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04 November 2021

## CSMP – Field Advisory Notice (FAN)

QC2 Alignment Tool - Water Tight Design Update

041121QC20026

### Identified Issue

The QC2 tool has previously been subject to damage when the optical surface was exposed to liquids. As a result, it was not possible to fully clean and disinfect the QC2 tool. Use of the tool on a weekly basis would require disinfecting the incubator chamber that contains the TrakPod fiber optic.

### Analysis

The design of the QC2 tool has changed such that the optical components are now sealed in a water tight method, preventing damage to those components when exposed to liquids including those used for cleaning or disinfection. The design has also been modified such that there are no hard-to-reach crevices, and it is now possible to fully clean and disinfect the product following the same validated instructions for disinfecting incubator chambers.

### Impact to Owners

The updated QC2 tool is now fully cleanable and may be disinfected. Use of liquids on any part of the QC2 tool is acceptable. The QC2 tool should be fully dried prior to use during a QC alignment test with a TrakPod and TrakStation.

The updated QC2 tool has a new exterior shape and current users will notice the difference to the part. Part of the change means that the QC2 tool does not stand up vertically as easily and care should be taken such that when the QC2 tool is laying sideways that it does not roll off a work bench. As with the previous design, users should continue storing their QC2 tool protected in the provided packaging when not in use.

### Procedure

The same cleaning and disinfection protocols for your incubator may be applied to the new QC2 tool. Liquids including OOSAFE, water, and ethanol have been verified to not impact the QC2 tool’s optical performance.

This change begins with QC2 tools starting with serial numbers Y000. Please contact me should you require additional information. Thank you for your continued interest in the TrakStation system.

Steve Geelhood  
Business Director  
support@safesens.com

04 November 2021

Date

Transmittal & receipt acknowledged by CSMP

Signature

Date