

**BrainScope® Company Inc.**

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# **Software Release Report & Notes, Release 1801-CUT41-1.5.4.0, Ahead 500**

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## 1.0 Purpose and Scope

This document summarizes the known issues for Ahead 500 BrainScope Software Release. This is a customer-facing document. All the known issues reported in this document are relevant to customers. For a list of all known issues, please contact BrainScope Company.

## 2.0 Introduction

Every BrainScope software release is accompanied by a corresponding release note that describes the features and known issues incorporated into the release.

The known issues listed in this document are such that they do not compromise the primary function of the device and appropriate workarounds are provided for the user and defined for each issue.

## 3.0 Release Notes

### 3.1 Release 1.5.4.0

Table 1 Version Information on the About Screen

<b>Application</b>	1.5.4.0
<b>Firmware</b>	2.12.3599
<b>Algorithm</b>	2.1.156.12
<b>Xloader</b>	2.0.6-B123
<b>Bootloader</b>	2.0.6-B123-8-ge48b989
<b>Kernel</b>	2.0.5-B122-30-g2d5e6a5
<b>Recovery</b>	2.0.6-B123-10-gb49b71f
<b>System</b>	2.0.6-134

### 3.2 Known Issues

Table 2 Known Issues in Release 1.5.4.0

Ticket #	Issue	Type	Component	Severity
#366	<p><b>Description:</b> Cognitive Performance: Volume buttons generate a volume display on top of the assessment screen</p> <p><b>User Impact:</b> A user may be unable to see the content on the screen clearly.</p> <p><b>Summary:</b> A user who attempts to use the volume button during the assessment will generate a temporary volume overlay at the top of the assessment screen.</p>	Issue	Velocity Application	N/A

Ticket #	Issue	Type	Component	Severity
	<p><b>Workaround:</b> This issue can be avoided by not pressing the volume buttons during a cognitive performance assessment. Given that there is no sound output of the device there is no need for the user to control sound. Also, the volume buttons control brightness on other screens, however, a user can establish the brightness level they desire prior to initiating the cognitive performance assessment. In summary, the volume buttons are not needed during the cognitive performance assessment and users should avoid using them. If pressed, the volume display only appears temporarily and is unlikely to compromise a user's ability to read and interact with the screen.</p>			
#380	<p><b>Description:</b> Message Screen 249-M14b Logic Not per SPC-00249 Revision 006  <b>User Impact:</b> User must Click "OK" to proceed to the results, even though the message was only meant to appear when an SIC Positive result was obtained.  <b>Summary:</b> The message informing users that CI does not correspond to a structural injury assessment will appear every time a CI result is calculated, rather than only when an SIC Positive result has been previously obtained for that session.  <b>Workaround:</b> This behavior is considered acceptable and the user does not have to perform a workaround other than clicking "OK" to proceed to the results. The message was intended to appear only when an SIC Positive result was obtained, but the current implementation exceeds the intent of the risk mitigation as the user will now always be informed that CI does not correspond to a structural injury. This does not increase the risk profile of the device and is considered acceptable.</p>	Issue	EEG User Interface Application	N/A
#383	<p><b>Description:</b> Keyboard issues related to</p>	Issue	Standard	N/A

Ticket #	Issue	Type	Component	Severity
	<p>Next/Done buttons</p> <p><b>User Impact:</b> Users will need to hit the mechanical back button to exit the keyboard and then proceed to select whatever next item they choose.</p> <p><b>Summary:</b> In some text fields where users may be entering a longer description, there would not be a "Next" or "Done" type of button for them to press to exit the keyboard and proceed to the next question. This is because the keyboard is providing them the option to start a new line instead.</p> <p><b>Workaround:</b> Users will be able to hit the mechanical back button to exit the keyboard and then proceed to select whatever next item they choose. This is considered to pose no extra risk and it requires minimal user intervention to use the back button to leave the keyboard.</p>		Clinical Assessment: SCAT5	
#405	<p><b>Description:</b> MACE2 Review screens workflow</p> <p><b>User Impact:</b> A user would not be immediately brought to the review screen related to the first screen of patient information they entered.</p> <p><b>Summary:</b> The user would not be brought to the first patient information screen in SCAT5 when they click the review button from the full assessment screen.</p> <p><b>Workaround:</b> The user would not be brought all the way back to the first sequence of SCAT5 information entry screens when they click the review button from the Full Assessment summary screen. However, those review screens are still accessible via the review button on the Concussion Screening summary screen, therefore users have a workaround to access all review screens. There is no known risk associated with this work around and the user is only required to navigate additional screens.</p>	Issue	Standard Clinical Assessment: MACE2	N/A

Ticket #	Issue	Type	Component	Severity
#413	<p><b>Description:</b> Screen Brightness Overlay</p> <p><b>User Impact:</b> The user would notice the screen brightness change when appearing on the Warning Screen, Main Menu, Patient List, and Encounter List.</p> <p><b>Summary:</b> When rebooting the device after setting the brightness below 50%, the user will observe the screen go from a lower brightness level on certain login screens and hub screens to bright on certain information entry screens (it varies based on the screen the user is on). The risk of this issue is considered negligible as the screen brightness is still within normal brightness level ranges which ensures the user is still able to see the screen and functionality of the device is not impacted, only the brightness level of certain screens.</p> <p><b>Workaround:</b> This brightness issue can be resolved by after logging into the device - on the Warning screen, pressing the mechanical back button, or pressing Volume Up / Down to force the Activity to connect to the Brightness Service.</p>	Issue	Main APK	N/A
#417	<p><b>Description:</b> qEEG Feature tables are not displaying when user clicks on Additional Details button</p> <p><b>User Impact:</b> At this time there is no risk of the user encountering an incorrect value in a qEEG feature, however, they will be unable to access the qEEG feature table in its entirety.</p> <p><b>Summary:</b> A user will be unable to access the qEEG feature tables behind the EEG Additional Details button. This has no impact on the calculation of any assessment results and is only additional details related to the collected EEG.</p> <p><b>Workaround:</b> This feature is currently unavailable in the software. There is no user workaround that can be performed to access the table. Based on input from clinical and customer teams, it has been</p>	Issue	EEG User Interface Application	minor

Ticket #	Issue	Type	Component	Severity
	determined that most users will not incorporate the qEEG feature values into their clinical workflows.			
#418	<p><b>Description:</b> Logic Handling Issue with Concussion Index (CI), Procedural Reaction Time (PRT) and Structural Injury Classifier (SIC)</p> <p><b>User Impact:</b> A user may unexpectedly regain access to the CI assessment and be able to complete the assessment even after collecting PRT data prior to EEG.</p> <p><b>Summary:</b> The CI assessment will show Data Quality Failure instead of Assessment Not Available when a separate EEG assessment (SIC in this case) obtains a Data Quality Failure even if PRT was completed before EEG collection. Via the New EEG button provided by a Data Quality Failure, a user could collect EEG after PRT and then compute a CI result.</p> <p><b>Workaround:</b> The scenario where a user would collect PRT first, but desire a CI result, and then regain access to CI through an SIC Data Quality Failure is considered unlikely. However, in that scenario, to prevent CI from being computed when EEG is collected after PRT, a user could create a new session referencing the same injury and then collect EEG before PRT.</p>	Issue	Main APK	minor
#424	<p><b>Description:</b> Logic Handling Issue - SIC/BFI/CI/PRT</p> <p><b>User Impact:</b> A user may unexpectedly regain access to CI after completing PRT before EEG. They could then compute a CI result after collecting EEG after PRT.</p> <p><b>Summary:</b> After running PRT, BFI should replace CI (which is what is happening). However, after running SIC and obtaining a DQF Result, the software should not switch back to CI; it should remain as BFI and display DQF as a result. In addition, if you were to Re-Run an EEG assessment within the CI</p>	Issue	Main APK	minor

Ticket #	Issue	Type	Component	Severity
	<p>test that became available, and EEG data was collected, it would then allow you to use your pre-existing PRT data and not ask to you to re-do PRT.</p> <p><b>Workaround:</b> The scenario where a user would collect PRT first, but desire a BFI result, and then regain access to BFI through an SIC Data Quality Failure is considered unlikely. However, in that scenario, to prevent BFI from being computed when EEG is collected after PRT, a user could create a new session referencing the same injury and then collect EEG before PRT.</p>			
#425	<p><b>Description:</b> Password setting screen dropdown issue</p> <p><b>User Impact:</b> This has negligible impact on the user as they can see they are selecting a dropdown menu related to the number of previous passwords that may not be used, and the occasional omission of the word "passwords" from the dropdown should not change their understanding of the menu.</p> <p><b>Summary:</b> The user will occasionally not be able to see the word "passwords" in the number of previous passwords drop down message. This has negligible impact on the user as they can see they are selecting a dropdown menu related to the number of previous passwords that may not be used, and the occasional omission of the word "passwords" from the dropdown should not change their understanding of the menu.</p> <p><b>Workaround:</b> There is no user work around required for this issue, as they will be able to determine the meaning of the drop down based on the description of the field accompanying the dropdown that indicates it is to select the number of previous passwords which may not be used.</p>	Issue	Device Configuration	N/A