

Urgent Field Safety Notice

SBN-CPS-2017-011

CPS / Elecsys 2010
Version 1
21-Jun-2017

Elecsys 2010 analyzer: Software malfunction in the database

Product Name	Elecsys 2010 analyzer (disk system) (GMMI 11568248001) Elecsys 2010 analyzer (rack system) (GMMI 11804014001)
Product Description	Elecsys 2010 analyzer for Immuno Chemistry
GMMI / Part No	Elecsys 2010 analyzer (disk system) (GMMI 11568248001)
Device Identifier	Elecsys 2010 analyzer (rack system) (GMMI 11804014001)
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that in very rare cases a software (SW) malfunction in the Sample&Control datafile can occur which may lead to a potential data mismatch. This SW malfunction only occurs:

- when the “Sample Data Clear” function is not performed daily as indicated in the Operator’s Manual, and
- when the Sample&Control datafile of the **Elecsys 2010** analyzer is filled with > 600 records.

Roche has received no customer complaints for this issue. This error only occurs if deletion of documented results or samples is not performed as pre or post operation function.

Actions taken by Roche Diagnostics (if applicable)

The manufacturer Hitachi High Technologies Corporation (HHT) has confirmed this malfunction of the system. The lifetime of the Elecsys 2010 ended in December 2014, no new SW version will be made available.

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Actions to be taken by the customer/user

The customer is advised to perform daily the following action:

- Delete open, not processed samples (if appropriate) on the "Order" screen.
- Delete documented samples on the "Result" screen.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Best regards,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com