

Asnières, May 16th, 2012

Reference: RC-12-0005

URGENT FIELD SAFETY NOTICE
COMBINED USE OF AN EXTERNAL PRINTER WITH THE CUSTOMER PRINTOUT
MODE OF STA SATELLITE®

Dear Madam, Dear Sir,

You are currently a user of our automated haemostasis instruments STA Satellite®. We have detected an issue regarding the combined use of an external printer with the customer printout mode of this instrument.

Please find hereafter some information related to this subject.

✓ **Identification and description of the defect:**

Following a customer complaint, we have investigated and confirmed a potential risk of printing mismatch when using an external printer on STA Satellite®.

It occurs:

- under very specific printing conditions: only when using the customer printout mode (see § 8.8 of the STA Satellite®'s reference manual),
- randomly and with a low occurrence.

It only concerns the secondary units: INR (International Normalized Ratio) or seconds for PT tests (in both cases, the primary unit is %) or ratio for APTT tests (primary unit: seconds). The associated results can be erroneously printed (zero or wrong value) **even if information are correctly displayed on the instrument screen.**

In any case, the primary units are not affected and could help to detect a potential mismatch with a secondary unit.

The risk is null when using:

- a LIS (Laboratory Information System) which manages the printouts,
- the classical printout modes with external printers: "single file" and "all files" (see § 8.5.6 of the STA Satellite®'s reference manual),
- the integrated printer of the STA Satellite®.

Therefore, there is no risk for your laboratory if you do not use the customer printout mode of STA Satellite®.

✓ **Actions :**

A corrective action has been identified and a solution is currently being developed to remove this potential defect. Pending the availability of this solution:

- If you still want to use the customer printout mode, we ask you to **activate the "Stop Sample Pipetting" function before printing.** This action prevents the defect from occurring. In order to activate this function, you have to access to the "Status" sub-menu and switch the option from NO to YES (see § 10.1.5.1 of the STA Satellite®'s reference manual).
- You can also use one of the other printing modes described above, which are not concerned by the defect.

Your Competent Administrative Authority has been informed regarding this issue.

For additional information, please contact Stago distributor or affiliate.

Please accept our apologies for this inconvenience.

We are thanking you in advance for your confidence.

Sincerely yours,