on electromagnetic interference, all cables must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing or responding to radio frequency interference, in violation of FCC regulations.

- Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment such as BrainScope One. Intrinsic RF transmitters such as cellular phones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, should preferably not be operated near BrainScope One. See table on page 10-10 for recommended minimum separation distances between portable and mobile RF communications equipment and BrainScope One. Any electrical device can unintentionally emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified radiation. When BrainScope One is used adjacent to or in close proximity to other equipment the user should be attentive to unexpected device behavior which may be caused by such radiation. BrainScope One is intended for use in the electromagnetic environment specified in the tables below. The user of BrainScope One should assure that the device is used in such an environment.

BrainScope One 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		
BrainScope One is intended for use in the electromagnetic environment specified below. The customer or the user of BrainScope One should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF emissions CISPR 11	Group I	BrainScope One 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 B	BrainScope One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant	

The Essential Performance of BrainScope One is:

- The ability to display accurate results based on clean EEG data
- The ability to measure and display accurate impedance data for each EEG channel, and to prevent display of results if impedance is too high
- The ability to record EEG data with RMS noise below 0.4 µV between 0.67 Hz and 43Hz on all channels
- The ability to prevent display of results if an inauthentic or expired electrode headset is being used for EEG data collection

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
BrainScope One is intended for use in the electromagnetic environment specified below. The customer or the user of BrainScope One 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 61000-4-4	±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 differential ±2 kV common	±1 kV differential ±2 kV common	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	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Mains power quality should be that of a typical commercial 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			
BrainScope One is intended for use in the electromagnetic environment specified below. The customer or the user of BrainScope One 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 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BrainScope One, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended 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: 
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.			

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

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and BrainScope One

BrainScope One is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BrainScope One can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BrainScope One as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	7.3
100	12	12	23

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 One 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: UUSBHAUB1	USB-A to Micro-B USB 1ft Cable	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 Cable Length: 1 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 One must be used with the following accessories included in the International Charging Kit (99-1403-028):

- USB-A Charger (PSA10F-050Q, PSA10F-050QR)
- USB-A to Micro-B USB 1ft Cable (40-1000-013)
- International Charging Clips (included in 50-1000-035)

Limited Warranty

BrainScope Company, Inc., ("BrainScope") warrants, to the original purchaser ("Customer"), that the BrainScope One Reusable System unit(s) (herein referred to as the "Products"), excluding any disposables or consumable supplies provided with or purchased for such units, such as disposable electrode headsets, patient single-use supplies or other accessories, purchased by Customer from BrainScope or a BrainScope authorized distributor are free from defects in materials or workmanship under normal use by Customer for a period of twelve (12) months from the date of shipment. Under this Limited Warranty, BrainScope will repair or replace, at its discretion, any manufacturer's defect in materials or workmanship (subject to the limitations and exclusions set forth below), on Products(s) purchased by Customer from BrainScope or an authorized BrainScope distributor and retained by the Customer. This Limited Warranty is non-transferable. THIS LIMITED WARRANTY SHALL BE IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, NON-INTERFERENCE, SYSTEM INTEGRATION, INFORMATIONAL CONTENT OR DATA ACCURACY, ALL OF WHICH ARE EXPRESSLY DISCLAIMED BY BRAINSCOPE. REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS THE CUSTOMER'S SOLE REMEDY. BRAINSCOPE SHALL NOT BE LIABLE FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES AND EXPENSES, INCLUDING DAMAGES OR INJURY TO PERSON OR PROPERTY, IN CONNECTION WITH ANY BREACH OF THIS WARRANTY. SOME STATES AND JURISDICTIONS MAY NOT ALLOW THESE LIMITATIONS ON WARRANTIES. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE OR JURISDICTION TO JURISDICTION.

Warranty coverage includes:

- Parts* and labor
- BrainScope Customer Technical Support by phone, 24 hours a day 7 days a week
- Loaner unit while out for repair
- Transportation of Products for repair
- Basic functionality training (one time)**
- Software upgrades

* Excludes consumable components such as disposable electrode headsets, patient single-use supplies, filters, batteries, etc.

** Customer will receive training on the operation of the Products after the sale is final, at the Customer's location, at a time that is mutually agreed upon. A User Manual and other user documentation will be provided with each Product, which may not be copied or re-distributed.

** Customer will receive training on the operation of the Products after the sale is final, at the Customer's location, at a time that is mutually agreed upon. A User Manual will be provided with each Product, which may not be copied or re-distributed.

WARRANTY EXCLUSIONS:

This Limited Warranty does not extend to any Products that has been damaged or rendered defective: (1) through normal wear and tear; (2) as a result of failure to follow Products instructions for use and published specifications and/or proper maintenance procedures as described in the Product labeling and published operations and maintenance information; (3) as a result of accident, neglect, misuse or abuse; (4) by the use of parts not manufactured, sold or otherwise authorized by BrainScope for use in or with the Products; (5) by modification of the Products without express written authorization of BrainScope; (6) as a result of service or repair by anyone other than BrainScope authorized repair personnel (other than routine service performed in accordance with the Product's published operations and maintenance information that is not expressly limited to BrainScope authorized personnel), or (7) if Customer uses a Products for non-medical or entertainment purposes or outside the United States. This Limited Warranty does not extend to: (1) damage, including corrosion or Products failure, due to causes beyond BrainScope's control such as, but not limited to, theft, fire, flood, wind, lightening, storm, natural disaster, electrical or power outages and surges, and acts of third parties.

THIS LIMITED WARRANTY IS VOID IF:

- Proof of Customer's original purchase cannot be provided by the Customer; or
- The factory applied serial number has been altered or removed; or
- The Products are used or stored in a manner inconsistent with specifications, including but not limited to electrical systems for which the Products is not designed; or
- Any component parts or patient single-use disposables that are not intended for use with the Products, other than those expressly approved by BrainScope, are used.

CUSTOMER SUPPORT:

BrainScope Customer Support is available by phone to answer questions and provide product-related technical support. To access this service, please call 1-855-9-BRAIN-1 (1-855-927-2461) and ask for product technical assistance.