BrainScope® Company Inc.

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Software Release Notes (External), Release 1801-CUT41-1.7.1.0, 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 1.7.1.0

Table 1 Version Information on the About Screen

Application	1.7.1.0
Firmware	2.12.3599
Algorithm	2.1.156.12
Xloader	2.0.6-B123
Bootloader	2.0.6-B123-8-ge48b989
Kernel	2.0.5-B122-30-g2d5e6a5
Recovery	2.0.6-B123-10-gb49b71f
System	2.0.6-134

3.2 Known Issues

Table 2 Known Issues in Release 1.7.1.0

Ticket #	Issue	Severity
#470	**Description:** The file pathway location displayed for PDF reports exported via the multiple-PDF export feature does not match the actual file path on the device. **User Impact:** A user may be unable to immediately locate PDF reports generated on the device's storage media **Summary:** A user who attempts to generate PDF reports for multiple patients will be presented with a dialog box indicating that the generated PDF reports are stored on SD Card within Patient Files. Upon connection of the device to a PC, the user may notice that there is no Patient Files folder on the SD card, instead only an Assessment results folder, where the PDFs are stored. **Workaround:** The user has only one folder after export and as such can open the Assessment Results folder to access the PDF reports generated.	N/A

Ticket #	Issue	Severity
#472	**Description:** In mTBI Triage workflow, if a Patient ID collision (duplicate patient ID present on device) occurs and the Patient ID is updated to be unique, user will not be able to proceed past the date of birth screen. **User Impact:** A user may be unable to continue through the mTBI workflow even after correcting the Patient ID with a non-conflicting Patient ID. **Summary:** A user who attempts to correct a Patient ID collision by going back to the Patient ID screen and modifying the input will be allowed to move forward to the date of birth entry screen. Once a date of birth is entered, the software will not allow a user to proceed forward. This is isolated to the case where a colliding Patient ID has been corrected and is deemed low occurrence. **Workaround:** From the Date of Birth screen, the mechanical back button can be used to back out of the mTBI flow (two screens). At this point a user can re-start the mTBI triage workflow and enter the correct Patient ID.	N/A
#474	**Description:** In mTBI Triage workflow, if a patient has a resulting BFI of 2.5th percentile, the screen will show 2nd percentile. **User Impact:** A user may be confused by the discrepancy in mTBI mode between the 2nd percentile shown in text versus the arrow on the scale showing 2.5th percentile. **Summary:** If a patient has a resulting BFI of 2.5th percentile, this falls directly on the cutoff between Below Average and Clearly Below Average. The user interface correctly displays the arrow on the sliding scale at the 2.5% mark and the text indicates the patient is in the Below Average category, however the percentile is labeled incorrectly as 2nd percentile. In large sample sizes of clinical data collected, less than 3% of participants fell directly on the cutoff of 2.5th percentile. **Workaround:** The patient assessment can be reviewed in Concussion Assessment and Patient Management mode to review the resultant 2.5th percentile and on the PDF report.	Low

Ticket #	Issue	Severity
#366	**Description:** Cognitive Performance: Volume buttons generate a volume display on top of the assessment screen **User Impact:** A user may be unable to see the content on the screen clearly. **Summary:** 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. **Workaround:** 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.	N/A
#405	**Description:** MACE2 Review screens workflow **User Impact:** A user would not be immediately brought to the review screen related to the first screen of patient information they entered. **Summary:** The user would not be brought to the first patient information screen in MACE2 when they click the review button from the full assessment screen. **Workaround:** The user would not be brought all the way back to the first sequence of MACE2 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.	N/A

Ticket #	Issue	Severity
#413	**Description:** Screen Brightness automatically changed during transition to specific screens. **User Impact:** The user would notice the screen brightness change when appearing on the Warning Screen, Main Menu, Patient List, and Encounter List. **Summary**: 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. **Workaround:** 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.	N/A
#417	**Description:** qEEG Feature tables are not displaying when user clicks on Additional Details button **User Impact:** 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. **Summary:** 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. **Workaround:** 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 determined that most users will not incorporate the qEEG feature values into their clinical workflows.	Minor
#432	**Description:** Overlapping PDF Report Content **User Impact:** This has negligible impact on the user given that there is no risk of incorrect results and users are still able to access all results normally via the device. **Summary:** A user would observe a header bar on the PDF report overlapping with some of the norms comparison data. This has negligible impact on the user given that there is no risk of incorrect results and users are still able to access all results normally via the device. **Workaround:** Users can access all results normally via the device.	Minor