Urgent Field Safety Notice

SBN-CPS-2017-013

CPS / Immunology
Version 1
28-June-2017

Elecsys Digoxin – Erroneous Unit used for Interference of Special Cardiac Drugs

Product Name	Elecsys Digoxin
GMMI / Part No **Device Identifier**	07027214190
Instrument/System Affected	**cobas e** 801 module
SW Version	n/a
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We regret to inform you that an erroneous unit was used in the method sheet of Elecsys Digoxin on **cobas e** 801 (version 1.0), section “limitations – interference” where the potential interference of “Special cardiac drugs” is listed. In the column “Concentration tested” “mg/mL” is written instead of the correct unit “mg/L”.

Because of erroneous information (false units for concentrations of potentially interfering special cardiac drugs for drug concentrations), interference may remain undetected, as physician/laboratory staff might not be aware of the potential interference, considering much higher concentration that are shown in the table.

Actions taken by Roche Diagnostics

The root cause has been clearly identified: a typographical error occurred in the course of the creation of the method sheet which was not detected in the review process. The method sheet has been corrected and version 2 is available from June 2017.

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Actions to be taken by the customer/user

Please consider the correct table in section "limitations – interference" where the potential interference of "Special cardiac drugs" is listed:

Drug	Concentration tested mg/L
Carvedilol	37.5
Clopidogrel	75.0
Epinephrine (adrenaline)	0.50
Insulin	1.60
Lidocaine	80.0
Lisinopril	10.0
Methylprednisolone	7.50
Metoprolol	150
Nifedipine	30.0
Phenprocoumon	3.00
Propafenone	300
Reteplase	33.3
Simvastatin	30.0
Spironolactone	15.0
Tolbutamide	1500
Torasemide	15.0
Verapamil	240

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:

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

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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