

# Urgent Field Safety Notice

## SBN-CPS-2018-015

CPS / ClinChem fully automated  
Version 1  
Sep-2018

### COBAS INTEGRA<sup>®</sup> 400 plus analyzer: Mandatory software update version 3.6.1

<b>Product Name</b>	COBAS INTEGRA <sup>®</sup> 400 plus analyzer	
<b>Product Description</b>	COBAS INTEGRA <sup>®</sup> 400 plus analyzer for fully automated clinical chemistry testing	
<b>GMMI / Part No</b>	COBAS INTEGRA <sup>®</sup> 400 plus analyzer with ISE	(03245233001)
<b>Device Identifier</b>	COBAS INTEGRA <sup>®</sup> 400 plus analyzer w/o (without) ISE	(04922859001)
<b>Production Identifier (Lot No./Serial No.)</b>	COBAS INTEGRA <sup>®</sup> 400 plus analyzer with ISE	
	S/N 399748	S/N 410893
	S/N 400492	S/N 420001
	S/N 401749	S/N 420002
	S/N 402239	S/N 420003
	COBAS INTEGRA <sup>®</sup> 400 plus analyzer w/o (without) ISE	
	S/N 520001	S/N 520005
	S/N 520002	S/N 520006
	S/N 520003	S/N 520008
<b>SW Version</b>	3.6.0	
<b>Type of Action</b>	Field Safety Corrective Action (FSCA)	

Dear Valued Customer,

#### Description of Situation

We wish to inform you about a limitation in system software version 3.6.0 that was found during our First Customer Monitoring study. This limitation can have an impact on the ISE performance due to a missing calibration. In previous software versions the ISE performed an automatic re-calibration after the following service actions:

- Electrode service started in standby
- Prime ISE calibrators started in standby
- Replace electrode (Electrode service incl.)
- BOD (Begin of Day) manually started

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This re-calibration is not automatically performed with the newest system software version 3.6.0. Therefore, the ISE calibration will only be performed five hours after the last ISE calibration. This is not sufficient to guarantee ISE functionality as specified. The provided workaround as listed below guarantees the proper function of the ISE.

The risk associated with this issue is the possibility that the system measures wrong results for the ISE parameters (especially for sodium) with an estimated bias in the magnitude of ~ 13.1 – 14.1%. In this situation, for example, a sample with actual level below the normal range (hence requiring urgent treatment) would appear as a normal result (incorrect).

## Actions taken by Roche Diagnostics (if applicable)

1. The root cause of this limitation was identified within the software version 3.6.0 and will be fixed with the new system software version 3.6.1. which has been developed and will be available depending on local licensing requirements.
2. The local Roche service organization contact you to arrange the software update as soon as possible.

## Actions to be taken by the customer/user

You, as a participant in the FCM (first customer monitoring) and owner of an instrument with ISE, are advised to perform the following actions until the new system software version 3.6.1 has been installed on your instrument:

Manually perform the ISE calibration after the following service actions:

- Electrode service started in standby
- Prime ISE calibrators started in standby
- Replace electrode (Electrode service incl.)
- BOD (Begin of Day) manually started

Note: This workaround does not apply to instruments without ISE (S/N >= 520001). In that case only the software update to 3.6.1 is required.

## Communication of this Field Safety Notice (if appropriate)

*<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:*

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. (If appropriate).

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

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

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

*Include if applicable:* 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.

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<closing salutations>,

## Contact Details

*To be completed locally:*

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

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

*Include if applicable:* The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.