



Blood Cell Storage, Inc. (BCSI)
4203 23rd Ave W
Seattle, WA 98199

07-June-2022

CSMP – Field Advisory Notice (FAN)

sv² sensor pHID characters - 0 vs O

070622SV20029

Identified Issue & Analysis

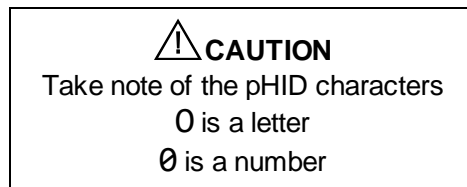
Each lot of sv² sensors has a unique pHID code assigned during calibration at manufacture. This pHID code is entered into the TrakStation when a pH test is started, and tells the system how to interpret the fluorescent properties of that lot. pHID codes typically consist of a combination of numbers, letters, and symbols. They may contain the number zero “0” or the letter “O.” These two characters can inadvertently be interchanged during use if the distinction on the product labeling is not obvious to users.

Impact to Owners

Inadvertently swapping the number “0” and the letter “O” will have an impact on how the system interprets the pH values. If these characters are exchanged, then the pH difference may be substantial, and appear as unexpected or unacceptable performance for the user. The pH may suddenly appear unacceptably high or low.

Procedure

If unexpected performance occurs with a new pH test, then users should check that the appropriate pHID is entered into the TrakStation. With the pHID codes on the sv² sensor kit labeling, the number “0” will always have a slash through it, while the letter “O” will not. An extra label will also be added to kits with pHID codes that contain either of these characters, to better illustrate the distinction for the user. This extra label content is below:



Thank you for your continued interest in the SAFE Sens products. Please contact me should you require additional information.


Elaine Neyens
Operations Director
Blood Cell Storage, Inc.
support@safesens.com

24 June 2022
Date

Transmittal & receipt acknowledged by CSMP

Signature

Date