TECAN.

Field Safety Notice

1   Urgent safety notice

Urgent advice on starting up EVOware Version 1.4 (that includes SOE Version 1.1) twice.

2   Dear customer

During regular post market surveillance activities Tecan Schweiz AG has recognized an unanticipated customer complaint for laboratories running pooling applications. Depending on your implemented laboratory process this may negatively influence your daily work.

3   Subject

All Tecan Schweiz AG customers using the following laboratory equipment combination are potentially affected by this event.

Freedom EVO Clinical (xxx) using
EVOware Version 1.4 as a base software, and using
SOE Version 1.1 for pooling and sample distribution purposes.

Your laboratory has been identified as being potentially affected.

4   Reason for the Field Safety Notice

Whenever EVOware is started up while EVOware is already running you laboratory will be confronted with the sequence described below.

EVOware will prompt restarting with the following dialog which allows you to detect the error.
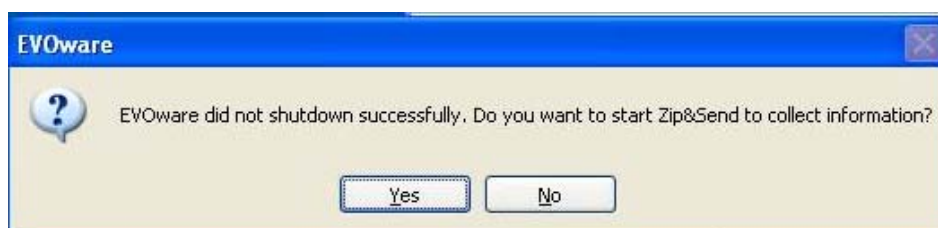
Upon confirmation of the message a system internal communication error will inhibit proper internal system communication between EVOware and SOE. In this particular case the system will react in the same way whether you click Yes or No.

5 Hazards associated with the specific failure

Communication between EVOware and SOE breaks down, preventing newly read barcodes being send from EVOware to SOE. As a result, the IDs of the previous run may be taken instead of the IDs of the actual barcode samples. This may happen whenever an operator tries to start EVOware while EVOware is already running.

For pooling applications this may have serious consequences such as:

• Wrong sample IDs in pool file (LGC or TPL). The file contains the IDs from the previous run.

• Samples are not pipetted. The number of samples pipetted is the same as the previous run.

6 Recommended action

Before starting EVOware make sure the software is not already running.

If this situation will occurs in your laboratory and the EVOware dialog shown in section 4 is displayed, the following procedure must be followed.

• Close EVOware
• Shut down the computer system
• Restart the computer and EVOware again
• Repeat the testing

7 Contact point

Tecan Schweiz AG is developing a technical solution to eliminate the possibility of the described malfunction. You will be contacted once the solution is available.

We apologize for any inconvenience caused by this issue.

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