



Blood Cell Storage, Inc. (BCSI)
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05 February 2018

CSMP – Field Advisory Notice (FAN)

SAFE Sens TrakPod Electro Magnetic Interference (EMI)

050218POD0014

Identified Issue

Multiple sites reported “variability” in TrakPod readings during routine pH monitoring. The behavior presented as rapid fluctuations in pH readings, and was not typical or expected of pH measurements taken with the SAFE Sens system.

Analysis

The pH monitoring data from the affected customer sites showed the TrakPod’s fluorescent signals varying from reading to reading, in some case by significant counts. The behavior appeared situational, seemed specific to the TrakPod when placed in a certain condition, and could not always be replicated upon examination. Further investigation found that sufficiently-powerful localized Electro-Magnetic Interference (EMI) may influence the behavior of the current TrakPod design. EMI causes variability in TrakPod measurements, manifesting as noisy pH data. See Figure 1.

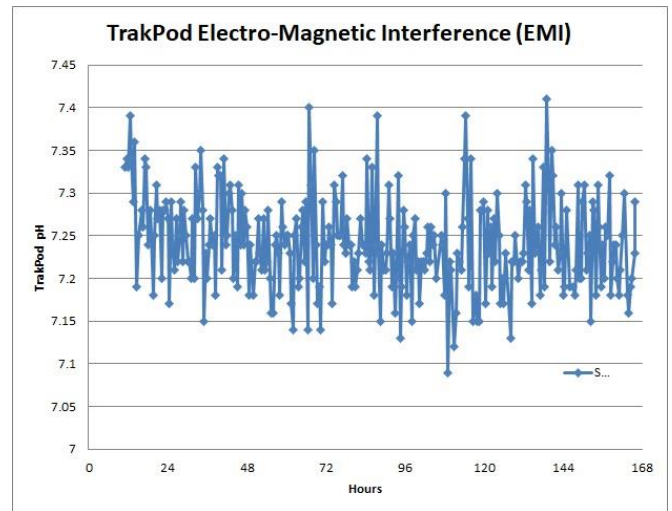


Figure 1: TrakPod Electro-Magnetic Interference (EMI) - Example

Impact to Owners

Most TrakPods do not exhibit noisy pH data from EMI Interference. However, in instances where this behavior is observed, the user may not be able to get consistently meaningful pH monitoring data until the issue has been addressed. The proposed solution has been shown to address this behavior under certain conditions, but is not guaranteed in all environments.

Procedure

Service Plan instructions and materials for impacted users are provided by BCSI. Please contact our support team at support@safesens.com for more information on servicing this issue.

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

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05 February 2018

Date

Transmittal & receipt acknowledged by CSMP

Signature

Date