BrainScope®

Software Release Notes

Release 1.7.1.1

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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.

2

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.

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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.

4

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. percentile.

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.

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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.

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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.

7

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.

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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.

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Description:
Hub Screen SIC Information Button: Still references prior "Positive" result terminology instead of "Evaluate"

User Impact:
A user may be confused by the message which continues to use the previous SIC result terminology of "Positive" instead of "Evaluate". There is no other impact expected as the actual result outputs of SIC are accurate.

Summary:
When a user navigates to the main hub with SIC enabled and click on the information "i" button next to the SIC assessment, the user would observe a message which references the previous SIC result term of "Positive" instead of "Evaluate".

Workaround:
There is no workaround for this message text. However, users will see the correct result terminology in all other parts of the device GUI and results outputs.

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Description:
Glitch of BFI Score 100

User Impact:
When a user has a BFI computation out of range (0-100th percentile), no BFI score will be reported.

Summary:
When BFI computation is within range, the BFI score is correctly returned; however, when the BFI computation is out of range (0-100th percentile), no BFI score will be reported.

Workaround:
There is no current workaround for this issue. However, the likelihood of the occurrence of this issue is extremely low.

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Description:
Cognitive Performance Norms Comparison Group Table Discrepancy

User Impact:
When viewing the cognitive test summary, a user would observe discrepancies in the Norms Comparison Group table on the device and on the PDF report. However, this does not impact the calculation of the user's scores.

Summary:
The Go/No Go Comparison Group displays discrepancies. This does not impact the calculation of the percentile scores for a patient session. This is purely an issue with the display and printing of the comparison group data.

Workaround:
There is no workaround for this issue, however this display discrepancy does not impact the accuracy of the patient's percentile scores.

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Description:
GCS Calculator Bug

User Impact:
A user is only impacted if they select a GCS score prior to using the GCS Calculator and the calculated value is greater than the value initially selected.

Summary:
If a user has selected a GCS option, either one of the three listed or a number from the GCS drop-down menu, then tries using the GCS calculator, the GCS selection only gets updated to the calculated value only if it is greater than the value picked earlier. This bug is only found in "Concussion Assessment and Patient Management" mode, and not in "mTBI Triage" mode.

Workaround:
If a GCS score is selected prior to using the GCS calculator, then the user can manually re-select the new correct GCS value afterwards.