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## CSMP – Field Advisory Notice (FAN)

TrakStation QC test function (1.1.0 & 2.1.0 SW versions)

220121TAB0024

### Background

The TrakStation’s QC Alignment test function in software versions 1.1.0 and 2.1.0 contains additional steps to prevent unanticipated adjustments to the TrakPod optical settings. The initial steps evaluate QC tolerance, but do not make any adjustments. If the QC evaluation is within tolerance, the user will receive a passing QC test result. If the QC evaluation is out of tolerance, the test will fail and the user will have additional opportunities to perform the test.

If the QC test fails three (3) times, the user may then perform a TrakPod Realignment, which adjusts the TrakPod’s optical settings as needed. Following a successful TrakPod Re-alignment, the TrakPod has passed QC testing and the user may continue with their pH monitoring.

### Identified Issue and analysis

The QC test steps in Software versions 1.1.0 and 2.1.0 did not apply values appropriately during the initial QC evaluation steps, impacting QC test outcomes on select TrakPods. Affected users report that a QC failure – QC Re-alignment success cycle repeats every time their QC test is run.

### Impact to Owners

A software patch will be made available. In the meantime, users experiencing a repeating cycle of QC test failures and QC Realignment successes should temporarily discontinue their QC testing until a software patch is available. The passing re-alignment step indicates that the TrakPod is functional and does not require any further adjustments.

Users experiencing repeated failures with the re-alignment step should contact our support team at [support@safesens.com](mailto:support@safesens.com) for further advice.

### Procedure

BCSI will inform the user base when the software patch is available. Please contact our support team at [support@safesens.com](mailto:support@safesens.com) if you require more information on this issue.

Thank you for your continued interest in the SAFE Sens products.

Logan Crecraft  
Software Developer I / QC Leader  
Blood Cell Storage, Inc.

22 January 2021

Date

Transmittal & receipt acknowledged by CSMP

Signature

Date