# BrainScope® Company Inc.

**Document #:R-00522 R001**

# Software Release Notes (External), Release 1801-CUT41-1.6.1.0, Ahead 500

Author(s): BrainScope Software Team

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Page 1 of 6

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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.

Confidential     Page 2 of 6

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## 3.0    Release Notes

### 3.1    Release 1.6.1.0

Table 1 Version Information on the About Screen

| | |
|---|---|
| **Application** | 1.6.1.0 |
| **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 1.6.1.0

| Ticket # | Issue | Severity |
|---|---|---|
| #366 | **Description:** Cognitive Performance: Volume buttons generate a volume display on top of the assessment screen<br>**User Impact:** A user may be unable to see the content on the screen clearly.<br>**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.<br>**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 |

| Ticket # | Issue | Severity |
|---|---|---|
| #380 | **Description:** Message Screen 249-M14b Logic Not per SPC-00249 Revision 006<br>**User Impact:** 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.<br>**Summary:** 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.<br>**Workaround:** 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. | N/A |
| #383 | **Description:** Keyboard issues related to Next/Done buttons<br>**User Impact:** Users will need to hit the mechanical back button to exit the keyboard and then proceed to select whatever next item they choose.<br>**Summary:** 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.<br>**Workaround:** 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. | N/A |
| #405 | **Description:** MACE2 Review screens workflow<br>**User Impact:** A user would not be immediately brought to the review screen related to the first screen of patient information they entered.<br>**Summary:** 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.<br>**Workaround:** 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. | N/A |

| Ticket # | Issue | Severity |
|---|---|---|
| #413 | **Description:** Screen Brightness Overlay<br>**User Impact:** The user would notice the screen brightness change when appearing on the Warning Screen, Main Menu, Patient List, and Encounter List.<br>**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.<br>**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<br>**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.<br>**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.<br>**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 |

| Ticket # | Issue | Severity |
|---|---|---|
| #425 | **Description:** Password setting screen dropdown issue<br>**User Impact:** 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.<br>**Summary:** 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.<br>**Workaround:** 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. | N/A |
| #432 | **Description:** Overlapping PDF Report Content<br>**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.<br>**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.<br>**Workaround:** Users can access all results normally via the device. | Minor |
| #435 | **Description:** Central Daylight Time (CDT) Zone reverts to Central Standard Time (CST) Zone<br>**User Impact:** This has negligible impact on the user given that there is no risk of incorrect results. Furthermore, this will impact users in the Central time zone only.<br>**Summary:** When attempting to update the time zone from Central Standard Time to Central Daylight Time, during a specific time of the year, a user may note that both time zones reflect the same UTC offset and if daylight time is selected, the time is not updated and may be off by one hour. This has negligible impact on the user given that there is no risk of incorrect results.<br>**Workaround:** During the time period where this issue may surface, a user may opt to change the time zone to Eastern Standard Time (EST) since both EST and CDT have the same -05:00 offset from Coordinated Universal Time (UTC). | Minor |