

ELITech V-Twin Analyzer

Sample Result/Patient ID Mismatch

Our records indicate that your facility may have received the following product:

Table 1. Affected Products:

System	Catalog Number	Siemens Material Number	Lot Numbers	First Shipment Date
ELITech V-Twin® Analyzer	6002-800	10462027 10462487 10457145	3-3021 through 18-3345	April 2003

Reason for Correction

Siemens Healthineers is issuing an Urgent Field Safety Notice on behalf of ELITech, the Legal Manufacturer of the V-Twin Analyzer.

ELITechGroup B.V. has found the following issue during in-house testing. In very rare cases there is a possibility that during a run, the instrument may aspirate sample from the wrong sample container resulting in “a sample result and patient ID mismatch.” If not detected, this may lead to an incorrect patient report.

As the distributor of the V-Twin product, Siemens is informing our customers of this issue reported by ELITech.

The probability of this scenario occurring is very low. ELITech internal investigations have shown it can only happen if all of the following conditions are met:

1. PSID function of the instrument is enabled;
2. The balance between tests requested from the left reagent rotor and the tests requested from right reagent rotor for the total workload of the run is not optimal (for example 10 tests from the right and 1 from the left);
3. The verification barcode scanning that occurs immediately before sampling, finds no barcode (e.g. non-barcoded tubes are used, barcode is not read), triggering a “b” test flag with the result and this flag is ignored and accepted by the operator.

Actions to be Taken by the Customer

- To guarantee a safe operation of the referenced products the following instructions **must** be followed:
 - In case PSID is switched off by default; no further action required.

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- In case non-barcoded sample containers are used disable the PSID in all instances.
 - In case barcoded sample containers are used and they are positioned by using the PSID functionality or manually assigned a position, please pay attention to a “b” flag or “barcode not scanned” flag. The b-flag may appear with the result if during the run the barcode could not be verified. Whenever a b-flag is present reject the result and repeat the test for the requested sample.
- **Disable the PSID** - Please follow the instructions below to disable the internal barcode reader. Disable PSID when non-barcoded sample containers are used.

Disabling the System Barcode:

1. From the Main Menu, Click **F5 Special Functions**.
2. Click **F2 Installation**
3. Select **System parameters**
4. Set **Use system barcode to NO**

For more information about the system parameters see the V-Twin Operator’s Manual chapter **3.2.5 System parameters**).

➤ **“b-flag” (barcode not scanned):**

Just before sampling the instrument will scan the barcode. When it cannot read the barcode a “b-flag” will appear with the result. Whenever the “b-flag” appears, reject the result and repeat the test.

Please check the custom automatic evaluation setting for the “b-flag” in the [Install menu]. For your convenience you can use the custom automatic evaluation setting and set the “b-flag” to REJECT. In this situation the result will always be rejected. Please make sure that the setting is NOT set to ACCEPT (for more information about the custom automatic evaluation see the V-Twin Operator’s Manual chapter 5.9.4 Custom automatic evaluation and rerun).

- Complete and return the Field Correction Effectiveness Check form attached to this letter to Siemens within 7 days. **Do not send this information to ELITech.**

ELITechGroup is working with the highest priority on a permanent solution to this problem. When a permanent solution is released from ELITech, Siemens will contact you concerning the next step.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. **If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support Representative.**

V-Twin is registered trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

**ELITech V-Twin Analyzer
Sample Result/Patient ID Mismatch**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, Syl-19-01.A.OUS, dated December 2018 regarding ELITech V-Twin Analyzer, Sample Result/Patient ID Mismatch.

Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice and accompanying Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Customer Sold To #:

Customer Ship To #:

To fax this completed form please send it to your local Siemens Technical Support Representative. If you have any questions, contact your local Siemens Technical Support Representative.

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Urgent Field Safety Notice

Commercial name of the affected product: V-Twin
FSCA-identifier: PR4670_181
Type of action: For Immediate Action

Date: 15 November 2018, updated version: 22 November 2018, 2nd update: 30 November 2018

Attention: **all users of the V-Twin analyzer**

Details on affected devices:

Product name	Catalogue number	Serial numbers
V-Twin	6002-800	From 3-3021 till 18-3345 (sold from April 2003 till November 2018)
V-Twin US	6002-850	From 3-3006 till 9-4037 (sold from February 2003 till January 2009)



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Description of the problem:

ELITechGroup B.V. (the manufacturer of the V-Twin) has found during in-house testing the following issue. In very rare cases there is a possibility that during a run, the instrument may aspirate sample from the wrong sample container resulting in “a sample result and patient ID mismatch”. If not detected, this may lead to an incorrect patient report.

The probability of this scenario occurring is very low. As internal investigations have shown it can only happen if **all** of the following conditions are met:

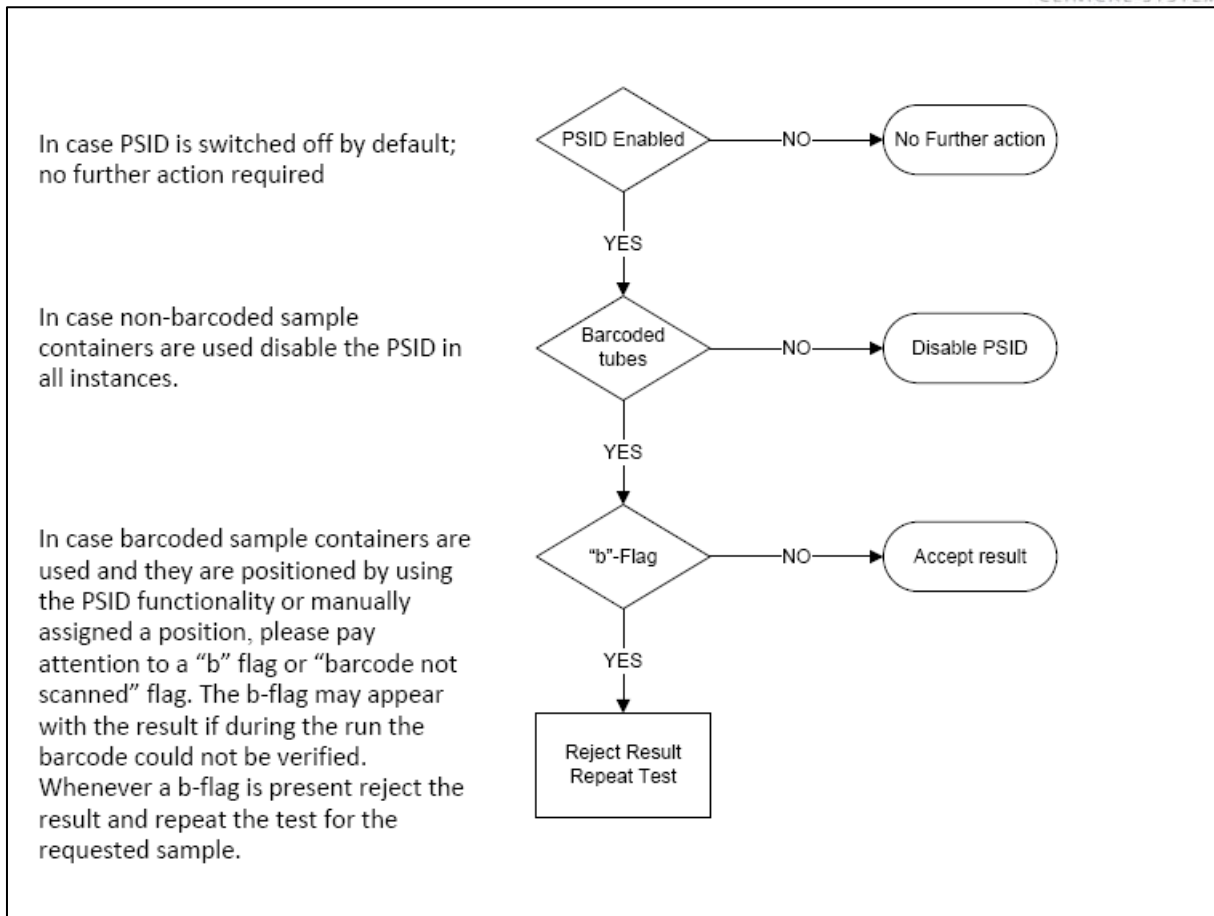
1. PSID function of the instrument is enabled;
2. The balance between tests requested from the left reagent rotor and the tests requested from right reagent rotor for the total workload of the run is not optimal (for example 10 tests from the right and 1 from the left);
3. The verification barcode scanning that occurs immediately before sampling, finds no barcode (e.g. non-barcode tubes are used, barcode is not read), triggering a “b” test flag with the result and this flag is ignored and accepted by the operator.

Action to be taken by the user:

ELITechGroup is working with the highest priority on a permanent solution to this problem. Pending this permanent fix, we are requesting your cooperation to carry out this **mandatory instruction** for each active analyzer used.

To guarantee a safe operation of the referenced products the following flowchart and instruction **must** be followed:

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Disabling the PSID:

Please follow the instructions below to disable the internal barcode reader. Disable PSID when non-barcoded sample containers are used.

Disabling the System Barcode:

- 1.From the Main Menu, Click **F5 Special Functions**
- 2.Click **F2 Installation**
- 3.Select **System parameters**
- 4.Set **Use system barcode** to **NO**

For more information about the system parameters see the V-Twin Operator’s Manual chapter **3.2.5 System parameters**).

“b-flag” (barcode not scanned):

Just before sampling the instrument will scan the barcode. When it cannot read the barcode a “b-flag” will appear with the result. Whenever the “b-flag” appears, reject the result and repeat the test.

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Please check the custom automatic evaluation setting for the “b-flag” in the [Install menu]. For your convenience you can use the custom automatic evaluation setting and set the “b-flag” to REJECT. In this situation the result will always be rejected. Please make sure that the setting is NOT set to ACCEPT (for more information about the custom automatic evaluation see the V-Twin Operator’s Manual chapter 5.9.4 Custom automatic evaluation and rerun).

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to others where the potentially affected devices have been transferred.

[Redacted]

[Redacted]

ELITechGroup B.V.



Adriaan P. Intveld
Quality Assurance & Regulatory Affairs Manager

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